Analysis of the proposal for IVD Regulation

CONFIDENTIAL – NOT TO BE SHARED OUTSIDE OF EDMA – Draft 23 June 2015

	European Commission proposal for IVD Regulation Dated 26 September 2012	European Parliament Integrated Text Dated 22 October 2013	Latvian Presidency Consolidated Text Dated 02 June 2015	Comments
1.	**Chapter I** **Scope and definitions**	**Chapter I** **Scope and definitions**	**Chapter I** **Scope and definitions**	
2.	**Article 1** **Scope** 1. This Regulation establishes rules to be complied with by in vitro diagnostic medical devices and accessories to in vitro diagnostic medical devices that are placed on the market or put into service in the Union for human use.	**Article 1** **Scope** 1. This Regulation establishes rules to be complied with by in vitro diagnostic medical devices and accessories to in vitro diagnostic medical devices that are placed on the market or put into service in the Union for human use.	**Article 1** **Scope** 1. This Regulation lays down rules concerning the placing on the market, making available on the market or putting into service of in vitro diagnostic medical devices and accessories to in vitro diagnostic medical devices for human use in the Union. This regulation also applies to performance studies on in vitro diagnostic medical devices conducted in the Union**.**	**Includes making available on the market as a point where the regulation applies. This therefore triggers requirements on second-hand sales, lease extensions, refurbishment etc.**
3.	For the purposes of this Regulation, in vitro diagnostic medical devices and accessories to in vitro diagnostic medical devices shall hereinafter be referred to as 'devices'.	For the purposes of this Regulation, in vitro diagnostic medical devices and accessories to in vitro diagnostic medical devices shall hereinafter be referred to as 'devices'.	1a. For the purposes of this Regulation, in vitro diagnostic medical devices and accessories to in vitro diagnostic medical devices shall hereinafter be referred to as 'devices'.	No change
4.	2. This Regulation shall not apply to:	2. This Regulation shall not apply to:	2. This Regulation shall not apply to:	No change
5.	(a) products for general laboratory use, unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for in vitro diagnostic examination;	(a) products for general laboratory use, unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for in vitro diagnostic examination;	(a) products for general laboratory use or research-use only products, unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for in vitro diagnostic examination;	Explicitly excludes RuO devices – no impact.
6.	(b) invasive sampling devices or those which are directly applied to the human body for the purpose of obtaining a specimen;	(b) invasive sampling devices or those which are directly applied to the human body for the purpose of obtaining a specimen;	(b) invasive sampling devices or those which are directly applied to the human body for the purpose of obtaining a specimen;	No change

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7.	(c) higher metrological order reference materials.	(c) higher metrological order reference materials.	(c) internationally certified reference materials.;	Minor change – step towards recognition by JCTLM
8.			(d) materials used for external quality assessment schemes;	Minor change – already de facto the case. No impact.
9.	3. Any device which, when placed on the market or used in accordance with the manufacturer's instructions, incorporates as an integral part a medical device as defined in Article 2 of Regulation (EU) [Ref. of future Regulation on medical devices] on medical devices without being an in vitro diagnostic medical device, shall be governed by this Regulation, provided that the principal intended purpose of the combination is that of an in vitro diagnostic medical device referred to in Article 2(2) of this Regulation. The relevant general safety and performance requirements set out in Annex I to Regulation (EU) [Ref. of future Regulation on medical devices] shall apply as far as the safety and performance of the medical device part that is not an in vitro diagnostic medical device are concerned.	3. Any device which, when placed on the market or used in accordance with the manufacturer's instructions, incorporates as an integral part a medical device as defined in Article 2 of Regulation (EU) [Ref. of future Regulation on medical devices] on medical devices without being an in vitro diagnostic medical device, shall be governed by this Regulation, provided that the principal intended purpose of the combination is that of an in vitro diagnostic medical device referred to in Article 2(2) of this Regulation. The relevant general safety and performance requirements set out in Annex I to Regulation (EU) [Ref. of future Regulation on medical devices] shall apply as far as the safety and performance of the medical device part that is not an in vitro diagnostic medical device are concerned.	3. Any device which, when placed on the market or put into service and used in accordance with the manufacturer's instructions incorporates as an integral part a medical device as defined in Article 2 of Regulation (EU) [Ref. of future Regulation on medical devices] on medical devices shall be governed by this Regulation, requirements of Regulation (EU) [Ref. of future Regulation on medical devices] shall apply to the medical device part.	**If any IVD function is present in a device, then the entire device becomes an IVD. For instance – according to this an artificial pancreas becomes an IVD not a MD.**
10.	4. This Regulation is a specific Union legislation within the meaning of Article 1(4) of Directive 2004/108/EC and within the meaning of Article 3 of Directive 2006/42/EC.	4. This Regulation is a specific Union legislation within the meaning of Article 1(4) of Directive 2004/108/EC and within the meaning of Article 3 of Directive 2006/42/EC.	4. This Regulation is a specific Union legislation within the meaning of Article 1(4) of Directive 2004/108/EC.	**Major impact – Machinery Directive would apply in full if Lex Specialis provision is removed.**
11.	5. This Regulation shall not affect the application of Council Directive 96/29/Euratom, nor of Council Directive 97/43/Euratom.	5. This Regulation shall not affect the application of Council Directive 96/29/Euratom, nor of Council Directive 97/43/Euratom.	5. This Regulation shall not affect the application of Council Directive 2013/59/Euratom.	No impact – there has simply been an updating of the Euratom directives since the Commission published its proposal.

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12.	6. This Regulation shall not affect national laws which require that certain devices may only be supplied on a medical prescription.	6. This Regulation provides that certain devices may only be supplied on a medical prescription but shall not affect national laws which require that certain other devices may also only be supplied on a medical prescription. Direct to consumer advertising of devices classed as prescription only by this regulation shall be illegal. The following devices may only be supplied on a medical prescription: 1) Class D devices 2) Class C devices in the following categories: (a) devices for genetic testing; (b) companion diagnostics.	6. This Regulation shall not affect national law concerning the organisation, delivery or financing of health services and medical care, such as the requirement that certain devices may only be supplied on a medical prescription, the requirement that only certain health professionals or health care institutions may dispense or apply certain devices or that their application must be accompanied by specific professional counselling.	In direct opposition with parliamentary amendments which seek to have genetic tests delivered only upon prescription. Point of contention between Council and Parliament but not a point of impact for industry.
13.		By derogation, justified by the attainment of a high level of public health protection, Member States may maintain or introduce national provisions allowing special class D tests to also be available without a medical prescription. In that case, they shall duly inform the Commission. The Commission shall be empowered to adopt delegated acts in accordance with Article 85 to decide on other category C tests after consultation with stakeholders.		
14.			6a. This Regulation shall be without prejudice to national laws regarding public access to official documents and regarding freedom of the press and freedom of expression in other media.	New provision, no specific known impact (as this was de facto already the case)
15.	7. References to a Member State in this Regulation shall be understood as	7. References to a Member State in this Regulation shall be understood as		**Issue – this could mean that there is a discrepancy on the**

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	including any other country with which the Union has concluded an agreement which confers on that country the same status as a Member State for the purpose of application of this Regulation.	including any other country with which the Union has concluded an agreement which confers on that country the same status as a Member State for the purpose of application of this Regulation.		**status of countries like Switzerland or Turkey with regards to the implementation of the Regulation (e.g. no authorized reps in those countries and manufacturers in those countries would need an authorized rep in the EU?)**
16.		7a. The regulation of in-vitro diagnostic medical devices at Union level shall not interfere with the freedom of Member States to decide whether to restrict the use of any specific type of in-vitro diagnostic device in relation to aspects that are not covered by this Regulation.		
17.	**Article 2** **Definitions** For the purposes of this Regulation, the following definitions shall apply:	**Article 2** **Definitions** For the purposes of this Regulation, the following definitions shall apply:	**Article 2** **Definitions** For the purposes of this Regulation, the following definitions shall apply:	No change
18.	Definitions related to devices: (1) 'medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific medical purposes of:	Definitions related to devices: (1) 'medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific direct or indirect medical purposes of:	Definitions related to devices: (1) 'medical device' means any instrument, apparatus, appliance, software, implant, reagent material or other article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific medical purposes of:	No change
19.	- diagnosis, prevention, monitoring, treatment or alleviation of disease,	- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,	– diagnosis, prevention, monitoring, treatment or alleviation of disease,	No change
20.	– diagnosis, monitoring, treatment,	– diagnosis, monitoring, treatment,	– diagnosis, monitoring, treatment,	No change

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	alleviation of or compensation for an injury or disability,	alleviation of or compensation for an injury or disability,	alleviation of or compensation for an injury or disability,	
21.	– investigation, replacement or modification of the anatomy or of a physiological process or state,	– investigation, replacement or modification of the anatomy or of a physiological process or state,	- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,	Includes pathological process or state, logical alignment with IVD definition – no impact.
22.	– control or support of conception,	– control or support of conception,		is replaced by the last paragraph of the definition – no impact.
23.	– disinfection or sterilisation of any of the above-mentioned products,	– disinfection or sterilisation of any of the above-mentioned products,		is replaced by the last paragraph of the definition – no impact.
24.		- providing information concerning direct or indirect impacts on health,		
25.			– providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations	**Potential Impact – this change means that all in vitro examinations are devices unless they are IVDs. As the definition of IVD is not change this means that lifestyle tests, forensic assays, RuO tests and general laboratory assays intended for the examination of human specimens all become medical devices.** **While this text comes literally from the GHTF definition of a medical device, within the EU framework it causes significant concerns.**

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26.	and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.	and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.	and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.	No change
27.			Products specifically intended for the cleaning, disinfection or sterilisation of medical devices and devices for the purpose of control or support of conception shall be considered medical devices.	Includes products specifically intended for cleaning devices, which is not part of the Commission proposal. This should still exclude general laboratory reagents used for cleaning, disinfection or sterilization. Only if the cleaning, disinfecting or sterilizing product is specifically intended to be used with a device (sometimes the case) will they be covered.
28.	(2) 'in vitro diagnostic medical device' means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, software or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:	(2) 'in vitro diagnostic medical device' means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, software or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:	(2) 'in vitro diagnostic medical device' means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, software or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:	No change
29.	– concerning a physiological or pathological state;	– concerning a physiological or pathological state;	– concerning a physiological or pathological process or state;	Adds the concept of processes (both pathological and physiological)
30.	– concerning a congenital abnormality;	– concerning congenital physical or mental impairments;	– concerning a congenital abnormality;	No change

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31.	– concerning the predisposition to a medical condition or a disease;	– concerning the predisposition to a medical condition or a disease;	– concerning the predisposition to a medical condition or a disease;	No change
32.	– to determine the safety and compatibility with potential recipients;	– to determine the safety and compatibility with potential recipients;	– to determine the safety and compatibility with potential recipients;	No change
33.	– to predict treatment response or reactions;	– to predict treatment response or reactions;	– to predict treatment response or reactions;	No change
34.	– to define or monitor therapeutic measures.	– to define or monitor therapeutic measures.	– to define or monitor therapeutic measures.	No change
35.	Specimen receptacles are considered to be in vitro diagnostic medical devices. For the purposes of this Regulation, ‘specimen receptacle’ means devices, whether vacuum-type or not, specifically intended by their manufacturers for the primary containment and preservation of specimens derived from the human body for the purpose of in vitro diagnostic examination.	Specimen receptacles are considered to be in vitro diagnostic medical devices. For the purposes of this Regulation, ‘specimen receptacle’ means devices, whether vacuum-type or not, specifically intended by their manufacturers for the primary containment and preservation of specimens derived from the human body for the purpose of in vitro diagnostic examination.	Specimen receptacles are considered to be in vitro diagnostic medical devices. For the purposes of this Regulation, ‘specimen receptacle’ means devices, whether vacuum-type or not, specifically intended by their manufacturers for the primary containment and preservation of specimens derived from the human body for the purpose of in vitro diagnostic examination.	No change
36.		(2a) In vitro diagnostic medical devices used for DNA-testing shall be subject to this Regulation.		
37.	(3) 'accessory to an in vitro diagnostic medical device' means an article which, whilst not being an in vitro diagnostic medical device, is intended by its manufacturer to be used together with one or several particular in vitro diagnostic medical device(s) to specifically enable or assist the in vitro diagnostic medical device(s) to be used in accordance with its/their intended purpose(s);	(3) 'accessory to an in vitro diagnostic medical device' means an article which, whilst not being an in vitro diagnostic medical device, is intended by its manufacturer to be used together with one or several particular in vitro diagnostic medical device(s) to specifically enable or assist the in vitro diagnostic medical device(s) to be used in accordance with its/their intended purpose(s);	(3) 'accessory to an in vitro diagnostic medical device' means an article which, whilst not being an in vitro diagnostic medical device, is intended by its manufacturer to be used together with one or several particular in vitro diagnostic medical device(s) to specifically enable the in vitro diagnostic medical device(s) to be used in accordance with its/their intended purpose(s);	No change

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38.	(4) 'device for self-testing' means any device intended by the manufacturer to be used by lay persons;	(4) 'device for self-testing' means any device intended by the manufacturer to be used by lay persons; including testing services offered to lay persons by means of information society services;	(4) 'device for self-testing' means any device intended by the manufacturer to be able to be used by lay persons;	**Modification – Able to be used by lay persons. Ability of use has never been defined nor has it ever been a criteria before, unclear impact.**
39.	(5) 'device for near-patient testing' means any device that is not intended for self-testing but is intended to perform testing outside a laboratory environment, generally near to, or at the side of, the patient;	(5) 'device for near-patient testing' means any device that is not intended for self-testing but is intended to perform testing outside a laboratory environment, generally near to, or at the side of, the patient;	(5) 'device for near-patient testing' means any device that is not intended for self-testing but is intended to perform testing outside a laboratory environment, generally near to, or at the side of, the patient;	No change
40.	(6) 'companion diagnostic' means a device specifically intended to select patients with a previously diagnosed condition or predisposition as eligible for a targeted therapy;	(6) 'companion diagnostic' means a device specifically intended for and essential to the selection of patients with a previously diagnosed condition or predisposition as suitable or unsuitable for a specific therapy with a medicinal product or a range of medicinal products;	(6) 'companion diagnostic' means a device which is essential for the safe and effective use of a corresponding medicinal product to: - identify patients who are most likely to benefit from the medicinal product, or; - identify patients likely to be at increased risk for serious adverse reactions as a result of treatment with the medicinal product, or; - monitor response to treatment by the medicinal product for the purpose of adjusting treatment to achieve improved safety or effectiveness;	**Major impact – this greatly extends the definition what a CoDx is – it would include HIV assays (identifies patients which would benefit from retroviral therapy), cholesterol tests (monitors response to statin treatment) etc.** **Very basic concepts have been left out of this definition** **1) Intended purpose as established by the manufacturer** **2) Eligibility for targeted therapy** **3) Previously diagnosed condition** **Parliamentary amendment would be a viable compromise:** **(6) 'companion diagnostic' means a device specifically**

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				intended for and essential to the selection of patients with a previously diagnosed condition or predisposition as suitable or unsuitable for a specific therapy with a medicinal product or a range of medicinal products;
41.	(7) 'generic device group' means a set of devices having the same or similar intended purposes or commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics;	(7) 'generic device group' means a set of devices having the same or similar intended purposes or commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics;	(7) 'generic device group' means a set of devices having the same or similar intended purposes or commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics;	No change
42.	(8) 'single-use device' means a device that is intended to be used on an individual patient during a single procedure; The single procedure may involve several uses or prolonged use on the same patient.	(8) 'single-use device' means a device that is intended to be used on an individual patient during a single procedure; The single procedure may involve several uses or prolonged use on the same patient.	(8) 'single-use device' means a device that is intended to be used during a single procedure;	Removes the concept of multiple uses during a single procedure, the change in definition does not impact IVDs.
43.			(8a) 'falsified medical device' means any device with a false presentation of its identity, and/or of its source and/or its CE marking certificates or documents relating to CE marking procedures. This definition does not include unintentional non-compliance and is without prejudice to infringements of intellectual property rights;	New definition. Carefully avoids the word counterfeit which was used during the TRIPS agreement negotiations.
44.			(8a) 'kit' means a set of components that are packaged together and intended to be used to perform a specific in vitro diagnostic examination, or a part thereof;	New definition (seems ok)

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45.	(9) 'intended purpose' means the use for which the device is intended according to the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or statements;	(9) 'intended purpose' means the use for which the device is intended according to the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or statements;	(9) 'intended purpose' means the use for which the device is intended according to the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or statements;	No change
46.	(10) 'label' means the written, printed, or graphic information appearing either on the device itself, or on the packaging of each unit, or on the packaging of multiple devices;	(10) 'label' means the written, printed, or graphic information appearing either on the device itself, or on the packaging of each unit, or on the packaging of multiple devices;	(10) 'label' means the written, printed, or graphic information appearing either on the device itself, or on the packaging of each unit, or on the packaging of multiple devices;	No change
47.	(11) 'instructions for use' means the information provided by the manufacturer to inform the user of the device's intended purpose and proper use and of any precautions to be taken;	(11) 'instructions for use' means the information provided by the manufacturer to inform the user of the device's intended purpose and proper use and of any precautions to be taken;	(11) 'instructions for use' means the information provided by the manufacturer to inform the user of the device's intended purpose and proper use and of any precautions to be taken;	No change
48.	(12) 'Unique Device Identification' ('UDI') means a series of numeric or alphanumeric characters that is created through internationally accepted device identification and coding standards and that allows unambiguous identification of specific devices on the market;	(12) 'Unique Device Identification' ('UDI') means a series of numeric or alphanumeric characters that is created through internationally accepted device identification and coding standards and that allows unambiguous identification of specific devices on the market;	(12) 'Unique Device Identification' ('UDI') means a series of numeric or alphanumeric characters that is created through internationally accepted device identification and coding standards and that allows unambiguous identification of specific devices on the market;	No change
49.	Definitions related to the making available of devices:	Definitions related to the making available of devices:	Definitions related to the making available of devices:	
50.		(12a) ' device for genetic testing' means an in vitro diagnostic medical device the purpose of which is to identify a genetic characteristic of a person which is inherited or acquired during prenatal development.		

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51.	(13) 'making available on the market' means any supply of a device, other than a device for performance evaluation, for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;	(13) 'making available on the market' means any supply of a device, other than a device for performance evaluation, for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;	(13) 'making available on the market' means any supply of a device, other than a device for performance evaluation, for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;	No change – however see change in scope (line 2)
52.	(14) 'placing on the market' means the first making available of a device, other than a device for performance evaluation, on the Union market;	(14) 'placing on the market' means the first making available of a device, other than a device for performance evaluation, on the Union market;	(14) 'placing on the market' means the first making available of a device, other than a device for performance evaluation, on the Union market;	No change
53.	(15) 'putting into service' means the stage at which a device, other than a device for performance evaluation, has been made available to the final user as being ready for use on the Union market for the first time for its intended purpose;	(15) 'putting into service' means the stage at which a device, other than a device for performance evaluation, has been made available to the final user as being ready for use on the Union market for the first time for its intended purpose;	(15) 'putting into service' means the stage at which a device, other than a device for performance evaluation, has been made available to the final user as being ready for use on the Union market for the first time for its intended purpose;	No change
54.		(15a) 'Information Society service' means any service, normally provided for remuneration, at a distance, by electronic means and at the individual request of a recipient of services;		
55.			(15a) 'safety' means the absence of unacceptable risks, when using the device according to the manufacturer's instructions for use;	New definition. Comes from risk management or electrical safety standard?
56.			(15b) 'benefit-risk determination' means the integration of all assessments of benefit and risk of possible relevance for the use of the device for the intended purpose, when used in accordance with the instructions of use;	New definition. Term then not used. Intent unclear.

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57.	Definitions related to economic operators, users and specific processes:	Definitions related to economic operators, users and specific processes:	Definitions related to economic operators, users and specific processes:	
58.	(16) 'manufacturer' means the natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under his name or trademark.	(16) 'manufacturer' means the natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under that person's own name, regardless of whether those operations are carried out by that person or on that person's behalf by a third party. The obligations of this Regulation to be met by manufactures also apply to natural or legal persons who assemble, package, process, fully refurbish or label one or more ready-made products and/or assign to them their intended purpose as devices with a view to their being placed on the market under that person's own name or trademark.	(16) 'manufacturer' means the natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under his name or trademark, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.	Makes it clear manufacturer can have certain operations carried out on his behalf by a third party. (OEM manufacturing). Text comes from the directive definitions
59.	For the purposes of the definition of manufacturer, fully refurbishing is defined as the complete rebuilding of a device already placed on the market or put into service, or the making of a new device from used devices, to bring it in conformity with this Regulation, combined with the assignment of a new lifetime to the refurbished device;	For the purposes of the definition of manufacturer, fully refurbishing is defined as the complete rebuilding of a device already placed on the market or put into service, or the making of a new device from used devices, to bring it in conformity with this Regulation, combined with the assignment of a new lifetime to the refurbished device;	For the purposes of the definition of manufacturer, fully refurbishing is defined as the complete rebuilding of a device already placed on the market or put into service, or the making of a new device from used devices, to bring it in conformity with this Regulation, combined with the assignment of a new lifetime to the refurbished device;	No change
60.			(16a) 'compatibility' is the ability of a medical device, including software, when used together with one or more other devices in accordance with its intended purpose, to: - perform without losing or compromising the ability to perform as intended, and/or - integrate and/or operate without the need	New definition.

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			for modification or adaption of any part of the combined devices, and/or - be used together without conflict/interference or adverse reaction.	
61.			(16b) 'interoperability' is the ability of two or more medical devices, including software, from the same manufacturer or from different manufacturers, to - exchange information and use the information that has been exchanged for correct execution of specified function without changing the content of the data, and/or - enable the communication of one or more devices, and/or - enable one or more devices to work together as intended.	New definition. Does this replace the concept of use in combination?
62.	(17) 'authorised representative' means any natural or legal person established within the Union who has received and accepted a written mandate from a manufacturer to act on his behalf in relation to specified tasks with regard to the latter's obligations under this Regulation;	(17) 'authorised representative' means any natural or legal person established within the Union who has received and accepted a written mandate from a manufacturer to act on his behalf in relation to specified tasks with regard to the latter's obligations under this Regulation;	(17) 'authorised representative' means any natural or legal person established within the Union who has received and accepted a written mandate from a manufacturer, located outside the European Union, to act on his behalf in relation to specified tasks with regard to the latter's obligations under this Regulation;	Emphasis on the fact that if located outside the EU (Turkey and Switzerland again?) an authorized rep will be needed.
63.	(18) 'importer' means any natural or legal person established within the Union who places a device from a third country on the Union market;	(18) 'importer' means any natural or legal person established within the Union who places a device from a third country on the Union market;	(18) 'importer' means any natural or legal person established within the Union who places a device from a third country on the Union market;	No change
64.	(19) 'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a device available on the market;	(19) 'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a device available on the market;	(19) 'distributor' means any natural or legal person in the supply chain, other than the manufacturer or the importer, who makes a device available on the market;	No change

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65.	(20) 'economic operators' means the manufacturer, the authorised representative, the importer and the distributor;	(20) 'economic operators' means the manufacturer, the authorised representative, the importer and the distributor;	(20) 'economic operators' means the manufacturer, the authorised representative, the importer and the distributor;	No change
66.	(21) 'health institution' means an organisation whose primary purpose is the care or treatment of patients or the promotion of public health;	(21) health institution' means an organisation whose primary purpose is the care or treatment of patients and which has the legal capacity to carry out such activities; commercial laboratories which provide diagnostic services shall not be considered a health institution;	(21) 'health institution' means an organisation whose primary purpose is the care or treatment of patients or the promotion of public health;	No change
67.	(22) 'user' means any healthcare professional or lay person who uses a device;	(22) 'user' means any healthcare professional or lay person who uses a device;	(22) 'user' means any healthcare professional or lay person who uses a device;	No change
68.	(23) 'lay person' means an individual who does not have formal education in a relevant field of healthcare or medical discipline;	(23) 'lay person' means an individual who does not have formal education in a relevant field of healthcare or medical discipline;	(23) 'lay person' means an individual who does not have formal education in a relevant field of healthcare or medical discipline;	No change
69.	Definitions related to conformity assessment:	Definitions related to conformity assessment:	Definitions related to conformity assessment:	
70.	(24) 'conformity assessment' means the process demonstrating whether the requirements of this Regulation relating to a device have been fulfilled;	(24) 'conformity assessment' means the process demonstrating whether the requirements of this Regulation relating to a device have been fulfilled;	(24) 'conformity assessment' means the process demonstrating whether the requirements of this Regulation relating to a device have been fulfilled;	No change
71.	(25) 'conformity assessment body' means a body that performs third-party conformity assessment activities including calibration, testing, certification and inspection;	(25) 'conformity assessment body' means a body that performs third-party conformity assessment activities including testing, certification and inspection;	(25) 'conformity assessment body' means a body that performs third-party conformity assessment activities including calibration, testing, certification and inspection;	No change
72.	(26) 'notified body' means a conformity assessment body designated in accordance with this Regulation;	(26) 'notified body' means a conformity assessment body designated in accordance with this Regulation;	(26) 'notified body' means a conformity assessment body designated in accordance with this Regulation;	No change

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73.	(27) 'CE marking of conformity' or 'CE marking' means a marking by which the manufacturer indicates that the device is in conformity with the applicable requirements set out in this Regulation and other applicable Union harmonisation legislation providing for its affixing;	(27) 'CE marking of conformity' or 'CE marking' means a marking by which the manufacturer indicates that the device is in conformity with the applicable requirements set out in this Regulation and other applicable Union harmonisation legislation providing for its affixing;	(27) 'CE marking of conformity' or 'CE marking' means a marking by which the manufacturer indicates that the device is in conformity with the applicable requirements set out in this Regulation and other applicable Union harmonisation legislation providing for its affixing;	No change
74.	Definitions related to clinical evidence:	Definitions related to clinical evidence:	Definitions related to clinical evidence:	
75.	(28) 'clinical evidence' means the information that supports the scientific validity and performance for the use of a device as intended by the manufacturer;	(28) 'clinical evidence' means the data, positive and negative, supporting the evaluation of the scientific validity and performance for the use of a device as intended by the manufacturer;	(28) 'clinical evidence' means the clinical data and performance evaluation results pertaining to a device of sufficient amount and quality to allow a qualified assessment of whether the device achieves the intended clinical benefit(s) and safety, when used as intended by the manufacturer;	**Major change – clinical evidence is no longer scientific validity, analytical performance and clinical performance. Instead it is clinical data (undefined) and the results of performance evaluation. Also introduces the concept of intended clinical benefit – however it is unclear whether the intended purpose of IVDs includes an intended clinical benefit (which is not defined, and generally relevant and used in the context of pharma assessment)**
76.	(29) 'scientific validity of an analyte' means the association of an analyte to a clinical condition or a physiological state;	(29) 'scientific validity of an analyte' means the association of an analyte to a clinical condition or a physiological state;	(29) 'scientific validity of an analyte' means the association of an analyte to a clinical condition or a physiological state;	No change
77.	(30) 'performance of a device' means the ability of a device to achieve its intended purpose as claimed by the manufacturer. It consists of the analytical and, where applicable, the clinical performance supporting the intended purpose of the	(30) 'performance of a device' means the ability of a device to achieve its intended purpose as claimed by the manufacturer. It consists of attainment of technical capabilities, analytical performance and, where applicable, the clinical performance	(30) 'performance of a device' means the ability of a device to achieve its intended purpose as claimed by the manufacturer. It consists of the analytical and, where applicable**,** the clinical performance supporting the intended purpose of the	No change

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	device;	supporting the intended purpose of the device;	device;	
78.	(31) 'analytical performance' means the ability of a device to correctly detect or measure a particular analyte;	(31) 'analytical performance' means the ability of a device to correctly detect or measure a particular analyte;	(31) 'analytical performance' means the ability of a device to correctly detect or measure a particular analyte;	No change
79.	(32) 'clinical performance' means the ability of a device to yield results that are correlated with a particular clinical condition or a physiological state in accordance with the target population and intended user;	(32) 'clinical performance' means the ability of a device to yield results that are correlated with a particular clinical condition or a physiological state in accordance with the target population and intended user;	(32) 'clinical performance' means the ability of a device to yield results that are correlated with a particular clinical condition or a physiological state in accordance with the target population and intended user;	No change
80.	(33) 'clinical performance study' means a study undertaken to establish or confirm the clinical performance of a device;	(33) 'clinical performance study' means a study undertaken to establish or confirm the clinical performance of a device;	(33) 'performance study' means a study undertaken to establish or confirm the clinical performance of a device;	Clinical performance study becomes performance study – semantic change. No clear reason why.
81.	(34) 'clinical performance study protocol' means the document(s) setting out the rationale, objectives, design and proposed analysis, methodology, monitoring, conduct and record-keeping of the clinical performance study;	(34) 'clinical performance study protocol' means the document(s) setting out the rationale, objectives, design and proposed analysis, methodology, monitoring, conduct and record-keeping of the clinical performance study;	(34) 'clinical performance study plan' means the document(s) setting out the rationale, objectives, design and proposed analysis, methodology, monitoring, conduct and record-keeping of the clinical performance study;	Clinical performance study protocol becomes: Clinical performance study plan. Why?
82.	(35) 'performance evaluation' means the assessment and analysis of data to establish or verify the analytical and, where applicable, the clinical performance of a device;	(35) 'performance evaluation' means the assessment and analysis of data to establish or verify the analytical and, where applicable, the clinical performance of a device;	(35) 'performance evaluation' means the assessment and analysis of data to establish or verify the scientific validity, the analytical and, where applicable, the clinical performance of a device;	Performance evaluation can now also establish or verify the scientific validity.
83.	(36) 'device for performance evaluation' means a device intended by the manufacturer to be subject to one or more performance evaluation studies in laboratories for medical analyses or in other appropriate environments outside	(36) 'device for performance evaluation' means a device intended by the manufacturer to be subject to one or more performance evaluation studies in laboratories for medical analyses or in other appropriate environments outside	(36) 'device for performance evaluation' means a device intended by the manufacturer to be subject to one or more performance evaluation in laboratories for medical analyses or in other appropriate environments outside the manufacturer's	No change

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	the manufacturer's own premises. Devices intended to be used for research purposes, without any medical objective, are not regarded as devices for performance evaluation;	the manufacturer's own premises. Devices intended to be used for research purposes, without any medical objective, are not regarded as devices for performance evaluation;	own premises. Devices intended to be used for research purposes, without any medical objective, are not regarded as devices for performance evaluation;	
84.	(37) 'interventional clinical performance study' means a clinical performance study where the test results may influence patient management decisions and/or may be used to guide treatment;	(37) 'interventional clinical performance study' means a clinical performance study where the test results may influence patient management decisions and/or may be used to guide treatment;	(37) 'interventional clinical performance study' means a clinical performance study where the test results may influence patient management decisions and/or may be used to guide treatment;	No change
85.		(37a) 'Ethics committee' means an independent body in a Member State, consisting of healthcare professionals and non-medical members including at least one wellexperienced, knowledgeable patient or patient representative. Its responsibility is to protect the rights, safety, physical and mental integrity, dignity and well-being of subjects involved in interventional clinical performance studies and other clinical performance studies involving risk for the subject and to provide public assurance of that protection in full ransparency. In cases of such studies involving minors, the ethics committee shall include at least one healthcare professional with paediatric expertise.	(45b) 'Ethics committee' means an independent body established in a Member State in accordance with the law of that Member State and empowered to give opinions for the purposes of this Regulation, taking into account the views of laypersons, in particular patients or patients' organisations;	New definition – no impact per se (however most ethics committees are currently established at the hospital level)
86.			(37a) 'subject ' means an individual who participates in a performance study either as recipient of a device for performance evaluation or as control;	New definition – but subjects in IVD studies do not receive devices.
87.	(38) 'diagnostic specificity' means the ability of a device to recognize the	(38) 'diagnostic specificity' means the ability of a device to recognize the	(38) 'diagnostic specificity' means the ability of a device to recognize the	No change

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	absence of a target marker associated with a particular disease or condition;	absence of a target marker associated with a particular disease or condition;	absence of a target marker associated with a particular disease or condition;	
88.	(39) 'diagnostic sensitivity' means the ability of a device to identify the presence of a target marker associated with a particular disease or condition;	(39) 'diagnostic sensitivity' means the ability of a device to identify the presence of a target marker associated with a particular disease or condition;	(39) 'diagnostic sensitivity' means the ability of a device to identify the presence of a target marker associated with a particular disease or condition;	No change
89.	(40) 'predictive value' means the probability that a person with a positive device test result has a given condition under investigation, or that a person with a negative device test result does not have a given condition;	(40) 'predictive value' means the probability that a person with a positive device test result has a given condition under investigation, or that a person with a negative device test result does not have a given condition;	(40) 'predictive value' means the probability that a person with a positive device test result has a given condition under investigation, or that a person with a negative device test result does not have a given condition;	No change
90.	(41) 'positive predictive value' means the ability of a device to separate true positive results from false positive results for a given attribute in a given population;	(41) 'positive predictive value' means the ability of a device to separate true positive results from false positive results for a given attribute in a given population;	(41) 'positive predictive value' means the ability of a device to separate true positive results from false positive results for a given attribute in a given population;	No change
91.	(42) 'negative predictive value' means the ability of a device to separate true negative results from false negative results for a given attribute in a given population;	(42) 'negative predictive value' means the ability of a device to separate true negative results from false negative results for a given attribute in a given population;	(42) 'negative predictive value' means the ability of a device to separate true negative results from false negative results for a given attribute in a given population;	No change
92.	(43) 'likelihood ratio' means the likelihood that a given result would be expected in an individual with the target clinical condition or physiological state compared to the likelihood that the same result would be expected in an individual without that clinical condition or physiological state;	(43) 'likelihood ratio' means the likelihood that a given result would be expected in an individual with the target clinical condition or physiological state compared to the likelihood that the same result would be expected in an individual without that clinical condition or physiological state;	(43) 'likelihood ratio' means the likelihood that a given result would be expected in an individual with the target clinical condition or physiological state compared to the likelihood that the same result would be expected in an individual without that clinical condition or physiological state;	No change
93.	(44) 'calibrators and control materials' means any substance, material or article intended by the manufacturer either to establish measurement relationships or to verify the performance characteristics of a	(43a) 'calibrator' means a measurement standard used in the calibration of a device;	(44) 'calibrators and control materials' means any substance, material or article intended by the manufacturer either to establish measurement relationships or to verify the performance characteristics of a	No change
94.		(44) 'control material' means a substance,		

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	device in conjunction with the intended purpose of that device;	material or article intended by its manufacturer to be used to verify the performance characteristics of a device;	device in conjunction with the intended purpose of that device;	
95.	(45) 'sponsor' means any individual, company, institution or organisation which takes responsibility for the initiation and management of a clinical performance study;	(45) 'sponsor' means any individual, company, institution or organisation which takes responsibility for the initiation and management, conduct or financing of a clinical performance study;	(45) 'sponsor' means any individual, company, institution or organisation which takes responsibility for the initiation for the management and for setting up the financing of the performance study;	**Potential issue – if a performance study is setup by one organization which takes responsibility for the study, but is financed by another organization, this would mean a single study would have multiple sponsors. Unnecessarily complex. (Clinical Trials regulation update?)**
96.			(45a) 'informed consent' means a subject's free and voluntary expression of his or her willingness to participate in a particular clinical investigation, after having been informed of all aspects of the performance evaluation study that are relevant to the subject's decision to participate or, in case of minors and of incapacitated subjects, an authorisation or agreement from their legally designated representative to include them in the performance evaluation study;	New definition – no impact per se, but need to get rid of the clinical investigation term
97.	(46) 'adverse event' means any untoward medical occurrence, unintended disease or injury or any untoward clinical signs, including an abnormal laboratory finding, in subjects, users or other persons in the context of a clinical performance study, whether or not related to the device for performance evaluation;	(46) 'adverse event' means any untoward medical occurrence, unintended disease or injury or any untoward clinical signs, including an abnormal laboratory finding, in subjects, users or other persons in the context of a clinical performance study, whether or not related to the device for performance evaluation;	(46) 'adverse event' means any untoward medical occurrence, inappropriate patient management decision, unintended disease or injury or any untoward clinical signs, including an abnormal laboratory finding, in subjects, users or other persons in the context of a performance study, whether or not related to the device for performance study;	**Potential issue – adds question of inappropriate management decisions. However this would only be applicable in the case of an interventional study as only in interventional studies would there be patient management decisions as part of the**

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				performance study.
98.	(47) 'serious adverse event' means any adverse event that led to any of the following:	(47) 'serious adverse event' means any adverse event that led to any of the following:	(47) 'serious adverse event' means any adverse event that led to any of the following:	No change
99.			- a patient management decision resulting in an imminent life-threatening situation to the individual being tested, or in the death of the individual's offspring,	**See line 90**
100.	- death,	- death,	- death,	No change
101.	– serious deterioration in the health of the subject, that resulted in any of the following:	– serious deterioration in the health of the subject, that resulted in any of the following:	– serious deterioration in the health of the individual being tested or the recipient of tested donations or materials, that resulted in any of the following:	Includes potential impact to the recipient of a donation or transfusion. No impact expected though.
102.	(i) life-threatening illness or injury, (ii) permanent impairment of a body structure or a body function, (iii) hospitalisation or extending the duration of hospitalisation, (iv) medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function,	(i) life-threatening illness or injury, (ii) permanent impairment of a body structure or a body function, (iii) hospitalisation or extending the duration of hospitalisation or prolongation of patient hospitalisation, (iv) medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function,	(i) life-threatening illness or injury, (ii) permanent impairment of a body structure or a body function, (iii) hospitalisation or extending the duration of hospitalisation, (iv) medical or surgical intervention to prevent life-threatening illness or injury or permanent impairment to a body structure or a body function, (v) chronic disease,	Adds the concept of chronic disease (point v). If someone develops a chronic disease following participation in a performance study this would be triggered… If someone develops diabetes as part of a study of HbA1C would this be triggered?
103.	- foetal distress, foetal death or a congenital abnormality or birth defect.	- foetal distress, foetal death or a congenital abnormality or birth defect.	- foetal distress, foetal death or a congenital abnormality or birth defect.	No change
104.	(48) 'device deficiency' means any inadequacy in the identity, quality, durability, reliability, safety or performance	(48) 'device deficiency' means any inadequacy in the identity, quality, stability, reliability, safety or performance of a	(48) 'device deficiency' means any inadequacy in the identity, quality, durability, reliability, safety or performance	No change

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	of a device for performance evaluation, including malfunction, use errors or inadequacy in the information supplied by the manufacturer;	device for performance evaluation, including malfunction, use errors or inadequacy in the information supplied by the manufacturer;	of a device for performance evaluation, including malfunction, use errors or inadequacy in the information supplied by the manufacturer;	
105.		(48a) 'inspection' means an official review, carried out by a competent authority, of documents, facilities, records, quality assurance arrangements, and any other resources that are deemed by that authority to be related to a clinical performance study and that may be located at the site of the trial, at the sponsor's and/or contract research organisation's facilities, or at other establishments which the competent authority sees fit to inspect;		
106.	Definitions related to vigilance and market surveillance:	Definitions related to vigilance and market surveillance:	Definitions related to vigilance and market surveillance:	
107.			(48a) 'Market Surveillance' means all activities carried out by the manufacturers in cooperation with other economic operators to institute and keep up to date a systematic procedure to proactively collect and review experience gained from their devices placed on the market, made available or put into service for the purpose of identifying any need to immediately apply any necessary, corrective or preventive actions;	**New definition. Note the emphasis on proactive collection of experience gained from their devices.**
108.	(49) 'recall' means any measure aimed at achieving the return of a device that has already been made available to the end user;	(49) 'recall' means any measure aimed at achieving the return of a device that has already been made available to the end user;	(49) 'recall' means any measure aimed at achieving the return of a device that has already been made available to the end user;	No change

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109.	(50) 'withdrawal' means any measure aimed at preventing a device in the supply chain from further being made available on the market;	(50) 'withdrawal' means any measure aimed at preventing a device in the supply chain from further being made available on the market;	(50) 'withdrawal' means any measure aimed at preventing a device in the supply chain from further being made available on the market;	No change
110.	(51) 'incident' means any malfunction or deterioration in the characteristics or performance of a device made available on the market, any inadequacy in the information supplied by the manufacturer and any unexpected undesirable effect;	(51) 'incident' means any malfunction or deterioration in the characteristics or performance of a device made available on the market, any inadequacy in the information supplied by the manufacturer and any unexpected undesirable effect;	(51) 'incident' means any malfunction or deterioration in the characteristics or performance of a device made available on the market including use-error due to ergonomic features, any inadequacy in the information supplied by the manufacturer and any harm as a consequence of the medical decision, action taken or not taken on the basis of information or result(s) provided by the device;	**Adds two elements:** • **Ergonomic feature induced user error (becomes then reportable)** • **Harm as a consequence of a medical decision… this is potentially a very big change**
111.	(52) 'serious incident' means any incident that directly or indirectly led, might have led or might lead to any of the following: – death of a patient, user or other person, – temporary or permanent serious deterioration of the patient's, user's or other person's state of health, – serious public health threat;	(52) 'serious incident' means any incident that directly or indirectly led, might have led or might lead to any of the following: – death of a patient, user or other person, – temporary or permanent serious deterioration of the patient's, user's or other person's state of health, – serious public health threat;	(52) 'serious incident' means any incident that directly or indirectly led, might have led or might lead to any of the following: – death of a patient, user or other person, - temporary or permanent serious deterioration of the patient's, user's or other person's state of health, –serious public health threat;	No change
112.			(52a) 'serious public health threat' means any event type which results in imminent risk of death, serious deterioration in state of health, or serious illness that may requires prompt remedial action;	Misleading. This is not a public health threat. This is impact on a single patient.
113.	(53) 'corrective action' means action taken to eliminate the cause of a potential or real non-conformity or other undesirable situation;	(53) 'corrective action' means action taken to eliminate the cause of a potential or real non-conformity or other undesirable situation;	(53) 'corrective action' means action taken to eliminate the cause of a potential or real non-conformity or other undesirable situation;	No change

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114.	(54) 'field safety corrective action' means corrective action taken by the manufacturer for technical or medical reasons to prevent or reduce the risk of a serious incident in relation to a device made available on the market;	(54) 'field safety corrective action' means corrective action taken by the manufacturer for technical or medical reasons to prevent or reduce the risk of a serious incident in relation to a device made available on the market;	(54) 'field safety corrective action' means corrective action taken by the manufacturer for technical or medical reasons to prevent or reduce the risk of a serious incident in relation to a device made available on the market;	No change
115.	(55) 'field safety notice' means the communication sent by the manufacturer to users or customers in relation to a field safety corrective action;	(55) 'field safety notice' means the communication sent by the manufacturer to users, waste disposal operators or customers in relation to a field safety corrective action;	(55) 'field safety notice' means the communication sent by the manufacturer to users or customers in relation to a field safety corrective action;	No change
116.	(56) 'market surveillance' means the activities carried out and measures taken by public authorities to ensure that products comply with the requirements set out in the relevant Union harmonisation legislation and do not endanger health, safety or any other aspect of public interest protection; Definitions related to standards and other technical specifications:	(56) 'market surveillance' means the activities carried out and measures taken by public authorities to ensure that products comply with the requirements set out in the relevant Union harmonisation legislation and do not endanger health, safety or any other aspect of public interest protection; Definitions related to standards and other technical specifications :	(56) 'market surveillance' means the activities carried out and measures taken by public authorities to check and ensure that devices comply with the requirements set out in the relevant Union harmonisation legislation and do not endanger health, safety or any other aspect of public interest protection;	Slight modification, no impact.
117.		(56a) 'unannounced inspection' means an inspection conducted without advance notice		
118.	Definitions related to standards and other technical specifications:	Definitions related to standards and other technical specifications:	Definitions related to standards and other technical specifications:	
119.	(57) 'harmonised standard' means a European standard as defined in Article 2(1)(c) of Regulation (EU) No [Ref. of future Regulation on European standardisation];	(57) 'harmonised standard' means a European standard as defined in Article 2(1)(c) of Regulation (EU) No [Ref. of future Regulation on European standardisation];	(57) 'harmonised standard' means a European standard as defined in Article 2(1)(c) of Regulation (EU) No [Ref. of future Regulation on European standardisation];	No change
120.	(58) 'common technical specifications'	(58) 'common technical specifications'	(58) 'common specifications' means a	CTS becomes CS – unclear

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	means a document other than a standard that prescribes technical requirements that provide a means to comply with the legal obligations applicable to a device, process or system.	means a document other than a standard that prescribes technical requirements that provide a means to comply with the legal obligations applicable to a device, process or system.	document other than a standard that prescribes technical requirements that provide a means to comply with the legal obligations applicable to a device, process or system.	why.
121.	**Article 3** **Regulatory status of products**	**Article 3** **Regulatory status of products**	**Article 3** **Regulatory status of products**	
122.	1. The Commission may, at the request of a Member State or on its own initiative, by means of implementing acts, determine whether or not a specific product, or category or group of products, falls within the definitions of an in vitro diagnostic medical devices or of an accessory to an in vitro diagnostic medical device. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).	1. The Commission may on its own initiative or shall at the request of a Member State, by means of implementing acts on the basis of the opinions of the MDCG and the MDAC referred to in Articles 76 and 76a respectively, determine whether or not a specific product, or category or group of products, including borderline products, falls within the definitions of an in vitro diagnostic medical devices or of an accessory to an in vitro diagnostic medical device. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).	1. Without prejudice to Article 2(2) of Directive 2001/83**,** at a duly substantiated request of a Member State, the Commission shall, after consulting the MDCG, by means of implementing acts, determine whether or not a specific product, or category or group of products, falls within the definitions of an in vitro diagnostic medical devices or of an accessory to an in vitro diagnostic medical device. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).	Gives precedence to 2001/83 (directive relating to medicinal products for human use). Article 2.2 of 2001/83: *In cases of doubt, where, taking into account all its characteristics, a product may fall within the definition of a 'medicinal product' and within the definition of a product covered by other Community legislation the provisions of this [2001/83] shall apply.*
123.			1a. The Commission may also, on its own initiative, after consulting the MDCG, decide, by means of implementing acts, on the issues referred to in paragraph 1.	New text, right of initiative to the commission. No impact.
124.	2. The Commission shall ensure the sharing of expertise between Member States in the fields of in vitro diagnostic medical devices, medical devices, medicinal products, human tissues and cells, cosmetics, biocides, food and, if necessary, other products in order to determine the appropriate regulatory		2. The Commission shall ensure the sharing of expertise between Member States, in the fields of in vitro diagnostic medical devices, medical devices, medicinal products, human tissues and cells, cosmetics, biocides, food and, if necessary, other products in order to determine the appropriate regulatory	No change

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	status of a product, or category or group of products.		status of a product, or category or group of products.	
125.	**Chapter II Making available of devices, obligations of economic operators, CE marking, free movement**	**Chapter II Making available and application of devices, obligations of economic operators, CE marking, free movement**	**Chapter II Making available of devices, obligations of economic operators, CE marking, free movement**	
126.	**Article 4 Placing on the market and putting into service**	**Article 4 Placing on the market and putting into service**	**Article 4 Placing on the market and putting into service**	
127.	1. A device may be placed on the market or put into service only if it complies with this Regulation when duly supplied and properly installed, maintained and used in accordance with its intended purpose.	1. A device may be placed on the market or put into service only if it complies with this Regulation when duly supplied and properly installed, maintained and used in accordance with its intended purpose.	1. A device may be placed on the market or put into service only if it complies with this Regulation when duly supplied and properly installed, maintained and used in accordance with its intended purpose.	No change
128.	2. A device shall meet the general safety and performance requirements which apply to it, taking into account its intended purpose. General safety and performance requirements are set out in Annex I.	2. A device shall meet the general safety and performance requirements which apply to it, taking into account its intended purpose. General safety and performance requirements are set out in Annex I.	2. A device shall meet the general safety and performance requirements which apply to it, taking into account its intended purpose. General safety and performance requirements are set out in Annex I.	No change
129.	3. Demonstration of conformity with the general safety and performance requirements shall be based on clinical evidence in accordance with Article 47.	3. Demonstration of conformity with the general safety and performance requirements shall include clinical evidence in accordance with Article 47.	3. Demonstration of conformity with the general safety and performance requirements shall include a performance evaluation in accordance with Article 47.	**Establishes performance evaluation rather than clinical evidence as the basis for conformity assessment.**
130.	4. Devices that are manufactured and used within a single health institution shall be considered as being put into service.	4. Devices that are manufactured and used within a single health institution shall be considered as being put into service.	4. Devices that are manufactured and used within health institutions shall be considered as being put into service.	No change
131.	5. With the exception of Article 59(4), the requirements of this Regulation shall not apply to devices classified as class A, B and C, in accordance with the rules set out	5. With the exception of Article 59(4), the requirements of this Regulation shall not apply to devices classified as class A, B and C, in accordance with the rules set out	5. With the exception of the relevant general safety and performance requirements set out in Annex I, the requirements of this Regulation shall not	**Needlessly limits the applicability of in-house restrictions to institutions based in the Union. Impact on**

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	in Annex VII, and manufactured and used only within a single health institution, provided	in Annex VII, and manufactured and used only within a single health institution, provided	apply to devices manufactured and used only within health institutions established in the Union, provided that the following conditions are met:	**the situation where samples are sent out of the EU for analysis. Conflict with articles on distance sales.**
132.			(aa) the device is not transferred to another legal entity	From current implementation
133.	manufacture and use occur solely under the health institution's single quality management system, and the health institution is compliant with standard EN ISO 15189 or any other equivalent recognised standard.	manufacture and use occur solely under the health institution's single quality management system, and the health institution is accredited with standard EN ISO 15189 or any other equivalent recognised standard. Howeever, the requirements of this Regulation shall continue to apply to clinical or commercial pathology laboratories which do not have health care (i.e. care and treatment of patients) or the promotion of public health as their primary purpose.	(a) manufacture and use of the device occur under appropriate quality management systems, (b) the laboratory of the health institution is compliant with standard EN ISO 15189 and where applicable national provisions, including national provisions regarding accreditation.	Focus on accreditation to ISO 15189
134.			(c) the health institution establishes in its documentation that it has given due consideration as to whether the target patient group's specific needs cannot be met or cannot be met at the appropriate level of performance by an equivalent device available on the market; (d) the health institution provides information on annual basis on the use of such devices to their competent authority, which shall include a justification of their manufacturing, modification and use; (e) the health institution draws up a declaration, that it shall make publicly available including: - the name and address of the manufacturing health institution;	In house assay rules which limit the use of in house assays to those situations where there are no commercial IVDs available.

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			- the details necessary to identify the devices; - a declaration that the devices meet the general safety and performance requirements set out in Annex I of this Regulation and, where applicable, information on which requirements are not fully met with reasoned justification, (f) as regards devices classified as class C and D in accordance with the rules set out in Annex VII, the health institution draws up documentation, allowing an understanding of the manufacturing facility, the manufacturing process, the design and performance data of the devices, including the intended purpose, sufficiently detailed to enable the competent authority to ascertain that the general safety and performance requirements set out in Annex I of this Regulation are met; Member States may apply this provision also to devices classified as class A and B in accordance with the rules set out in Annex VII; (g) the health institution takes all necessary measures to ensure that all devices are manufactured in accordance with the documentation referred to in the previous sub-paragraph, and (h) the health institution reviews experience gained from clinical use of the devices and takes all necessary corrective actions.	
135.	Member States may require that the health institutions submit to the competent authority a list of such devices which have been manufactured and used on their	Member States are to require that the health institutions submit to the competent authority a list of such devices which have been manufactured and used on their	Member States may require that the health institutions submit to the competent authority any further relevant information about such devices which have been	Member states can further legislation in house assays.

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	territory and may make the manufacture and use of the devices concerned subject to further safety requirements.	territory and shall make the manufacture and use of the devices concerned subject to further safety requirements.	manufactured and used on their territory. Member States shall retain the right to restrict the manufacture and use of any specific type of such devices and shall be permitted access to inspect the activities of the health institutions.	
136.	Devices classified as class D in accordance with the rules set out in Annex VII, even if manufactured and used within a single health institution, shall comply with the requirements of this Regulation. However, the provisions regarding CE marking set out in Article 16 and the obligations referred to in Articles 21 to 25 shall not apply to those devices.			Allows class D in house assays under the restrictive conditions outlined above. In particular – no commercial assays can be available.
137.			These provisions do not apply to devices which are manufactured on an industrial scale and which are used within the framework of a commercial diagnostic service.	Further restriction on in house assays. Based partially on the German MPG.
138.	6. The Commission shall be empowered to adopt delegated acts in accordance with Article 85, amending or supplementing, in the light of technical progress and considering the intended users or patients, the general safety and performance requirements set out in Annex I, including the information supplied by the manufacturer.		6. The Commission may adopt implementing acts to ensure the uniform application of Annex I. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3)	In principle not a great deal of impact – curiously Council has replaced a lot of delegated acts with implementing acts. They are very different instruments however and there will probably be some discussion between Council and Commission about this.
139.	**Article 5 Distance sales**	**Article 5 Distance sales**	**Article 5 Distance sales**	
140.	1. A device offered by means of information society services as defined in	1. A device offered by means of information society services as defined in	1. A device offered by means of information society services as defined in	No change

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	Article 1(2) of Directive 98/34/EC to a natural or legal person established in the Union shall comply with this Regulation at the latest when the device is placed on the market.	Article 1(2) of Directive 98/34/EC to a natural or legal person established in the Union shall comply with this Regulation at the latest when the device is placed on the market.	Article 1(2) of Directive 98/34/EC to a natural or legal person established in the Union shall comply with this Regulation when the device is placed on the market.	
141.	2. Without prejudice to national legislation regarding the exercise of the medical profession, a device that is not placed on the market but is used in the context of a commercial activity for the provision of a diagnostic or therapeutic service offered by means of information society services as defined in Article 1(2) of Directive 98/34/EC or by other means of communication to a natural or legal person established in the Union shall comply with this Regulation.	Without prejudice to national legislation regarding the exercise of the medical profession, a device that is not placed on the market but is used in the context of a commercial activity for the provision of a diagnostic or therapeutic service offered by means of information society services as defined in Article 1(2) of Directive 98/34/EC or by other means of communication to a natural or legal person established in the Union shall comply with this Regulation.	2. Without prejudice to national legislation regarding the exercise of the medical profession, a device that is not placed on the market but used in the context of a commercial activity, whether in return for payment or free of charge, for the provision of a diagnostic or therapeutic service offered by means of information society services as defined in Article 1(2) of Directive 98/34/EC or by other means of communication, directly or through intermediaries, to a natural or legal person established in the Union shall comply with this Regulation.	Clarifies that even if there is no payment and the transaction happens through intermediaries the rules on distance sales still apply.
142.		2a. Service providers providing means of distance communication shall be obliged, upon receiving a request from the competent authority, to disclose the details of entities engaging in distance selling.		
143.		2b. There shall be a prohibition on the marketing, placing in use, distribution, delivery and making available of products whose names, labelling or instructions for use may mislead with regard to the product's characteristics and effects by: a) Ascribing characteristics, functions and effects to the product which the product does not have; b) Creating the false impression that treatment or diagnosis using the product is		

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		sure to be successful, or failing to inform of a likely risk associated with the use of the product in line with its intended use or for a longer-than-anticipated period; c) Suggesting users or characteristics of the product other than those declared when the conformity assessment was carried out. Promotional materials, presentations and information about the products may not mislead in the manner referred to in the first subparagraph.		
144.			3. Upon request by a competent authority, the natural or legal person offering a device in accordance with paragraph 1 or providing a service in accordance with paragraph 2 shall make available a copy of the EU declaration of conformity of the device concerned.	More power to enforce provisions for distance sales by authorities.
145.			4. A Member State may on grounds of protection of public health, require a provider of information society services as defined in Article 1(2) of Directive 98/34/EC to cease its activity.	More power to enforce provisions for distance sales by authorities
146.	**Article 6 Harmonised standards**	**Article 6 Harmonised standards**	**Article 6 Harmonised standards**	
147.	1. Devices which are in conformity with the relevant harmonised standards, or parts thereof, the references of which have been published in the Official Journal of the European Union shall be presumed to be in conformity with the requirements of this Regulation covered by those standards or parts thereof. The first subparagraph shall	1. Devices which are in conformity with the relevant harmonised standards, or parts thereof, the references of which have been published in the Official Journal of the European Union shall be presumed to be in conformity with the requirements of this Regulation covered by those standards or parts thereof. The first subparagraph shall	1. Devices which are in conformity with the relevant harmonised standards, or parts thereof, the references of which have been published in the Official Journal of the European Union shall be presumed to be in conformity with the requirements of this Regulation covered by those standards or parts thereof.	No change

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148.	also apply to system or process requirements to be fulfilled by economic operators or sponsors in accordance with this Regulation, including those related to the quality management system, risk management, the post-market surveillance plan, clinical performance studies, clinical evidence or post-market follow-up.	also apply to system or process requirements to be fulfilled by economic operators or sponsors in accordance with this Regulation, including those related to the quality management system, risk management, the post-market surveillance plan, clinical performance studies, clinical evidence or post-market follow-up.	2. The first subparagraph shall also apply to system or process requirements to be fulfilled by economic operators or sponsors in accordance with this Regulation, including those related to the quality management system, risk management, the post-market surveillance plan, clinical performance studies, clinical evidence or post-market performance follow-up.	Paragraph split into two points, only change – post market ***performance*** follow-up.
149.	2. Reference to harmonised standards also includes the monographs of the European Pharmacopoeia adopted in accordance with the Convention on the Elaboration of a European Pharmacopoeia.	2. Reference to harmonised standards also includes the monographs of the European Pharmacopoeia adopted in accordance with the Convention on the Elaboration of a European Pharmacopoeia.	3. Reference to harmonised standards also includes the monographs of the European Pharmacopoeia adopted in accordance with the Convention on the Elaboration of a European Pharmacopoeia, the references of which have been published in the Official Journal of the European Union.	Clarifies that harmonized standards will have had their references published in the OJEU.
150.	**Article 7** **Common technical specifications**	**Article 7** **Common technical specifications**	**Article 7** **Common specifications**	CTS becomes CS
151.	1. Where no harmonised standards exist or where relevant harmonised standards are not sufficient, the Commission shall be empowered to adopt common technical specifications (CTS) in respect of the general safety and performance requirements set out in Annex I, the technical documentation set out in Annex II or the clinical evidence and post-market follow-up set out in Annex XII. The CTS shall be adopted by means of implementing acts in accordance with the examination procedure referred to in Article 84(3).	1. Where no harmonised standards exist or where there is a need to address public health concerns, the Commission, after having consulted the MDCG and the MDAC, shall be empowered to adopt common technical specifications (CTS) in respect of the general safety and performance requirements set out in Annex I, the technical documentation set out in Annex II or the clinical evidence and post-market follow-up set out in Annex XII. The CTS shall be adopted by means of implementing acts in accordance with the examination procedure referred to in Article 84(3).	1. Where no harmonised standards exist or where relevant harmonised standards are not sufficient, the Commission, after having consulted the MDCG, may adopt common specifications (CS) in respect of the general safety and performance requirements set out in Annex I, the technical documentation set out in Annex II, the performance evaluation and post-market performance clinical follow-up set out in Annex XII or the requirements regarding clinical performance studies set out in Annex XIII. The CS shall be adopted by means of implementing acts in accordance with the examination	CS can now be developed for: • Performance evaluations • Post-market performance clinical follow-up • Clinical performance studies Terminology inconsistency – sometimes the text refers to post-market performance follow-up, sometimes to post-market performance clinical follow-up.

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			procedure referred to in Article 84(3).	
152.		1a. Before adopting CTS referred to in paragraph 1, the Commission shall ensure that the CTS have been developed with the appropriate support of the relevant stakeholders and that they are coherent with the European and international standardisation system. CTS are coherent if they do not conflict with European standards, meaning they cover areas where no harmonised standards exist, the adoption of new European standards is not foreseen within a reasonable period, where existing standards have not gained market uptake or where those standards have become obsolete or have been demonstrated as clearly insufficient according to vigilance or surveillance data, and where the transposition of the technical specifications into European standardisation deliverables is not foreseen within a reasonable period.		
153.	2. Devices which are in conformity with the CTS referred to in paragraph 1 shall be presumed to be in conformity with the requirements of this Regulation covered by those CTS or parts thereof.	2. Devices which are in conformity with the CTS referred to in paragraph 1 shall be presumed to be in conformity with the requirements of this Regulation covered by those CTS or parts thereof.	2. Devices which are in conformity with the CS referred to in paragraph 1 shall be presumed to be in conformity with the requirements of this Regulation covered by those CS or parts thereof.	No change (except CTS becomes CS)
154.	3. Manufacturers shall comply with the CTS unless they can duly justify that they have adopted solutions ensuring a level of safety and performance that is at least equivalent thereto.	3. Manufacturers shall comply with the CTS unless they can duly justify that they have adopted solutions ensuring a level of safety and performance that is at least equivalent thereto.	3. Manufacturers shall comply with the CS unless they can duly justify that they have adopted solutions ensuring a level of safety and performance that is at least equivalent thereto.	No change (except CTS becomes CS)
155.	**Article 8** **General obligations of the manufacturer**	**Article 8** **General obligations of the manufacturer**	**Article 8** **General obligations of the manufacturer**	

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156.	1. When placing their devices on the market or putting them into service, manufacturers shall ensure that they have been designed and manufactured in accordance with the requirements of this Regulation.	1. When placing their devices on the market or putting them into service, manufacturers shall ensure that they have been designed and manufactured in accordance with the requirements of this Regulation.	1. When placing their devices on the market or putting them into service, manufacturers shall ensure that they have been designed and manufactured in accordance with the requirements of this Regulation.	No change
157.			1a.Manufacturers shall establish, execute, maintain and document a system for Risk Management as described in Section I.2 in Annex I.	Ensures that risk management is exclusively the responsibility of the manufacturer.
158.			1c. Manufacturers shall conduct a performance evaluation in accordance with the principles set out in Article 47 and Annex XII, including post-market performance follow-up.	Performance evaluation in this context is an assessment of data – needed for every device. (Not necessarily a study)
159.	2. Manufacturers shall draw up the technical documentation which shall allow assessment of the conformity of the device with the requirements of this Regulation. The technical documentation shall include the elements set out in Annex II. The Commission shall be empowered to adopt delegated acts in accordance with Article 85 amending or supplementing, in the light of technical progress, the elements in the technical documentation set out in Annex II.	2. Manufacturers shall draw up the technical documentation which shall allow assessment of the conformity of the device with the requirements of this Regulation. The technical documentation shall include the elements set out in Annex II.	2. Manufacturers shall draw up and keep up to date the technical documentation which shall allow assessment of the conformity of the device with the requirements of this Regulation. The technical documentation shall include the elements set out in Annex II. The Commission shall be empowered to adopt delegated acts in accordance with Article 85 amending or supplementing, in the light of technical progress, the elements in the technical documentation set out in Annex II.	Only change – explicit requirement that technical documentation be kept up to date
160.	3. Where compliance of a device with the applicable requirements has been demonstrated following the applicable conformity assessment procedure, manufacturers of devices, other than devices for performance evaluation, shall	3. Where compliance of a device with the applicable requirements has been demonstrated following the applicable conformity assessment procedure, manufacturers of devices, other than devices for performance evaluation, shall	3. Where compliance with the applicable requirements has been demonstrated following the applicable conformity assessment procedure, manufacturers of devices, other than devices for performance evaluation, shall draw up an	Removed compliance of a device – not clear why as the CE mark can only be affixed on a device.

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	draw up an EU declaration of conformity in accordance with Article 15 and affix the CE marking of conformity in accordance with Article 16.	draw up an EU declaration of conformity in accordance with Article 15 and affix the CE marking of conformity in accordance with Article 16.	EU declaration of conformity in accordance with Article 15, and affix the CE marking of conformity in accordance with Article 16.	
161.			3a. Manufacturers shall comply with the obligations related to the UDI system referred to in Articles 22 and with the registration obligations referred to in Article 23.	Link UDI and registration
162.	4. Manufacturers shall keep the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate including any supplement, issued in accordance with Article 43, available to the competent authorities for a period of at least five years after the last device covered by the declaration of conformity has been placed on the market.	4. Manufacturers shall keep the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate including any supplement, issued in accordance with Article 43, available to the competent authorities for a period of at least five years after the last device covered by the declaration of conformity has been placed on the market.	4. Manufacturers shall keep the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate including any amendments and supplements, issued in accordance with Article 43, available to the competent authorities for a period of at least five years after the last device covered by the declaration of conformity has been placed on the market.	Need to keep any amendments technical documentation and certificates.
163.	Where the technical documentation is voluminous or held in different locations, the manufacturer shall provide, upon request by a competent authority, a summary technical documentation (STED) and grant access to the full technical documentation upon request.	Where the technical documentation is voluminous or held in different locations, the manufacturer shall provide, upon request by a competent authority, a summary technical documentation (STED) and grant access to the full technical documentation upon request.	Upon request by a competent authority, the manufacturer shall provide the full technical documentation or a summary technical documentation (STED) as indicated in the request.	Emphasis that authorities may request STED or full technical documentation.
164.			Manufacturer with registered place of business outside the Union, to allow the authorised representative to fulfil the tasks mentioned in Article 9, paragraph 3 shall ensure that the authorised representative has permanently available to the necessary documentation.	**If this implies that authorized rep has to hold technical documentation then there is a problem. (see article 9)**

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165.	5. Manufacturers shall ensure that procedures are in place to keep series production in conformity with the requirements of this Regulation. Changes in product design or characteristics and changes in the harmonised standards or CTS by reference to which conformity of a product is declared shall be adequately taken into account. Proportionate to the risk class and the type of device, manufacturers of devices, other than devices for performance evaluation, shall institute and keep up to date a quality management system that shall address at least the following aspects:	5. Manufacturers shall ensure that procedures are in place to keep series production in conformity with the requirements of this Regulation. Changes in product design or characteristics and changes in the harmonised standards or CTS by reference to which conformity of a product is declared shall be adequately taken into account. Proportionate to the risk class and the type of device, manufacturers of devices, other than devices for performance evaluation, shall institute and keep up to date a quality management system that shall address at least the following aspects:	5. Manufacturers shall ensure that procedures are in place to keep series production in conformity with the requirements of this Regulation. Changes in product design or characteristics and changes in the harmonised standards or CS by reference to which conformity of a product is declared shall be adequately taken into account in a timely manner. Proportionate to the risk class and the type of device, manufacturers of devices, other than devices for performance evaluation, shall establish, document, implement, maintain, keep up to date and continually improve a quality management system that shall ensure compliance with this regulation in the most effective manner.	**Unclear what continuous improvement of the quality management system actually is – the quality management system is the tool through which continuous improvement to device, production processes etc. take place. But the quality management system itself is not under continuous improvement. (Too confusing)**
166.			The QMS consists of all parts and components of a manufacturer's organisation dealing with the quality of processes, procedures and devices. It is managing the structure, responsibilities, procedures, processes and management resources to implement the needed principles and actions to achieve compliance with the provisions of this regulation.	Is this really needed in a regulation? Too much detail.
167.			The quality management system shall address at least the following aspects:	Idem
168.			(aa) a strategy for regulatory compliance, including compliance with conformity assessment procedures and management change;	Idem
169.			(ab) identification of applicable general	Idem

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			safety and performance requirements and exploration of options to address these;	
170.	(a) the responsibility of the management;	(a) the responsibility of the management;	(a) the responsibility of the management;	No change
171.	(b) resource management, including selection and control of suppliers and sub-contractors;	(b) resource management, including selection and control of suppliers and sub-contractors;	(b) resource management, including selection and control of suppliers and sub-contractors;	No change
172.			(ba) risk management according to section I. 2 of Annex I;	QMS to explicitly include risk management
173.			(bc) clinical evaluation, according to Article 49 and Annex XIII, including post-market clinical follow-up;	Article 49 would only be applicable for at risk or interventional studies.
174.	(c) product realisation;	(c) product realisation;	(c) product realisation, including planning, design, development, production and service provision;	Further explanation – detail from standard practice.
175.			(ca) control of the UDI-Code assignments to all relevant devices and ensuring consistency and validity of information provided according to Article 25;	QMS system expands to UDI data management and assignment
176.			(cb) setting-up, implement and maintain a systematic post-market surveillance plan according to Article58b;	Systematic post market surveillance issue
177.			(cc) handling communication with competent authorities, notified bodies, other economic operators, customers and/or other stakeholders;	Would all communication be covered or only certain types?

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178.			(cd) processes for reporting of serious incidents and field safety corrective actions in the context of vigilance;	Normal part of QMS
179.			(ce) management of corrective and preventive actions and verification of their effectiveness;	Normal part of QMS
180.	(d) processes for monitoring and measurement of output, data analysis and product improvement.	(d) processes for monitoring and measurement of output, data analysis and product improvement.	(d) processes for monitoring and measurement of output, data analysis and product improvement.	No change
181.	6. Proportionate to the risk class and the type of device, manufacturers of devices shall institute and keep up to date a systematic procedure to collect and review experience gained from their devices placed on the market or put into service, and to apply any necessary corrective action, hereinafter referred to as 'post-market surveillance plan'. The post-market surveillance plan shall set out the process for collecting, recording and investigating complaints and reports from healthcare professionals, patients or users on suspected incidents related to a device, keeping a register of non- conforming products and product recalls or withdrawals, and if deemed appropriate due to the nature of the device, sample testing of marketed devices. Part of the post-market surveillance plan shall be a plan for post-market follow-up in accordance with Part B of Annex XII. Where post-market follow-up is not deemed necessary, this shall be duly justified and documented in the post-market surveillance plan.	6. Proportionate to the risk class and the type of device, manufacturers of devices shall institute and keep up to date a systematic procedure to collect and review experience gained from their devices placed on the market or put into service, and to apply any necessary corrective action, hereinafter referred to as 'post-market surveillance plan'. The post-market surveillance plan shall set out the process for collecting, recording, communicating to the electronic system on vigilance referred in Article 60 and investigating complaints and reports from healthcare professionals, patients or users on suspected incidents related to a device, keeping a register of non- conforming products and product recalls or withdrawals, and if deemed appropriate due to the nature of the device, sample testing of marketed devices. Part of the post-market surveillance plan shall be a plan for post-market follow-up in accordance with Part B of Annex XII. Where post-market follow-up is not deemed necessary, this shall be duly justified and documented in the post-	6. Proportionate to the risk class and the type of device, manufacturers of devices shall implement and keep up to date the 'post-market surveillance post-market surveillance system referred to in Article 58a.	Much of the text from COM is back in article 58a (NOTE: Typo in Council text)

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		market surveillance plan and subject to approval by the competent authority.		
182.	If in the course of the post-market surveillance a need for corrective action is identified, the manufacturer shall implement the appropriate measures.	If in the course of the post-market surveillance a need for corrective action is identified, the manufacturer shall implement the appropriate measures.		
183.	7. Manufacturers shall ensure that the device is accompanied by the information to be supplied in accordance with Section 17 of Annex I in an official Union language which can be easily understood by the intended user. The language(s) of the information to be supplied by the manufacturer may be determined by the law of the Member State where the device is made available to the user.	7. 7. Manufacturers shall ensure that the information to be supplied for the device in accordance with Section 17 of Annex I is provided in an official Union language which can be easily understood by the intended user.	7. Manufacturers shall ensure that the device is accompanied by the information to be supplied in accordance with Section 17 of Annex I in an official Union language determined by the concerned Member State. The language(s) of the information to be supplied by the manufacturer may be determined by the law of the Member State where the device is made available to the user. The particulars on the label shall be easily legible, clearly comprehensible and indelible.	Member state determines language to be used – this is a plus (prevents user requests for esoteric languages). Requirement for indelibility – may be an issue depending on what is meant by indelible.
184.	For devices for self-testing or near-patient-testing, the information supplied in accordance with Section 17 of Annex I shall be provided in the language(s) of the Member State where the device reaches its intended user.	For devices for self-testing or near-patient-testing, the information supplied in accordance with Section 17 of Annex I shall be easily understandable and provided in the language(s) of the Member State where the device reaches its intended user.	For devices for self-testing or near-patient-testing, the information supplied in accordance with Section 17 of Annex I shall be provided in the language(s) of the Member State where the device reaches its intended user.	No change
185.	8. Manufacturers who consider or have reason to believe that a device which they have placed on the market is not in conformity with this Regulation shall immediately take the necessary corrective action to bring that product into conformity, withdraw it or recall it, as appropriate. They shall inform the distributors and, where applicable, the authorised	8. 8. Manufacturers who consider or have reason to believe that a device which they have placed on the market is not in conformity with this Regulation shall immediately take the necessary corrective action to bring that product into conformity, withdraw it or recall it, as appropriate. They shall inform the responsible national competent authority, the distributors,	8. Manufacturers who consider or have reason to believe that a device which they have placed on the market or put into service is not in conformity with this Regulation shall immediately take the necessary corrective action to bring that product into conformity, withdraw it or recall it, as appropriate. They shall inform accordingly the distributors and, where	Requirement – inform importers of corrective actions Actions can include recall or withdrawal of product.

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	representative accordingly.	importers and, where applicable, the authorised representative accordingly.	applicable, the authorised representative and the importers.	
186.			Where the device presents a serious risk, manufacturers shall immediately inform the competent authorities of the Member States in which they made the device available and, where applicable, the notified body that issued a certificate for the device in accordance with Article 43, in particular, of the non-compliance and of any corrective action taken.	Redundant requirement as all corrective actions need to be reported to CAs in any case.
187.			8a. Manufacturers shall have a system for reporting of incidents and field safety corrective actions as described in Article 59.	Clarify that reporting incidents and FSCA is the responsibility of manufacturers
188.	9. Manufacturers shall, in response to a reasoned request from a competent authority, provide it with all the information and documentation necessary to demonstrate the conformity of the device, in an official Union language which can be easily understood by that authority.	9. Manufacturers shall, in response to a reasoned request from a competent authority, provide it with all the information and documentation necessary to demonstrate the conformity of the device, in an official Union language which can be easily understood by that authority.	9. Manufacturers shall, upon request from a competent authority, provide it with all the information and documentation necessary to demonstrate the conformity of the device, in an official Union language determined by the Member State concerned.	Requests from authorities need no longer be reasoned. (How big a problem is this?). Language may be a significant problem especially if multiple authorities request information in multiple languages at once.
189.		If a competent authority considers or has reason to believe that a device has caused damages, it shall ensure, where this is not already foreseen by national litigation or judicial proceedings, that the potentially harmed user, the user's successor in title, the user's health insurance company or other third parties affected by the damage caused to the user may request the information referred to i n the first subparagraph from the manufacturer or his authorised representative while		

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		ensuring due respect to the intellectual property rights.		
190.		If facts exist that give reason to assume that an in-vitro medical device has caused damage, the potentially harmed user, his successor in title, his compulsory health insurance or other third parties affected by the damage may also demand the information referred to in sentence 1 from the manufacturer or his authorized representative.		
191.		This right to information shall also exist, subject to the conditions set forth in sentence 1, against the competent authorities of the Member States which are responsible for the surveillance of the respective medical device, as well as against any notified body that issued a certificate pursuant to Article 45 or was otherwise involved in the conformity assessment procedure of the medical device in question.		
192.			The competent authority where the manufacturer has his registered place of business may require that the manufacturer provide samples of the device free of charge or, where impracticable, grant access to the device.	No comment
193.	They shall cooperate with that authority, at its request, on any corrective action taken to eliminate the risks posed by devices which they have placed on the market or put into service.		Manufacturers shall cooperate with a competent authority, at its request, on any corrective action taken to eliminate the risks posed by devices which they have placed on the market or put into service.	Essentially the same text. (minor changes)

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194.			If the manufacturer fails to cooperate or the information and documentation provided is incomplete or incorrect, the competent authority may suspend the involved device until its demonstration of conformity to the essential requirements.	Incomprehensible. There is no such thing as “device suspension”.
195.	10. Where manufacturers have their devices designed and manufactured by another legal or natural person, the information on the identity of that person shall be part of the information to be submitted in accordance with Article 23.	10. Where manufacturers have their devices designed and manufactured by another legal or natural person, the information on the identity of that person shall be part of the information to be submitted in accordance with Article 23.	10. Where manufacturers have their devices designed and manufactured by another legal or natural person the information on the identity of that person shall be part of the information to be submitted in accordance with Article 23.	No change
196.		10a. Before placing an in vitro diagnostic medical device on the market, manufacturers shall ensure they are covered by an appropriate liability insurance covering the risk of insolvency and any damages to patients or users that can be directly attributed to a manufacturing defect of the same medical device, with a level of coverage proportionate to the potential risk associated with the in vitro diagnostic medical device produced, and in accordance with Directive 85/374/ECC.	11. Natural or legal persons may claim compensation for damage caused by a defective device in accordance with applicable Union and national law. To this end, manufacturers shall consider taking out appropriate insurance or arranging for an equivalent financial guarantee, to cover the costs associated with defective devices.	Liability provision – these provisions are not as stringent as those setup by Parliament on liability.
197.	**Article 9 Authorised representative**	**Article 9 Authorised representative**	**Article 9 Authorised representative**	
198.	1. A manufacturer of a device that is placed on the Union market, or bears the CE marking without being placed on the Union market, who does not have a registered place of business in a Member State or does not carry out relevant activities at a registered place of business	1. A manufacturer of a device that is placed on the Union market, or bears the CE marking without being placed on the Union market, who does not have a registered place of business in a Member State or does not carry out relevant activities at a registered place of business	1. Where the manufacturer of a device is not established in any Member State, the device may only be placed on the Union market, if the manufacturer designates a single authorised representative.	**Change – if you CE mark a device but do not place it on the Union market (e.g. to export to third countries) no Authorized Representative is needed. Significant weakening of the CE mark as**

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	in a Member State, shall designate a single authorised representative.	in a Member State, shall designate a single authorised representative.		**a means to access markets beyond the EU.**
199.	2. The designation shall be valid only when accepted in writing by the authorised representative and shall be effective at least for all devices of the same generic device group.	2. The designation shall be valid only when accepted in writing by the authorised representative and shall be effective at least for all devices of the same generic device group.	2. The designation shall constitute the authorised representative's mandate, it shall be valid only when accepted in writing by the authorised representative and shall be effective at least for all devices of the same generic device group.	Clarified that the designation and the mandate are the same document.
200.	3. The authorised representative shall perform the tasks specified in the mandate agreed between the manufacturer and the authorised representative.	3. The authorised representative shall perform the tasks specified in the mandate agreed between the manufacturer and the authorised representative.	3. The authorised representative shall perform the tasks specified in the mandate agreed between the manufacturer and the authorised representative. The authorised representative shall provide a copy of the mandate to the competent authority.	Clarifies that the mandate needs to be provided to the CA.
201.	The mandate shall allow and require the authorised representative to perform at least the following tasks in relation to the devices that it covers:	The mandate shall allow and require the authorised representative to perform at least the following tasks in relation to the devices that it covers:	The mandate shall allow and require the authorised representative to perform at least the following tasks in relation to the devices that it covers:	No change
202.			(aa) verify that the EU declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer;	When is it applicable for an AR to verify that a conformity assessment procedure has been carried out?
203.	(a) keep the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate, including any supplement, issued in accordance with Article 43 at the disposal of competent authorities for the period referred to in Article 8(4);	(a) keep available the summary of technical documentation (STED) or on request the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate, including any supplement, issued in accordance with Article 43 at the disposal of competent authorities for the period referred to in Article 8(4);	(a) keep a copy of the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate including any supplement amendments and supplements issued in accordance with Article 43 at the disposal of competent authorities for the period referred to in Article 8(4);	**Significant change – "keep a copy" implies that the AR needs to be the holder of the technical documentation. This is not the case and is not always acceptable for competitive reasons. (Often a manufacturer can be the AR for other manufacturers)**

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204.		(b) keep the EU declaration of conformity and, if applicable, a copy of the relevant certificate, including any supplement, issued in accordance with Article 43 at the disposal of competent authorities for the period referred to in Article 8(4);		
205.			(ab) comply with the registration obligations laid down in Article 23a(1), (4) and (5);	Register as an authorized representative.
206.	(b) in response to a reasoned request from a competent authority, provide that competent authority with all the information and documentation necessary to demonstrate the conformity of a device;	(e) in response to a reasoned request from a competent authority, provide that competent authority with all the information and documentation necessary to demonstrate the conformity of a device;	(b) in response to a reasoned request from a competent authority, provide that competent authority with all the information and documentation necessary to demonstrate the conformity of a device in a language determined by Member State concerned;	**Language requirement could be a significant problem.**
207.			(ca) forward to the manufacturer any request by a competent authority where he has his registered place of business for samples, or access to a device and verify that the competent authority receives the samples or gets access to the device;	Ensure information gets to manufacturer from CA.
208.	(c) cooperate with the competent authorities on any corrective action taken to eliminate the risks posed by devices;	(f) cooperate with the competent authorities on any corrective action taken to eliminate the risks posed by devices;	(c) cooperate with the competent authorities on any corrective action taken to eliminate the risks posed by devices;	No change
209.	(d) immediately inform the manufacturer about complaints and reports from healthcare professionals, patients and users about suspected incidents related to a device for which they have been designated;	(g) immediately inform the manufacturer about complaints and reports from healthcare professionals, patients and users about suspected incidents related to a device for which they have been designated;	(d) immediately inform the manufacturer about complaints and reports from healthcare professionals, patients and users about suspected incidents related to a device for which they have been designated;	No change
210.	(e) terminate the mandate if the	(h) terminate the mandate if the	(e) terminate the mandate if the	No change

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	manufacturer acts contrary to his obligations under this Regulation.	manufacturer acts contrary to his obligations under this Regulation.	manufacturer acts contrary to his obligations under this Regulation.	
211.	To allow the authorised representative to fulfil the tasks mentioned in this paragraph, the manufacturer shall at least ensure that the authorised representative has permanent immediate access to the necessary documentation in one of the official Union languages.	To allow the authorised representative to fulfil the tasks mentioned in this paragraph, the manufacturer shall at least ensure that the authorised representative has permanent immediate access to the necessary documentation in one of the official Union languages.		Removed requirement that authorized rep has permanent immediate access to technical documentation in an official union language.
212.	4. The mandate referred to in paragraph 3 shall not include the delegation of the manufacturer's obligations laid down in Article 8(1), (2), (5), (6), (7) and (8).	4. The mandate referred to in paragraph 3 shall not include the delegation of the manufacturer's obligations laid down in Article 8(1), (2), (5), (6), (7) and (8).	4. The mandate referred to in paragraph 3 shall not include the delegation of the manufacturer's obligations laid down in Article 8(1), (2), (3), (3a), (5), (6), (7) and (8).	Clarifies that CE marking and UDI are the exclusive responsibility of the manufacturer.
213.			4a. Without prejudice to paragraph 4, where the manufacturer is not established in any Member State, and has not complied with the obligations laid down in Article 8, the authorised representative shall be legally liable for defective devices in accordance with Article 8(13).	**Liability of authorized representative for non-compliance from the part of the manufacturer. Very significant change for authorized representatives.**
214.	5. An authorised representative who terminates the mandate on the grounds referred to in point (e) of paragraph 3 shall immediately inform the competent authority of the Member State in which he is established and, where applicable, the notified body that was involved in the conformity assessment for the device of the termination of the mandate and the reasons therefor.	5. An authorised representative who terminates the mandate on the grounds referred to in point (e) of paragraph 3 shall immediately inform the competent authority of the Member State in which he is established and, where applicable, the notified body that was involved in the conformity assessment for the device of the termination of the mandate and the reasons therefor.	5. An authorised representative who terminates the mandate on the grounds referred to in point (e) of paragraph 3 shall immediately inform the competent authority of the Member State in which he is established and, where applicable, the notified body that was involved in the conformity assessment for the device of the termination of the mandate and the reasons therefor.	No change
215.	6. Any reference in this Regulation to the competent authority of the Member State	6. Any reference in this Regulation to the competent authority of the Member State	6. Any reference in this Regulation to the competent authority of the Member State	No change

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	where the manufacturer has his registered place of business shall be understood as a reference to the competent authority of the Member State where the authorised representative, designated by a manufacturer referred to in paragraph 1, has his registered place of business.	where the manufacturer has his registered place of business shall be understood as a reference to the competent authority of the Member State where the authorised representative, designated by a manufacturer referred to in paragraph 1, has his registered place of business.	where the manufacturer has his registered place of business shall be understood as a reference to the competent authority of the Member State where the authorised representative, designated by a manufacturer referred to in paragraph 1, has his registered place of business.	
216.	**Article 10** **Change of authorised representative**	**Article 10** **Change of authorised representative**	**Article 10** **Change of authorised representative**	
217.	The modalities of a change of authorised representative shall be clearly defined in an agreement between the manufacturer, the outgoing authorised representative and the incoming authorised representative. This agreement shall address at least the following aspects: (a) the date of termination of the mandate with the outgoing authorised representative and date of beginning of the mandate with the incoming authorised representative; (b) the date until which the outgoing authorised representative may be indicated in the information supplied by the manufacturer, including any promotional material; (c) the transfer of documents, including confidentiality aspects and property rights; (d) the obligation of the outgoing authorised representative after the end of the mandate to forward to the manufacturer or to the incoming authorised	The modalities of a change of authorised representative shall be clearly defined in an agreement between the manufacturer, the outgoing authorised representative and the incoming authorised representative. This agreement shall address at least the following aspects: (e) the date of termination of the mandate with the outgoing authorised representative and date of beginning of the mandate with the incoming authorised representative; (f) the date until which the outgoing authorised representative may be indicated in the information supplied by the manufacturer, including any promotional material; (g) the transfer of documents, including confidentiality aspects and property rights; (h) the obligation of the outgoing authorised representative after the end of the mandate to forward to the manufacturer or to the incoming authorised	The modalities of a change of authorised representative shall be clearly defined in an agreement between the manufacturer, where practicable, the outgoing authorised representative and the incoming authorised representative. This agreement shall address at least the following aspects: (a) the date of termination of the mandate with the outgoing authorised representative and date of beginning of the mandate with the incoming authorised representative; (b) the date until which the outgoing authorised representative may be indicated in the information supplied by the manufacturer, including any promotional material ; (c) the transfer of documents, including confidentiality aspects and property rights; (d) the obligation of the outgoing authorised representative after the end of the mandate to forward to the manufacturer or to the incoming authorised representative any complaints or reports from healthcare professionals,	No significant change

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	representative any complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device for which he had been designated as authorised representative.	representative any complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device for which he had been designated as authorised representative.	patients or users about suspected incidents related to a device for which he had been designated as authorised representative.	
218.	**Article 11 General obligations of importers**	**Article 11 General obligations of importers**	**Article 11 General obligations of importers**	
219.	1. Importers shall place on the Union market only devices that are in conformity with this Regulation.	1. Importers shall place on the Union market only devices that are in conformity with this Regulation.	1. Importers shall place on the Union market only devices that are in conformity with this Regulation.	No change
220.	2. Before placing a device on the market importers shall ensure the following:	2. Before placing a device on the market importers shall ensure the following:	2. In order to place a device on the market importers shall verify the following:	Verify vs ensure?
221.	(a) that the appropriate conformity assessment procedure has been carried out by the manufacturer;	(a) that the appropriate conformity assessment procedure has been carried out by the manufacturer;	(a) that the device has been CE marked and that the declaration of conformity of the device has been drawn up;	In line with points c & d of Com proposal
222.	(b) that an authorised representative in accordance with Article 9 has been designated by the manufacturer;	(b) that a manufacturer is identified and, that, an authorised representative in accordance with Article 9 has been designated by the manufacturer;	(b) that an authorised representative in accordance with Article 9 has been designated by the manufacturer;	No change
223.	(c) that the EU declaration of conformity and the technical documentation has been drawn up by the manufacturer; (d) that the device bears the required CE marking of conformity;	(c) that the EU declaration of conformity and the technical documentation has been drawn up by the manufacturer; (d) that the device bears the required CE marking of conformity;		See 204 above
224.	(e) that the device is labelled in accordance with this Regulation and accompanied by the required instructions for use and EU declaration of conformity;	(e) that the device is labelled in accordance with this Regulation and accompanied by the required instructions for use;	(e) that the device is labelled in accordance with this Regulation and accompanied by the required instructions for use;	DoC does not need to accompany device.

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	(f) that, where applicable, a Unique Device Identification has been assigned by the manufacturer in accordance with Article 22.	(f) that, where applicable, a Unique Device Identification has been assigned by the manufacturer in accordance with Article 22.	(f) that, where applicable, a Unique Device Identification has been assigned by the manufacturer in accordance with Article 22;	
225.	(g)	(fa) that the manufacturer has taken out appropriate liability insurance coverage pursuant to Article 8 (10a) , unless the importer himself ensures sufficient coverage that meets the requirements of this provision.		
226.	Where an importer considers or has reason to believe that a device is not in conformity with the requirements of this Regulation, he shall not place the device on the market until it has been brought into conformity. Where the device presents a risk, the importer shall inform the manufacturer and his authorised representative to that effect, as well as the competent authority of the Member State in which he is established.	Where an importer considers or has reason to believe that a device is not in conformity with the requirements of this Regulation, he shall not place the device on the market until it has been brought into conformity. Where the device presents a risk, the importer shall inform the manufacturer and his authorised representative to that effect, as well as the competent authority of the Member State in which he is established.	Where an importer considers or has reason to believe that a device is not in conformity with the requirements of this Regulation, he shall not place the device on the market until it has been brought into conformity and shall inform the manufacturer his authorised representative. Where the importer consider or has reason to believe that the device presents a serious risk or is falsified, he shall also inform the competent authority of the Member State in which he is established.	If a device is falsified or present serious risk – authoritites will be informed.
227.		Where an importer considers that a device is not in conformity with the requirements of this Regulation presents a risk, the importer shall inform the manufacturer and his authorized representative to that effect, as well as the competent authority of the Member State		
228.	3. Importers shall indicate their name, registered trade name or registered trade mark and the address of their registered place of business at which they can be	3. Importers shall indicate their name, registered trade name or registered trade mark and the address of their registered place of business at which they can be	3. Importers shall indicate their name, registered trade name or registered trade mark and the address of their registered place of business at which they can be	No change

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	contacted and their location can be established on the device or on its packaging or in a document accompanying the device. They shall ensure that any additional label does not obscure any information on the label provided by the manufacturer.	contacted and their location can be established on the device or on its packaging or in a document accompanying the device. They shall ensure that any additional label does not obscure any information on the label provided by the manufacturer.	contacted and their location can be established on the device or on its packaging or in a document accompanying the device. They shall ensure that any additional label does not obscure any information on the label provided by the manufacturer.	
229.	4. Importers shall ensure that the device is registered in the electronic system in accordance with Article 23(2).	4. Importers shall ensure that the device is registered in the electronic system in accordance with Article 23(2).	4. Importers shall verify that the device is registered in the electronic system in accordance with Article 22b, and shall add their details to that registration. Importers shall also verify that the registration includes details on the authorised representative and, if appropriate, inform the authorised representative or the manufacturer.	Importers to verify device is registered and add their own details to the registration.
230.	5. Importers shall ensure that, while a device is under their responsibility, storage or transport conditions do not jeopardise its compliance with the general safety and performance requirements set out in Annex I.	Importers shall ensure that, while a device is under their responsibility, storage or transport conditions do not jeopardise its compliance with the general safety and performance requirements set out in Annex I.	5. Importers shall ensure that, while a device is under their responsibility, storage or transport conditions do not jeopardise its compliance with the general safety and performance requirements set out in Annex I and shall comply with the conditions set by the manufacturer, where available.	Importer to follow conditions of storage and transport set by manufacturer
231.	6. When deemed appropriate with regard to the risks presented by a device, importers shall, in order to protect the health and safety of patients and users, carry out sample testing of marketed products, investigate complaints and keep a register of complaints, of non-conforming products and of product recalls and withdrawals, and shall keep the manufacturer, authorised representative and distributors informed of such	5. When deemed appropriate with regard to the risks presented by a device, importers shall, in order to protect the health and safety of patients and users, carry out sample testing of marketed products, investigate complaints and keep a register of complaints, of non-conforming products and of product recalls and withdrawals, and shall keep the manufacturer, authorised representative and distributors informed of such	6. Importers shall keep a register of complaints, of non-conforming products and of product recalls and withdrawals, and provide the manufacturer, authorised representative and distributors with any information requested by them, in order to allow them to investigate complaints.	Importers no longer test devices – but they keep a register of complaints, and inform manufacturer of issues to investigate.

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	monitoring.	monitoring.		
232.	7. Importers who consider or have reason to believe that a device which they have placed on the market is not in conformity with this Regulation shall immediately inform the manufacturer and his authorised representative and, if appropriate, take the necessary corrective action to bring that device into conformity, withdraw or recall it. Where the device presents a risk, they shall also immediately inform the competent authorities of the Member States in which they made the device available and, if applicable, the notified body that issued a certificate in accordance with Article 43 for the device in question, giving details, in particular, of the noncompliance and of any corrective action taken.	6. 5.6. Importers who consider or have reason to believe that a device which they have placed on the market is not in conformity with this Regulation shall immediately inform the manufacturer, and where applicable, and his authorised representative and, if appropriate, ensure that the necessary corrective action to bring that device into conformity, withdraw or recall it. Where the device presents a risk, they shall also immediately inform the competent authorities of the Member States in which they made the device available and, if applicable, the notified body that issued a certificate in accordance with Article 43 for the device in question, giving details, in particular, of the non-compliance and of any corrective action they have implemented.	7. Importers who consider or have reason to believe that a device which they have placed on the market is not in conformity with this Regulation shall immediately inform the manufacturer and his authorised representative. Importers shall co-operate with the manufacturer, his authorised representative and the competent authorities to ensure that the necessary corrective action to bring that device into conformity, withdraw or recall it is taken. Where the device presents a serious risk, they shall also immediately inform the competent authorities of the Member States in which they made the device available giving details, in particular, of the non-compliance and of any corrective action taken.	If device is not in conformity importers work with manufacturer to bring it into conformity and if a serious risk is present shall inform authorities.
233.	8. Importers who have received complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device which they have placed on the market shall immediately forward this information to the manufacturer and his authorised representative.	7. Importers who have received complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device which they have placed on the market shall immediately forward this information to the manufacturer and his authorised representative.	8. Importers who have received complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device which they have placed on the market shall immediately forward this information to the manufacturer and his authorised representative.	No change
234.	9. Importers shall, for the period referred to in Article 8(4), keep a copy of the EU declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation and, if applicable, a copy of the relevant certificate including any supplement,	8. Importers shall, for the period referred to in Article 8(4), keep a copy of the EU declaration of conformity at the disposal of the market surveillance authorities and ensure that the technical documentation and, if applicable, a copy of the relevant certificate including any supplement,	9. Importers shall, for the period referred to in Article 8(4), keep a copy of the EU declaration of conformity and, if applicable, a copy of the relevant certificate including any supplement, issued in accordance with Article 43.	Importers need to keep the DoC and a copy of the NB certificate for a the devices they import.

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	issued in accordance with Article 43, can be made available to those authorities, upon request. By written mandate, the importer and the authorised representative for the device in question may agree that this obligation is delegated to the authorised representative.	issued in accordance with Article 43, can be made available to those authorities, upon request. By written mandate, the importer and the authorised representative for the device in question may agree that this obligation is delegated to the authorised representative.		
235.	10. Importers shall, in response to a request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of a product. This obligation shall be considered fulfilled when the manufacturer or his authorised representative for the device in question provides the required information. Importers shall cooperate with a competent national authority, at its request, on any action taken to eliminate the risks posed by products which they have placed on the market.	9. Importers shall, in response to a request from a competent national authority, provide it with all the information and documentation necessary to demonstrate the conformity of a product. This obligation shall be considered fulfilled when the manufacturer or his authorised representative for the device in question provides the required information. Importers shall cooperate with a competent national authority, at its request, on any action taken to eliminate the risks posed by products which they have placed on the market.	10. Importers shall cooperate with competent national authorities, at their request, on any action taken to eliminate the risks posed by devices which they have placed on the market. Importers, upon request of a competent authority where the importer has his registered place of business, shall provide samples of the device free of charge or, where impracticable, grant access to the device.	Importers provide samples free of charge, but do not keep documentation necessary to demonstrate conformity.
236.	**Article 12** **General obligations of distributors**	**Article 12** **General obligations of distributors**	**Article 12** **General obligations of distributors**	
237.	1. When making a device available on the market, distributors shall act with due care in relation to the requirements applicable.	1. When making a device available on the market, distributors shall act with due care in relation to the requirements applicable.	1. In the context of their activities, when making a device available on the market, distributors shall act with due care in relation to the requirements applicable.	No significant change
238.	2. Before making a device available on the market distributors shall verify that the following requirements are met:	2. Before making a device available on the market distributors shall verify that the following requirements are met:	2. Before making a device available on the market distributors shall verify that the following requirements are met:	No change
239.	(a) the product bears the required CE marking of conformity;	(a) the product bears the required CE marking of conformity;	(a) the device has been CE marked and that the declaration of conformity of the device has been drawn up;	Verify also DoC

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240.	(b) the product is accompanied by the information to be supplied by the manufacturer in accordance with Article 8(7);	(b) the product is accompanied by the information to be supplied by the manufacturer in accordance with Article 8(7);	(b) the product is accompanied by the information to be supplied by the manufacturer in accordance with Article 8(7 and by the EU declaration of conformity;	**Product to be accompanied by the DoC? Odd as this is not an actual requirement anywhere else in the Regulation.**
241.	(c) the manufacturer and, where applicable, the importer have complied with the requirements set out in Article 22 and Article 11(3) respectively.	(c) the manufacturer and, where applicable, the importer have complied with the requirements set out in Article 22 and Article 11(3) respectively.	(c) the importer have complied with the requirements set out in Article 11(3);	Verify role of importer
242.			(d) that, where applicable, a Unique Device Identification has been assigned by the manufacturer.	UDI – new requirement
243.			In order to meet the requirements referred to in subparagraphs (a) and (b) the distributor may apply a sampling method representative of products supplied by that distributer.	Does not need to verify each individual IVD
244.	Where a distributor considers or has reason to believe that a device is not in conformity with the requirements of this Regulation, he shall not make the device available on the market until it has been brought into conformity. Where the device presents a risk, the distributor shall inform the manufacturer and, where applicable, his authorised representative and the importer to that effect, as well as the competent authority of the Member State in which he is established.	Where a distributor considers or has reason to believe that a device is not in conformity with the requirements of this Regulation, he shall not make the device available on the market until it has been brought into conformity. Where the device presents a risk, the distributor shall inform the manufacturer and, where applicable, his authorised representative and the importer to that effect, as well as the competent authority of the Member State in which he is established.	Where a distributor considers or has reason to believe that a device is not in conformity with the requirements of this Regulation, he shall not make the device available on the market until it has been brought into conformity and inform the manufacturer and, where applicable, his authorised representative, and the importer. Where the distributor consider or has reason to believe that the device presents a serious risk or is falsified, he shall also inform the competent authority of the Member State in which he is established.	If a device is a risk or falsified, distributor will inform authorities.
245.		Where a distributor considers that a device		

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		is not in conformity with the requirements of this Regulation or presents a risk, the shall inform the manufacturer and his authorised representative to that effect, as well as the competent authority of the Member State		
246.	3. Distributors shall ensure that, while a device is under their responsibility, storage or transport conditions do not jeopardise its compliance with the general safety and performance requirements set out in Annex I.	3. Distributors shall ensure that, while a device is under their responsibility, storage or transport conditions do not jeopardise its compliance with the general safety and performance requirements set out in Annex I.	3. Distributors shall ensure that, while the device is under their responsibility, storage or transport conditions comply with the conditions set by the manufacturer.	Distributors comply with storage and handling conditions set by the manufacturer
247.	4. Distributors who consider or have reason to believe that a device which they have made available on the market is not in conformity with this Regulation shall immediately inform the manufacturer and, where applicable, his authorised representative and the importer and make sure that the necessary corrective action to bring that device into conformity, withdraw or recall it, if appropriate, is taken. Where the device presents a risk, they shall also immediately inform the competent authorities of the Member States in which they made the device available, giving details, in particular, of the non-compliance and of any corrective action taken.	4. 4. Distributors who consider or have reason to believe that a device which they have made available on the market is not in conformity with this Regulation shall immediately inform the manufacturer and, where applicable, his authorised representative and the importer and make sure that, within the limits of its respective activities, the necessary corrective action to bring that device into conformity, withdraw or recall it, if appropriate, is taken. Where the device presents a risk, they shall also immediately inform the competent authorities of the Member States in which they made the device available, giving details, in particular, of the non-compliance and of any corrective action taken.	4. Distributors who consider or have reason to believe that a device which they have made available on the market is not in conformity with this Regulation shall immediately inform the manufacturer and, where applicable, his authorised representative and the importer. Distributors shall co-operate with the manufacturer and, where applicable his authorised representative and the importer, and with any competent authorities to ensure that the necessary corrective action to bring that device into conformity, withdraw or recall it, if appropriate, is taken. Where the distributor considers or has reason to believe that the device presents a serious risk, he shall also immediately inform the competent authorities of the Member States in which he made the device available, and, where applicable, the notified body that issued a certificate for the device in accordance with Article 43, giving details, in particular, of the non-compliance and of any	Distributors to inform NBs and authorities as well as manufacturers if device is non-compliant and presents a risk.

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			corrective action taken.	
248.	5. Distributors who have received complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device they have made available, shall immediately forward this information to the manufacturer and, where applicable, his authorised representative.	5. Distributors who have received complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device they have made available, shall immediately forward this information to the manufacturer and, where applicable, his authorised representative.	5. Distributors who have received complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device they have made available, shall immediately forward this information to the manufacturer and, where applicable, his authorised representative, They shall keep a register of complaints, of non-conforming products and of product recalls and withdrawals, and keep the manufacturer and, where available, the authorised representative informed of such monitoring and provide them with any information upon their request.	Distributors to keep a register of complaints and inform manuf/AR.
249.	6. Distributors shall, in response to a request from a competent authority, provide it with all the information and documentation necessary to demonstrate the conformity of a device. This obligation shall be considered fulfilled when the manufacturer or his authorised representative for the device in question, where applicable, provides the required information. Distributors shall cooperate with competent national authorities, at their request, on any action taken to eliminate the risks posed by devices which they have made available on the market.	6. Distributors shall, in response to a request from a competent authority, provide it with all the information and documentation necessary to demonstrate the conformity of a device. This obligation shall be considered fulfilled when the manufacturer or his authorised representative for the device in question, where applicable, provides the required information. Distributors shall cooperate with competent national authorities, at their request, on any action taken to eliminate the risks posed by devices which they have made available on the market.	6. Distributors shall, in response to a request from a competent authority, provide it with all the information and documentation that is at its disposal and is necessary to demonstrate the conformity of a device. This obligation shall be considered fulfilled when the authorised representative for the device in question, where applicable, provides the required information. Distributors shall cooperate with competent national authorities, at their request, on any action taken to eliminate the risks posed by devices which they have made available on the market. Distributors, upon request of a competent authority, shall provide free samples of the device or, where impracticable, grant access to the device.	Distributor will provide the information it has to authorities, as well as free samples or access to the device.
250.	**Article 13**	**Article 13**	**Article 13**	

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	Person responsible for regulatory compliance	**Person responsible for regulatory compliance**	**Person responsible for regulatory compliance**	
251.	1. Manufacturers shall have available within their organisation at least one qualified person who possesses expert knowledge in the field of in vitro diagnostic medical devices. The expert knowledge shall be demonstrated by either of the following qualifications:	1. Manufacturers shall have available within their organisation at least one person responsible for regulatory compliance who possesses the requisite expertise in the field of in vitro diagnostic medical devices. The requisite expertise shall be demonstrated by either of the following qualifications:	1. Manufacturers shall have available within their organisation, at least one person responsible for regulatory compliance activities who possesses expert knowledge in the field of in vitro diagnostic medical devices. The expert knowledge shall be demonstrated by either of the following qualifications:	Qualified person becomes: Person responsible for regulatory compliance
252.	(a) a diploma, certificate or other evidence of formal qualification awarded on completion of a university degree or of an equivalent course of study, in natural sciences, medicine, pharmacy, engineering or another relevant discipline, and at least two years of professional experience in regulatory affairs or in quality management systems relating to in vitro diagnostic medical devices;	(a) a diploma, certificate or other evidence of formal qualification awarded on completion of a university degree or of an equivalent course of study, in law, natural sciences, medicine, pharmacy, engineering or another relevant discipline;	(a) a diploma, certificate or other evidence of formal qualification awarded on completion of a university degree or of an a course of study recognized as by the Member States concerned, in medicine, pharmacy, engineering or another relevant discipline of sciences, and at least two years of professional experience in regulatory affairs or in quality management systems relating to devices;	MD experience is enough – no IVD experience is required
253.	(b) five years of professional experience in regulatory affairs or in quality management systems relating to in vitro diagnostic medical devices.	(b) three years of professional experience in regulatory affairs or in quality management systems relating to in vitro diagnostic medical devices.	(b) five years of professional experience in regulatory affairs related to devices including experience in quality management systems.	MD experience is enough – no IVD experience is required
254.			1a. Micro and small enterprises within the meaning of Commission Recommendation 2003/361/EC are not required to have the person responsible for regulatory compliance within their organisation but shall have such person permanently and continuously at their disposal.	By contrast, medium and large enterprises will need to have a person within their organisation.
255.	2. The qualified person shall at least be responsible for ensuring the following	2. The person responsible for regulatory compliance shall at least be responsible	2. The person responsible for regulatory compliance activities shall at least be	No significant change

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	matters:	for ensuring the following matters:	responsible for ensuring the following matters:	
256.	(a) that the conformity of the devices is appropriately assessed before a batch is released;	(a) that the conformity of the devices is appropriately assessed before a batch is released;	(a) that the conformity of the devices is appropriately checked in accordance with the quality management system under which these devices are manufactured before a product is released;	Responsible for product release (may include batch release?)
257.	(b) that the technical documentation and the declaration of conformity are drawn up and kept up-to-date;	(b) that the technical documentation and the declaration of conformity are drawn up and kept up-to-date;	(b) that the technical documentation and the declaration of conformity are drawn up and kept up-to-date;	No change
258.			(ca) that the post-market surveillance obligations according in accordance with Article 8(7) are complied with;	Responsible for post-market surveillance
259.	(c) that the reporting obligations in accordance with Articles 59 to 64 are fulfilled.	(c) that the reporting obligations in accordance with Articles 59 to 64 are fulfilled;	(c) that the reporting obligations in accordance with Articles 59 to 64 are fulfilled;	No change
260.	(d) in the case of devices for performance evaluation intended to be used in the context of interventional clinical performance studies or other clinical performance studies involving risks for the subjects, that the statement referred to in Section 4.1 of Annex XIII is issued;	(d) in the case of devices for performance evaluation intended to be used in the context of interventional clinical performance studies or other clinical performance studies involving risks for the subjects, that the statement referred to in Section 4.1 of Annex XIII is issued;	(d) in the case of devices for performance evaluation intended to be used in the context of interventional clinical performance studies or other clinical performance studies involving risks for the subjects, that the statement referred to in point 4.1 of Annex XIII is issued;	No change
261.		If a number of persons are jointly responsible for regulatory compliance in accordance with the provisions under paragraphs 1 and 2, their respective areas of responsibility shall be stipulated in writing.		
262.	3. The qualified person shall suffer no	3. The person responsible for regulatory	3. The person responsible for regulatory	No significant change

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	disadvantage within the manufacturer's organisation in relation to the proper fulfilment of his duties.	compliance shall suffer no disadvantage within the manufacturer's organisation in relation to the proper fulfilment of his duties.	compliance shall suffer no disadvantage within the manufacturer's organisation in relation to the proper fulfilment of his duties.	
263.	4. Authorised representatives shall have available within their organisation at least one qualified person who possesses expert knowledge regarding the regulatory requirements for in vitro diagnostic medical devices in the Union. The expert knowledge shall be demonstrated by either of the following qualifications: (a) a diploma, certificate or other evidence of formal qualification awarded on completion of a university degree or of an equivalent course of study, in law, natural sciences, medicine, pharmacy, engineering or another relevant discipline, and at least two years of professional experience in regulatory affairs or in quality management systems relating to in vitro diagnostic medical devices; (b) five years of professional experience in regulatory affairs or in quality management systems relating to in vitro diagnostic medical devices	4. Authorised representatives shall have available within their organisation at least one person responsible for regulatory compliance who possesses the requisite expertise regarding the regulatory requirements for in vitro diagnostic medical devices in the Union. The requisite expertise shall be demonstrated by either of the following qualifications: (a) a diploma, certificate or other evidence of formal qualification awarded on completion of a university degree or of an equivalent course of study, in law, natural sciences, medicine, pharmacy, engineering or another relevant discipline; (b) three years of professional experience in regulatory affairs or in quality management systems relating to in vitro diagnostic medical devices.	4. Authorised representatives shall have permanently and continuously at their disposal at least one person in charge for regulatory compliance activities who possesses expert knowledge regarding the regulatory requirements for in vitro diagnostic medical devices in the Union. The expert knowledge shall be demonstrated by either of the following qualifications: (a) a diploma, certificate or other evidence of formal qualification awarded on completion of a university degree or of an a course of study recognized as equivalent by the Member States concerned in medicine, pharmacy, engineering or another relevant sciences, and at least two years of professional experience in regulatory affairs or in quality management systems relating to in vitro diagnostic medical devices; (b) five years of professional experience in regulatory affairs or in quality management systems relating to in vitro diagnostic medical devices.	Authorized reps must always have a person for regulatory compliance available and that person must have IVD experience (in contrast to situation with manufacturer)
264.	**Article 14** **Cases in which obligations of manufacturers apply to importers, distributors or other persons**	**Article 14** **Cases in which obligations of manufacturers apply to importers, distributors or other persons**	**Article 14** **Cases in which obligations of manufacturers apply to importers, distributors or other persons**	
265.	1. A distributor, importer or other natural or	1. A distributor, importer or other natural or	1. A distributor, importer or other natural or	No change

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	legal person shall assume the obligations incumbent on manufacturers if he does any of the following:	legal person shall assume the obligations incumbent on manufacturers if he does any of the following:	legal person shall assume the obligations incumbent on manufacturers if he does any of the following:	
266.	(a) makes available on the market a device under his name, registered trade name or registered trade mark;	(a) makes available on the market a device under his name, registered trade name or registered trade mark;	(a) makes available on the market a device under his name, registered trade name or registered trade mark, except in cases where a distributor or importer enters into an agreement with a manufacturer whereby the manufacturer is identified as such on the label and is responsible for meeting the requirements placed on manufacturers in this Regulation;	If there is an agreement with manufacturer that he is responsible for regulatory compliance, then distributors or importers can put their name on devices without being responsible for them.
267.	(b) changes the intended purpose of a device already placed on the market or put into service;	(b) changes the intended purpose of a device already placed on the market or put into service;	(b) changes the intended purpose of a device already placed on the market or put into service;	No change
268.	(c) modifies a device already placed on the market or put into service in such a way that compliance with the applicable requirements may be affected.	(c) modifies a device already placed on the market or put into service in such a way that compliance with the applicable requirements may be affected.	(c) modifies a device already placed on the market or put into service in such a way that compliance with the applicable requirements may be affected.	No change
269.	The first subparagraph shall not apply to any person who, while not considered a manufacturer as defined in number (16) of Article 2, assembles or adapts a device already on the market to its intended purpose for an individual patient.	The first subparagraph shall not apply to any person who, while not considered a manufacturer as defined in number (16) of Article 2, assembles or adapts a device already on the market to its intended purpose for an individual patient or a specific limited group of patients within a single healthcare institution.	The first subparagraph shall not apply to any person who, while not considered a manufacturer as defined in number (16) of Article 2, assembles or adapts a device already on the market to its intended purpose for an individual patient.	No change
270.	2. For the purposes of point (c) of paragraph 1, the following shall not be considered to be a modification of a device that could affect its compliance with the	2. For the purposes of point (c) of paragraph 1, the following shall not be considered to be a modification of a device that could affect its compliance with the	2. For the purposes of point (c) of paragraph 1, the following shall not be considered to be a modification of a device that could affect its compliance with the	No change

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	applicable requirements: (a) provision, including translation, of the information supplied by the manufacturer in accordance with Section 17 of Annex I relating to a device already placed on the market and of further information which is necessary in order to market the product in the relevant Member State; (b) changes to the outer packaging of a device already placed on the market, including a change of pack size, if the repackaging is necessary in order to market the product in the relevant Member State and if it is carried out in such conditions that the original condition of the device cannot be affected by it. In the case of devices placed on the market in sterile condition, it shall be presumed that the original condition of the device is adversely affected if the package that shall ensure the sterile condition is opened, damaged or otherwise negatively affected by the repackaging.	applicable requirements: (c) provision, including translation, of the information supplied by the manufacturer in accordance with Section 17 of Annex I relating to a device already placed on the market and of further information which is necessary in order to market the product in the relevant Member State; (d) changes to the outer packaging of a device already placed on the market, including a change of pack size, if the repackaging is necessary in order to market the product in the relevant Member State and if it is carried out in such conditions that the original condition of the device cannot be affected by it. In the case of devices placed on the market in sterile condition, it shall be presumed that the original condition of the device is adversely affected if the package that shall ensure the sterile condition is opened, damaged or otherwise negatively affected by the repackaging.	applicable requirements: (a) provision, including translation, of the information supplied by the manufacturer in accordance with Section 17 of Annex I relating to a device already placed on the market and of further information which is necessary in order to market the product in the relevant Member State; (b) changes to the outer packaging of a device already placed on the market, including a change of pack size, if the repackaging is necessary in order to market the product in the relevant Member State and if it is carried out in such conditions that the original condition of the device cannot be affected by it. In the case of devices placed on the market in sterile condition, it shall be presumed that the original condition of the device is adversely affected if the package that shall ensure the sterile condition is opened, damaged or otherwise negatively affected by the repackaging.	
271.	3. A distributor or importer who carries out any of the activities mentioned in points (a) and (b) of paragraph 2 shall indicate the activity carried out together with his name, registered trade name or registered trade mark and the address at which he can be contacted and his location can be established on the device or, where that is not possible, on its packaging or in a document accompanying the device. He shall ensure that he has in place a quality management system that includes procedures which ensure that the	3. A distributor or importer who carries out any of the activities mentioned in points (a) and (b) of paragraph 2 shall indicate the activity carried out together with his name, registered trade name or registered trade mark and the address at which he can be contacted and his location can be established on the device or, where that is not possible, on its packaging or in a document accompanying the device. He shall ensure that he has in place a quality management system that includes procedures which ensure that the	3. A distributor or importer who carries out any of the activities mentioned in points (a) and (b) of paragraph 2 shall indicate the activity carried out together with his name, registered trade name or registered trade mark and the address at which he can be contacted and his location can be established on the device or, where impracticable, on its packaging or in a document accompanying the device. He shall ensure that he has in place a quality management system that includes procedures which ensure that the	No significant change

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	translation of information is accurate and up-to-date, and that the activities mentioned in points (a) and (b) of paragraph 2 are performed by means and under conditions that preserve the original condition of the device and that the packaging of the repackaged device is not defective, of poor quality or untidy. Part of the quality management system shall be procedures ensuring that the distributor or importer is informed of any corrective action taken by the manufacturer in relation to the device in question in order to respond to safety issues or to bring it in conformity with this Regulation.	translation of information is accurate and up-to-date, and that the activities mentioned in points (a) and (b) of paragraph 2 are performed by means and under conditions that preserve the original condition of the device and that the packaging of the repackaged device is not defective, of poor quality or untidy. Part of the quality management system shall be procedures ensuring that the distributor or importer is informed of any corrective action taken by the manufacturer in relation to the device in question in order to respond to safety issues or to bring it in conformity with this Regulation.	translation of information is accurate and up-to-date, and that the activities mentioned in points (a) and (b) of paragraph 2 are performed by means and under conditions that preserve the original condition of the device and that the packaging of the repackaged device is not defective, of poor quality or untidy. Part of the quality management system shall be procedures ensuring that the distributor or importer is informed of any corrective action taken by the manufacturer in relation to the device in question in order to respond to safety issues or to bring it in conformity with this Regulation.	
272.	4. Prior to making the relabelled or repackaged device available, the distributor or importer referred to in paragraph 3 shall inform the manufacturer and the competent authority of the Member State where he plans to make the device available and, upon request, shall provide them with a sample or a mock-up of the relabelled or repackaged device, including any translated label and instructions for use. He shall submit to the competent authority a certificate, issued by a notified body referred to in Article 27, designated for the type of devices that are subject to activities mentioned in points (a) and (b) of paragraph 2, attesting that the quality management system complies with the requirements laid down in paragraph 3.	4. Prior to making the relabelled or repackaged device available, the distributor or importer referred to in paragraph 3 shall inform the manufacturer and the competent authority of the Member State where he plans to make the device available and, upon request, shall provide them with a sample or a mock-up of the relabelled or repackaged device, including any translated label and instructions for use. He shall submit to the competent authority a certificate, issued by a notified body referred to in Article 27, designated for the type of devices that are subject to activities mentioned in points (a) and (b) of paragraph 2, attesting that the quality management system complies with the requirements laid down in paragraph 3.	4. Prior to making the relabelled or repackaged device available, the distributor or importer referred to in paragraph 3 shall inform the manufacturer and the competent authority of the Member State where he plans to make the device available and, upon request, shall provide them with a sample or a mock-up of the relabelled or repackaged device, including any translated label and instructions for use. He shall submit to the competent authority a certificate, issued by a notified body referred to in Article 27, designated for the type of devices that are subject to activities mentioned in points (a) and (b) of paragraph 2, attesting that the quality management system complies with the requirements laid down in paragraph 3.	No change
273.		(4a) Distributors or affiliates who carry out – on behalf of the manufacturer – one or		

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		several of the activities mentioned under paragraph 2 points (a) and (b) – are exempted from additional requirements under points (3) and (4).		
274.	**Article 15** **EU declaration of conformity**	**Article 15** **EU declaration of conformity**	**Article 15** **EU declaration of conformity**	
275.	1. The EU declaration of conformity shall state that fulfilment of the requirements specified in this Regulation has been demonstrated. It shall be continuously updated. The minimum content of the EU declaration of conformity is set out in Annex III. It shall be translated into the official Union language or languages required by the Member State(s) in which the device is made available.	1. The EU declaration of conformity shall state that fulfilment of the requirements specified in this Regulation has been demonstrated. It shall be continuously updated. The minimum content of the EU declaration of conformity is set out in Annex III. It shall be issued in one of the official Union languages.	1. The EU declaration of conformity shall state that fulfilment of the requirements specified in this Regulation has been demonstrated. It shall be continuously updated. The minimum content of the EU declaration of conformity is set out in Annex III. It shall be translated into an official Union language or languages required by the Member State(s) in which the device is made available.	Translated into ***an*** official language. Translation of DoC remains a problem. Parliament had a simpler solution (DoC issued in an official language, not imposed by MS)
276.		…The minimum content of the EU declaration of conformity is set out in Annex III. It shall be translated into the official Union language or languages required by the Member State(s) in which the device is made available.		
277.	2. Where, concerning aspects not covered by this Regulation, devices are subject to other Union legislation which also requires a declaration of conformity by the manufacturer that fulfilment of the requirements of that legislation has been demonstrated, a single EU declaration of conformity shall be drawn up in respect of all Union acts applicable to the device containing all information required for identification of the Union legislation to which the declaration relates.	2. Where, concerning aspects not covered by this Regulation, devices are subject to other Union legislation which also requires a declaration of conformity by the manufacturer that fulfilment of the requirements of that legislation has been demonstrated, a single EU declaration of conformity shall be drawn up in respect of all Union acts applicable to the device containing all information required for identification of the Union legislation to which the declaration relates.	2. Where, concerning aspects not covered by this Regulation, devices are subject to other Union legislation which also requires a declaration of conformity by the manufacturer that fulfilment of the requirements of that legislation has been demonstrated, a single EU declaration of conformity shall be drawn up in respect of all Union acts applicable to the device containing all information required for identification of the Union legislation to which the declaration relates.	No change

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278.	3. By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for compliance with the requirements of this Regulation and all other Union legislation applicable to the device.	3. By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for compliance with the requirements of this Regulation and all other Union legislation applicable to the device.	3. By drawing up the EU declaration of conformity, the manufacturer shall assume responsibility for compliance with the requirements of this Regulation and all other Union legislation applicable to the device.	No change
279.	4. The Commission shall be empowered to adopt delegated acts in accordance with Article 85 amending or supplementing the minimum content of the EU declaration of conformity set out in Annex III in the light of technical progress.	4. The Commission shall be empowered to adopt delegated acts in accordance with Article 85 amending or supplementing the minimum content of the EU declaration of conformity set out in Annex III in the light of technical progress.	4. The Commission shall be empowered to adopt delegated acts in accordance with Article 85 amending or supplementing the minimum content of the EU declaration of conformity set out in Annex III in the light of technical progress.	No change
280.	**Article 16** **CE marking of conformity**	**Article 16** **CE marking of conformity**	**Article 16** **CE marking of conformity**	
281.	1. Devices, other than devices for performance evaluation, considered to be in conformity with the requirements of this Regulation shall bear the CE marking of conformity, as presented in Annex IV.	1. Devices, other than devices for performance evaluation, considered to be in conformity with the requirements of this Regulation shall bear the CE marking of conformity, as presented in Annex IV.	1. Devices, other than devices for performance evaluation, considered to be in conformity with the requirements of this Regulation shall bear the CE marking of conformity, as presented in Annex IV.	No change
282.	2. The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.	2. The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.	2. The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.	No change
283.	3. The CE marking shall be affixed visibly, legibly and indelibly to the device or its sterile pack. Where that is not possible or not warranted on account of the nature of the device, it shall be affixed to the packaging. The CE marking shall also appear in the instructions for use and on the sales packaging where those are provided.	3. The CE marking shall be affixed visibly, legibly and indelibly to the device or its sterile pack. Where that is not possible or not warranted on account of the nature of the device, it shall be affixed to the packaging. The CE marking shall also appear in the instructions for use and on the sales packaging where those are provided.	3. The CE marking shall be affixed visibly, legibly and indelibly to the device or its sterile pack. Where that is not possible or not warranted on account of the nature of the device, it shall be affixed to the packaging. The CE marking shall also appear in the instructions for use and on the sales packaging where those are provided.	No change

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284.	4. The CE marking shall be affixed before the device is placed on the market. It may be followed by a pictogram or any other mark indicating a special risk or use.	4. The CE marking shall be affixed before the device is placed on the market. It may be followed by a pictogram or any other mark indicating a special risk or use.	4. The CE marking shall be affixed before the device is placed on the market. It may be followed by a pictogram or any other mark indicating a special risk or use.	No change
285.	5. Where applicable, the CE marking shall be followed by the identification number of the notified body responsible for the conformity assessment procedures set out in Article 40. The identification number shall also be indicated in any promotional material which mentions that a device fulfils the legal requirements for CE marking.	5. Where applicable, the CE marking shall be followed by the identification number of the notified body responsible for the conformity assessment procedures set out in Article 40. The identification number shall also be indicated in any promotional material which mentions that a device fulfils the legal requirements for CE marking.	5. Where applicable, the CE marking shall be followed by the identification number of the notified body responsible for the conformity assessment procedures set out in Article 40. The identification number shall also be indicated in any promotional material which mentions that a device fulfils the legal requirements for CE marking.	No change
286.	6. Where devices are subject to other Union legislation concerning other aspects which also provide for the affixing of the CE marking, the CE marking shall indicate that the devices also fulfil the provisions of the other legislation.	6. Where devices are subject to other Union legislation concerning other aspects which also provide for the affixing of the CE marking, the CE marking shall indicate that the devices also fulfil the provisions of the other legislation.	6. Where devices are subject to other Union legislation concerning other aspects which also provide for the affixing of the CE marking, the CE marking shall indicate that the devices also fulfil the provisions of the other legislation.	No change
287.	**Article 17 Devices for special purposes**	**Article 17 Devices for special purposes**	**Article 17 Devices for special purposes**	
288.	1. Member States shall not create any obstacle to devices for performance evaluation which are supplied for that purpose to laboratories or other institutions, if they meet the conditions laid down in Articles 48 to 58.	1. Member States shall not create any obstacle to devices for performance evaluation which are supplied for that purpose to laboratories or other institutions, if they meet the conditions laid down in Articles 48 to 58.	1. Member States shall not create any obstacle to devices for performance evaluation which are supplied for that purpose to laboratories or other institutions, if they meet the conditions laid down in Articles 48 to 58.	No change
289.	2. Those devices shall not bear the CE marking, with the exception of the devices referred to in Article 52.	2. Those devices shall not bear the CE marking, with the exception of the devices referred to in Article 52.	2. Those devices shall not bear the CE marking, with the exception of the devices referred to in Article 52.	No change

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290.	3. At trade fairs, exhibitions, demonstrations or similar events, Member States shall not create any obstacle to the showing of devices which do not comply with this Regulation, provided such devices are not used on specimens taken from the participants and a visible sign clearly indicates that such devices are intended for presentation or demonstration purposes only and cannot be made available until they have been made to comply with this Regulation.	3. At trade fairs, exhibitions, demonstrations or similar events, Member States shall not create any obstacle to the showing of devices which do not comply with this Regulation, provided such devices are not used on specimens taken from the participants and a visible sign clearly indicates that such devices are intended for presentation or demonstration purposes only and cannot be made available until they have been made to comply with this Regulation.	3. At trade fairs, exhibitions, demonstrations or similar events, Member States shall not create any obstacle to the showing of devices which do not comply with this Regulation, provided that a visible sign clearly indicates that such devices are intended for presentation or demonstration purposes only and cannot be made available until they have been made to comply with this Regulation.	Strange change – devices may now be used on specimens taken from participants at trade fairs?
291.	**Article 18 Systems and procedure packs**	**Article 18 Systems and procedure packs**	**.(Deleted from Council Proposal)**	
292.	1. Any natural or legal person shall draw up a statement referred to in paragraph 2 if he puts devices bearing the CE marking together with the following other devices or products, in accordance with the intended purpose of the devices or other products and within the limits of use specified by their manufacturers, in order to place them on the market as a system or procedure pack: – other devices bearing the CE marking; – medical devices bearing the CE marking in conformity with Regulation (EU) [Ref. of future Regulation on medical devices]; – other products which are in conformity with the legislation applicable to those products.	1. Any natural or legal person shall draw up a statement referred to in paragraph 2 if he puts devices bearing the CE marking together with the following other devices or products, in accordance with the intended purpose of the devices or other products and within the limits of use specified by their manufacturers, in order to place them on the market as a system or procedure pack: – other devices bearing the CE marking; – medical devices bearing the CE marking in conformity with Regulation (EU) [Ref. of future Regulation on medical devices]; – other products which are in conformity with the legislation applicable to those products.		Not relevant for IVDs – Deleted
293.	2. In the statement, the person referred to in paragraph 1 shall declare the following:	2. In the statement, the person referred to in paragraph 1 shall declare the following:		Not relevant for IVDs - Deleted

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	(a) that he verified the mutual compatibility of the devices and, if applicable other products, in accordance with the manufacturers' instructions and has carried out his operations in accordance with those instructions; (b) that he packaged the system or procedure pack and supplied relevant information to users incorporating the information to be supplied by the manufacturers of the devices or other products which have been put together; (c) that the activity of putting devices and, if applicable, other products together as a system or procedure pack was subject to appropriate methods of internal monitoring, verification and validation.	(d) that he verified the mutual compatibility of the devices and, if applicable other products, in accordance with the manufacturers' instructions and has carried out his operations in accordance with those instructions; (e) that he packaged the system or procedure pack and supplied relevant information to users incorporating the information to be supplied by the manufacturers of the devices or other products which have been put together; (f) that the activity of putting devices and, if applicable, other products together as a system or procedure pack was subject to appropriate methods of internal monitoring, verification and validation.		
294.	3. Any natural or legal person who sterilises systems or procedure packs referred to in paragraph 1 for the purpose of placing them on the market shall, at his choice, follow one of the procedures referred to in Annex VIII or in Annex X. The application of those Annexes and the involvement of the notified body shall be limited to the aspects of the procedure relating to ensuring sterility until the sterile package is opened or damaged. The person shall draw up a statement declaring that the sterilisation has been carried out in accordance with the manufacturer's instructions.	3. Any natural or legal person who sterilises systems or procedure packs referred to in paragraph 1 for the purpose of placing them on the market shall, at his choice, follow one of the procedures referred to in Annex VIII or in Annex X. The application of those Annexes and the involvement of the notified body shall be limited to the aspects of the procedure relating to ensuring sterility until the sterile package is opened or damaged. The person shall draw up a statement declaring that the sterilisation has been carried out in accordance with the manufacturer's instructions.		Not relevant for IVDs - Deleted

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295.	4. Where the system or procedure pack incorporate devices which do not bear the CE marking or where the chosen combination of devices is not compatible in view of their original intended purpose, the system or procedure pack shall be treated as a device in its own right and shall be subjected to the relevant conformity assessment procedure pursuant to Article 40.	4. Where the system or procedure pack incorporate devices which do not bear the CE marking or where the chosen combination of devices is not compatible in view of their original intended purpose, the system or procedure pack shall be treated as a device in its own right and shall be subjected to the relevant conformity assessment procedure pursuant to Article 40.		No relevant for IVDs - Deleted
296.	5. The systems or procedure packs referred to in paragraph 1 shall not themselves bear an additional CE marking but they shall bear the name, registered trade name or registered trade mark of the person referred to in paragraph 1 as well as the address at which he can be contacted and his location can be established. Systems or procedure packs shall be accompanied by the information referred to in Section 17 of Annex I. The statement referred to in paragraph 2 of this Article shall be kept at the disposal of the competent authorities, after the system or procedure pack has been put together, for the period that is applicable to the devices put together in accordance with Article 8(4). Where these periods differ, the longest period shall apply.	5. The systems or procedure packs referred to in paragraph 1 shall not themselves bear an additional CE marking but they shall bear the name, registered trade name or registered trade mark of the person referred to in paragraph 1 as well as the address at which he can be contacted and his location can be established. Systems or procedure packs shall be accompanied by the information referred to in Section 17 of Annex I. The statement referred to in paragraph 2 of this Article shall be kept at the disposal of the competent authorities, after the system or procedure pack has been put together, for the period that is applicable to the devices put together in accordance with Article 8(4). Where these periods differ, the longest period shall apply.		Not relevant for IVDs - Deleted
297.	**Article 19 Parts and components**	**Article 19 Parts and components**	**Article 19 Parts and components**	
298.	1. Any natural or legal person who makes available on the market an article intended specifically to replace an identical or similar integral part or component of a	1. Any natural or legal person who makes available on the market an article intended specifically to replace an identical or similar integral part or component of a	Any natural or legal person who makes available on the market an article intended specifically to replace an identical or similar integral part or component of a	No substantial change – spare parts cannot compromise safety and performance.

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	device that is defective or worn in order to maintain or re-establish the function of the device, without significantly changing its performance or safety characteristics, shall ensure that the article does not adversely affect the safety and performance of the device. Substantiating evidence shall be kept available to the competent authorities of the Member States.	device that is defective or worn in order to maintain or re-establish the function of the device, without changing its performance or safety characteristics, shall ensure that the article does not adversely affect the safety and performance of the device. Substantiating evidence shall be kept available to the competent authorities of the Member States.	device that is defective or worn in order to maintain or re-establish the function of the, shall ensure that the article does not adversely affect the safety and performance of the device. Supporting evidence shall be kept available to the competent authorities of the Member States.	
299.	2. An article that is intended specifically to replace a part or component of a device and that significantly changes the performance or safety characteristics of the device shall be considered a device.	2. An article that is intended specifically to replace a part or component of a device and that changes the performance or safety characteristics of the device shall be considered as a device and shall meet the requirements laid down in this Regulation.	An article that is intended specifically to replace a part or component of a device and that significantly changes the performance or safety characteristics of the device shall be considered a device.	No change
300.	**Article 20** **Free movement**	**Article 20** **Free movement**	**Article 20** **Free movement**	
301.	Member States shall not refuse, prohibit or restrict the making available or putting into service within their territory of devices which comply with the requirements of this Regulation.	Member States shall not refuse, prohibit or restrict the making available or putting into service within their territory of devices which comply with the requirements of this Regulation.	Except where otherwise provided in this regulation, Member States shall not refuse, prohibit or restrict the making available or putting into service within their territory of devices which comply with the requirements of this Regulation.	Not significant change per se
302.	**Chapter III** **Identification and traceability of devices, registration of devices and of economic operators, summary of safety and performance, European databank on medical devices**	**Chapter VII** **Identification and traceability of devices, registration of devices and of economic operators, summary of safety and performance, European databank on medical devices**	**Chapter III** **Identification and traceability of devices, registration of devices and of economic operators, summary of safety and performance, European databank on medical devices**	

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303.	**Article 21 Identification within the supply chain**	**Article 21 Identification within the supply chain**	**Article 21 Identification within the supply chain**	
304.			1. Distributors and importers shall co-operate with the manufacturer or authorized representative to achieve an appropriate level of traceability of devices.	Distributors and Importers are part of traceability requirements
305.	For devices, other than devices for performance evaluation, economic operators shall be able to identify the following, for the period referred to in Article 8(4):	For devices, other than devices for performance evaluation, economic operators shall be able to identify the following, for the period referred to in Article 8(4):	2. Economic operators shall be able to identify the following to the competent authority, for the period referred to in Article 8(4):	Includes traceability for devices for performance evaluation?
306.	(a) any economic operator to whom they have supplied a device;	(a) any economic operator to whom they have supplied a device;	(a) any economic operator to whom they have supplied a device;	No change
307.	(b) any economic operator who has supplied them with a device;	(b) any economic operator who has supplied them with a device;	(b) any economic operator who has supplied them with a device;	No change
308.	(c) any health institution or healthcare professional to whom they have supplied a device.	(c) any health institution or healthcare professional to whom they have supplied a device.	(c) any health institution to whom they have supplied a device.	Traceability to the healthcare professional is not needed.
309.	Upon request, they shall inform the competent authorities thereof.	Upon request, they shall inform the competent authorities thereof.		Deleted – unclear impact
310.			**Article 21a Medical devices nomenclature**	
311.			To facilitate the functioning of the European Databank on medical devices (Eudamed) established pursuant to Article 27 of Regulation (EU) [Ref. of future Regulation on medical devices] and the UDI database established pursuant to	New text – free medical devices nomenclature? What would be the impact on GMDN. Very unlikely that the Commission would accept this.

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			Article 24a of Regulation (EU) [Ref. of future Regulation on medical devices] the Commission shall ensure that a medical devices nomenclature shall be available free of charge to manufacturers, natural or legal persons required to use nomenclature for the purpose of this regulation. The Commission shall also endeavour to ensure that that nomenclature is available to other stakeholders free of charge, where reasonably practicable.	
312.	**Article 22 Unique device identification system**	**Article 22 Unique device identification system**	**Article 22 Unique device identification system**	
313.	1. For devices, other than devices for performance evaluation, a system for Unique Device Identification shall be put in place in the Union.	1. For devices, other than devices for performance evaluation, a system for Unique Device Identification shall be put in place in the Union.	**Art 22a 1**. The Commission, after consulting the MDCG shall set up and manage an electronic system on UDI (UDI database) in accordance with the conditions and modalities established by Article 24a of Regulation (EU) [Ref. of future Regulation on medical devices].	Equivalent text
314.	The UDI system shall allow the identification and traceability of devices and shall consist of the following:	The UDI system shall allow the identification and traceability of devices and shall consist of the following:	1. The Unique Device Identification (UDI) system shall allow the identification and facilitate the traceability of devices, other than a device for performance evaluation, and shall consist of the following:	No significant change
315.	(a) production of a UDI that comprises the following: (i) a device identifier specific to a manufacturer and a device model, providing access to the information laid down in Part B of Annex V; (ii) a production identifier that identifies data related to the unit of device	(a) production of a UDI that comprises the following: (iii) a device identifier specific to a manufacturer and a device model, providing access to the information laid down in Part B of Annex V; (iv) a production identifier that identifies data related to the unit of device	(a) production of a UDI that comprises the following: (i) a device identifier (DI) specific to a manufacturer and a device model, providing access to the information laid down in Part B of Annex V; (ii) a production identifier (PI) that identifies the produced device's unit and	Different package device levels may have different PI – weird change in definition of PI as it is no longer linked to production.

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	production.	production.	if applicable the packaged devices as specified in Annex V Part C;	
316.	(b) placement of the UDI on the label of the device;	(b) placement of the UDI on the label of the device;	(b) application of the UDI on the label of the device or on its package;	Need for consistency with article 22.4. UDI should be applied with the label (basic concept)
317.	(c) storage of the UDI by the economic operators and the health institutions through electronic means;	(c) storage of the UDI by the economic operators and the health institutions through electronic means;	**Art 22. 5a.** Member States shall encourage, and may require, health care professionals and health institutions to store and keep, preferably by electronic means, the UDI of the devices which they have been supplied with.	Compulsory for economic operators, MS to determine if health institutions have to keep the UDI.
318.	(d) establishment of an electronic system on UDI.	(d) establishment of an electronic system on UDI.	(d) establishment of an electronic system on UDI (UDI database) according to Article 24a of Regulation (EU) [Ref. of future Regulation on medical devices].	No significant change
319.	2. The Commission shall designate one or several entities that operate a system for assignment of UDIs pursuant to this Regulation and that satisfy all of the following criteria:	2. The Commission shall designate one or several entities that operate a system for assignment of UDIs pursuant to this Regulation and that satisfy all of the following criteria:	2. The Commission shall designate one or several entities that operate a system for assignment of UDIs pursuant to this Regulation and that satisfy all of the following criteria:	No change
320.	(a) the entity is an organisation with legal personality; (b) its system for the assignment of UDIs is adequate to identify a device through its distribution and use in accordance with the requirements of this Regulation; (c) its system for the assignment of UDIs conforms to the relevant international standards; (d) the entity gives access to its system for the assignment of UDIs to all interested users according to a set of	(a) the entity is an organisation with legal personality; (b) its system for the assignment of UDIs is adequate to identify a device through its distribution and use in accordance with the requirements of this Regulation; (c) its system for the assignment of UDIs conforms to the relevant international standards; (d) the entity gives access to its system for the assignment of UDIs to all interested users according to a set of predetermined and transparent terms and conditions;	(a) the entity is an organisation with legal personality; (b) its system for the assignment of UDIs is adequate to identify a device through its distribution and use in accordance with the requirements of this Regulation; (c) its system for the assignment of UDIs conforms to a relevant international standard; (d) the entity gives access to its system for the assignment of UDIs to all interested users according to a set of predetermined and transparent terms and conditions;	No change

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	predetermined and transparent terms and conditions;			
321.	(e) the entity undertakes the following:	(e) the entity undertakes the following:	(e) the entity undertakes the following:	
322.	(i) to operate its system for the assignment of UDIs for the period to be determined in the designation which shall at least be three years after its designation;	(i) to operate its system for the assignment of UDIs for the period to be determined in the designation which shall at least be five years after its designation;	(i) to operate its system for the assignment of UDIs at least ten years after its designation;	Ten years operation by the entities which operate UDI system.
323.	(ii) to make available to the Commission and to the Member States, upon request, information concerning its system for the assignment of UDIs and concerning manufacturers that place an UDI on the label of their device in accordance with the entity's system;	(ii) to make available to the Commission and to the Member States, upon request, information concerning its system for the assignment of UDIs and concerning manufacturers that place an UDI on the label of their device in accordance with the entity's system;	(ii) to make available to the Commission and to the Member States, upon request, information concerning its system for the assignment of UDIs;	Simpler requirement
324.	(iii) to remain in compliance with the criteria for designation and the terms of designation during the period for which it is designated.	(iii) to remain in compliance with the criteria for designation and the terms of designation during the period for which it is designated.	(iii) to remain in compliance with the criteria for designation and the terms of designation.	Designation does not have “terms”
325.			In exercising its powers under this paragraph the Commission shall endeavour to promote interoperability between different UDI assigning entity systems with a view to minimising financial and administrative burdens for economic operators and health institutions.	Interoperability of different UDI systems? GS1 and HIBBIC are not interoperable but they can both be read by the same system if need be.
326.	3. Before placing a device on the market, the manufacturer shall assign to the device a UDI provided by an entity designated by the Commission in accordance with paragraph 2, if that device belongs to the devices, categories	3. Before placing a device on the market, the manufacturer shall assign to the device a UDI provided by an entity designated by the Commission in accordance with paragraph 2, if that device belongs to the devices, categories	3. Before placing a device on the market, the manufacturer shall assign to the device and if applicable – to all higher levels of packaging a UDI created in compliance with the rules of provided by an entity designated by the Commission in	No significant change

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	or groups of devices determined by a measure referred to in point (a) of paragraph 7.	or groups of devices determined by a measure referred to in point (a) of paragraph 7.	accordance with paragraph 2.	
327.	4. The UDI shall be placed on the label of the device, in accordance with the conditions laid down by a measure referred to in point (c) of paragraph 7.	4. The UDI shall be placed on the label of the device, in accordance with the conditions laid down by a measure referred to in point (c) of paragraph 7.	4. The UDI carrier shall be placed on the label of the device and on all higher levels of packaging. Higher levels of packaging do not include shipping containers.	No significant change
328.	It shall be used for reporting serious incidents and field safety corrective actions in accordance with Article 59.	It shall be used for reporting serious incidents and field safety corrective actions in accordance with Article 59.	4a. The UDI shall be used for reporting serious incidents and field safety corrective actions in accordance with Article 59	No significant change
329.	The device identifier shall appear on the EU declaration of conformity referred to in Article 15 and in the technical documentation referred to in Annex II.	The device identifier shall appear on the EU declaration of conformity referred to in Article 15 and in the technical documentation referred to in Annex II.	4b. The Basic UDI device identifier (Basic UDI-DI as defined in Annex V Part C) of the device shall appear on the EU declaration of conformity referred to in Article 15.	**UDI on declaration of Conformity remains.**
330.			4c. The manufacturer has to keep up-to-date a list of all applied UDI as part of the technical documentation referred to in Annex II.	New requirement, in line with QMS however the keeping of a list is a problem as lists are not optimal way of managing UDIs.
331.	5. Economic operators and health institutions shall store and keep, by electronic means, the device identifier and the production identifier of the devices which they have supplied or they have been supplied with, if they belong to the devices, categories or groups of devices determined by a measure referred to in point (a) of paragraph 7.	5. Economic operators and health institutions shall store and keep, by electronic means, the device identifier and the production identifier of the devices which they have supplied or they have been supplied with, if they belong to the devices, categories or groups of devices determined by a measure referred to in point (a) of paragraph 7.	5. Economic operators shall store and keep, preferably by electronic means, the UDI of the devices which they have supplied or they have been supplied with, if they belong to the devices, categories or groups of devices determined by a measure referred to in point (a) of paragraph 7.	Excludes health institutions, allows for non-electronic recording of UDI…
332.			**5.a** With a view to ensuring a uniform approach to the manner in which the UDI of devices, categories or groups of devices	MS may require UDI to be kept by health institutions.

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			which health institutions have been supplied with is to be stored, the Commission may adopt implementing acts pursuant to point (aa) of paragraph 7.	
333.	6. The Commission, in cooperation with the Member States, shall set up and manage an electronic system on UDI to collate and process the information mentioned in Part B of Annex V. This information shall be accessible to the public.	6. The Commission, in cooperation with the Member States, shall set up and manage an electronic system on UDI to collate and process the information mentioned in Part B of Annex V. This information shall be accessible to the public.		…
334.	7. The Commission shall be empowered to adopt delegated acts in accordance with Article 85:	7. The Commission shall be empowered to adopt delegated acts in accordance with Article 85:	7. The Commission may, by means of implementing acts**,** specify the modalities and the procedural aspects with a view to ensuring harmonised application of the Unique Device Identification System for any of the following aspects:	Again confusing implementing and delegated acts.
335.	(a) determining the devices, categories or groups of devices, whose identification shall be based on the UDI system, as set out in paragraphs 1 to 6, and the timelines for implementing this. Following a risk-based approach, implementation of the UDI system shall be gradual, starting with devices falling in the highest risk class;	(a) determining the devices, categories or groups of devices, whose identification shall be based on the UDI system, as set out in paragraphs 1 to 6, and the timelines for implementing this. Following a risk-based approach, implementation of the UDI system shall be gradual, starting with devices falling in the highest risk class;	(a) the determination of the devices, categories or groups of devices, which the obligation laid down in paragraph 5 shall apply	Change not significant – timelines for UDI implementation included in transitional measures so not needed in implementing acts.
336.			(aa) the determination of the devices, categories or groups of devices to which paragraph 5a shall apply;	Commission will determine in which cases MS shall require health institutions to keep records of UDI?
337.	(b) specifying the data to be included in the production identifier which, following a risk-based approach, may vary	(b) specifying the data to be included in the production identifier which, following a risk-based approach, may vary depending	(b) the specification of the data to be included in the UDI production identifier (UDI-PI) of specific devices or device	No significant change

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	depending on the risk class of the device;	on the risk class of the device;	groups.	
338.	(c) defining the obligations of economic operators, of health institutions and of professional users, in particular regarding allocation of the numeric or alphanumeric characters, placement of the UDI on the label, storage of information in the electronic system on UDI, and use of the UDI in documentation and reporting related to the device provided for in this Regulation;	(c) defining the obligations of economic operators, of health institutions and of professional users, in particular regarding allocation of the numeric or alphanumeric characters, placement of the UDI on the label, storage of information in the electronic system on UDI, and use of the UDI in documentation and reporting related to the device provided for in this Regulation;		Obligations of economic operators may not be changed by the commission.
339.	(d) amending or supplementing the list of information set out in Part B of Annex V in the light of technical progress.	(d) amending or supplementing the list of information set out in Part B of Annex V in the light of technical progress.	**Art. 22 7.a** The Commission shall be empowered to adopt delegated acts in accordance with Article 85: (a) amending or supplementing the list of information set out in Part B of Annex V in the light of technical progress; and (b) amending or supplementing of Annex V in the light of international development in the field of unique device identification.	No significant change
340.			Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).	Needed because of the change from delegated to implementing act
341.	8. When adopting the measures referred to in paragraph 7, the Commission shall take into account the following:	8. When adopting the measures referred to in paragraph 7, the Commission shall take into account the following:	8. When adopting the measures referred to in paragraph 7, the Commission shall take into account the following:	No change
342.	(a) the protection of personal data; (b) the legitimate interest in protecting commercially sensitive information; (c) the risk-based approach; (d) the cost-effectiveness of the measures;	(a) the protection of personal data; (b) the legitimate interest in protecting commercially sensitive information, to the extent that it does not undermine public health protection; (c) the risk-based approach; (d) the cost-effectiveness of the measures;	(a) the protection of personal data; (b) the legitimate interest in protecting commercially sensitive information; (c) the risk-based approach; (d) the cost-effectiveness of the measures; (e) the convergence of UDI systems developed at international level;	No change

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	(e) the convergence of UDI systems developed at international level.	(e) the convergence of UDI systems developed at international level. (ea) the compatibility with other traceability systems used by the stakeholders involved with medical devices. (eb) compatibility with the other traceability systems used by medical device stakeholders.		
343.			(f) the need to avoid duplications in the UDI system.; (g) the needs of the health care systems of the Member States.	New requirements. Would be good if this applied to MS as well. How important will the needs of health care system of member states be? Can become very complex.
344.			**Article 22a Electronic system on UDI (UDI database)**	[Text of article 22a compares to parts of Article 23 of COM proposal]
345.			**Article 22b Process for registration of devices**	
346.			1. Before the device is placed on the market, the manufacturer of a device, other than custom made or investigational devices, shall, in compliance with the rules of the designated issuing entities, assign to the device a Basic UDI-DI as defined in Annex V Part C. 2. Where a manufacturer of a devices, other than devices for performance evaluation, applies a conformity assessment procedure according to Article 40(3) first sentence, (4) or (5) the manufacturer shall submit to the UDI	**Establishes UDI as the basis for registration of devices.** Concern – if database is not ready on time, then there will be an impossibility to comply with this requirement. Difference between unit of use UDI (FDA) and basic UDI (EU) can be problematic. Use of Basic UDI remains a problem. Notified bodies should link the

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			database the Basic UDI-DI and the linked information referred to in Part B of Annex V before placing the device on the market 3.Where a manufacturer of devices, other than devices for performance evaluation, applies a conformity assessment procedure according to Article 40 (2) or (3) second sentence (EC technical documentation assessment, EC type-examination) the manufacturer shall assign the Basic UDI-DI (Annex V Part C) to the device before applying for a conformity assessment procedure by a notified body. The Notified Body shall reference the Basic UDI-DI on the certificate issued (Annex XII I 4.a). After the issuing of the relevant certificate and before placing the device on the market the manufacturer or his authorised representative shall submit to the UDI database the Basic UDI-DI and the linked information referred to in Part B of Annex V.	certificates to UDIs in the database, not on the certificate itself as this would mean certificates would need to be constantly updated and renewed to reflect the new products being placed on the market.
347.	**Article 23** **Electronic system on registration of devices and economic operators**	**Article 23** **Electronic system on registration of devices and economic operators**	**Article 23** **Electronic system on registration of economic operators**	
348.	1. The Commission, in collaboration with the Member States, shall set up and manage an electronic system to collate and process information that is necessary	1. The Commission, in collaboration with the Member States, shall set up and manage an electronic system to collate and process information that is necessary	1. The Commission, after consulting the MDCG, shall set up and manage an electronic system to create the single registration number referred to in Article	Single registration number for economic operators introduced as a concept. This should not be relevant outside of the DB!

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	and proportionate to describe and identify the device and to identify the manufacturer and, where applicable, the authorised representative and the importer. The details regarding the information to be submitted by the economic operators are laid down in Part A of Annex V.	and proportionate to describe and identify the device and to identify the manufacturer and, where applicable, the authorised representative and the importer and to ensure transparency and safe and effective use by making available to users current evidence concerning the clinical validity and, where applicable, utility of the device. The details regarding the information to be submitted by the economic operators are laid down in Part A of Annex V.	23a and to collate and process information that is necessary and proportionate to identify the manufacturer and, where applicable, the authorised representative and the importer**.** The details regarding the information to be submitted by the economic operators are laid down in Part A of Annex V.	Issue – Annex V will also deal with devices. Economic operators – includes distributors, but distributors are excluded. If data is in the European electronic system it should not be requested again in national databases. Inconsistency – there is an issue here, as Part A of Annex V includes device data.
349.			1b. Member States may maintain or introduce national provisions on registration of distributors and importers of a device which have been made available in their territory.	**Distributors and importers to be controlled at the national level through national databases!**
350.	2. Before a device, other than a device for performance evaluation, is placed on the market the manufacturer or his authorised representative shall submit to the electronic system the information referred to in paragraph 1.	2. Before a device, other than a device for performance evaluation, is placed on the market the manufacturer or his authorised representative shall submit to the electronic system the information referred to in paragraph 1.	**Art 22a 2**. Before a device, other than a device for performance evaluation, is placed on the market the manufacturer or his authorised representative must ensure that the information referred to in Part B of Annex V of the device in question are correctly submitted and transferred to the UDI database.	No substantial change
351.	3. Within one week after placing a device, other than a device for performance evaluation, on the market, importers shall submit to the electronic system the information referred to in paragraph 1.	3. Within one week after placing a device, other than a device for performance evaluation, on the market, importers shall submit to the electronic system the information referred to in paragraph 1.	3. Within two weeks after placing a device, other than a device for performance evaluation, on the market, importers shall verify that the manufacturer or authorised representative has uploaded to the electronic system the information referred to in paragraph 1 and shall add their details to the relevant entry/entries.	Simplify requirements for importers However – what exactly at the importer details to the relevant entries? Also should importer be linked to specific devices?

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352.			Where applicable, importers shall also verify that the registration includes the details of the authorised representative and, if these details are not included, shall inform the relevant authorised representative.	Might be difficult to inform AR if the details are not known.
353.	4. Within one week of any change occurring in relation to the information referred to in paragraph 1, the relevant economic operator shall update the data in the electronic system.	4. Within one week of any change occurring in relation to the information referred to in paragraph 1, the relevant economic operator shall update the data in the electronic system.	**Art. 23 4.** Within one week of any change occurring in relation to the information referred to in paragraph 1, the relevant economic operator shall update the data in the electronic system.	Equivalent text – however one week is a big problem.
354.	5. Not later than two years after submission of the information in accordance with paragraphs 2 and 3, and then every second year, the relevant economic operator shall confirm the accuracy of the data. In the event of failure to confirm within six months of the due date, any Member State may take measures to suspend or otherwise restrict the making available of the device in question within its territory until the obligation referred to in this paragraph is complied with.	5. Not later than two years after submission of the information in accordance with paragraphs 2 and 3, and then every second year, the relevant economic operator shall confirm the accuracy of the data. In the event of failure to confirm within six months of the due date, any Member State may take measures to suspend or otherwise restrict the making available of the device in question within its territory until the obligation referred to in this paragraph is complied with.	**Art 23a 5.** Not later than one year after submission of the information in accordance with paragraph 1 , and then every second year thereafter, the relevant economic operator shall confirm the accuracy of the data. Without prejudice to the economic operator's responsibility for the data, the competent authority shall verify the confirmed data referred to in points 1-4a of Part A of Annex V. In the event of failure to confirm within six months of the due date, any Member State may take appropriate corrective measures within its territory until the obligation referred to in this paragraph is complied with.	More or less equivalent – first verification after one year, then every two years.
355.	6. The data contained in the electronic system shall be accessible to the public.	6. The data contained in the electronic system shall be accessible to the public.	**Art 23a 6.** The data contained in the electronic system shall be accessible to the public.	No substantial difference – however data which is uploaded prior to product launch should not be released until product launch.
356.	7. The Commission shall be empowered to adopt delegated acts in accordance with	7. The Commission shall be empowered to adopt delegated acts in accordance with	**Art 22 7a**. The Commission shall be empowered to adopt delegated acts in	No substantial difference, changes to the UDI dataset will

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	Article 85 amending the list of information to be submitted as set out in Part A of Annex V in the light of technical progress.	Article 85 amending the list of information to be submitted as set out in Part A of Annex V in the light of technical progress.	accordance with Article 85: (a) amending or supplementing the list of information set out in Part B of Annex V in the light of technical progress; and (b) amending or supplementing of Annex V in the light of international development in the field of unique device identification.	always be complex.
357.			**Article 23a** **Process for registration of manufacturers and Authorised Representatives, Single registration number**	
358.			1. The manufacturer or his authorised representative, who has not been registered before according to this article shall submit to the electronic system the information referred to in Annex V Part A before placing a device, other than a device for performance evaluation, on the market. In cases where the conformity assessment procedure requires the involvement of a notified body the information referred to in Annex V part A shall be submitted to the electronic system before applying to a notified body.	**Why would registration be required BEFORE working with a NB?**
359.			2. After having verified the data entered by the manufacturer or his authorised representative the competent authority shall procure from the electronic system referred to Article 23 a single registration number and issue it to the manufacturer or his authorised representative.	**Single registration number to be issued.** Timeline is needed.
360.			3. The manufacturer shall use the single registration number when applying to a	Single registration number relevant for certificates at the

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			notified body for certification according to Article 41 and for entering the electronic system on UDI (in order to fulfil their obligations according to Article 22a(2) and Article 22b(2) and (3)).	end of the NB assessment.
361.			7. The competent authority may use the data to administer a charge or fee to the manufacturer or the authorised representative pursuant to Article 82.	(NOTE – not an error – points 4-6 covered elsewhere) Fees to be expected.
362.	**Article 24 Summary of safety and performance**	**Article 24 Safety and clinical performance report**	**Article 24 Summary of safety and performance**	
363.	1. In the case of devices classified as class C and D, other than devices for performance evaluation, the manufacturer shall draw up a summary of safety and performance. It shall be written in a way that is clear to the intended user. The draft of this summary shall be part of the documentation to be submitted to the notified body involved in the conformity assessment in accordance with Article 40 and shall be validated by that body.	1. In the case of devices classified as class C and D, other than devices for performance evaluation, the manufacturer shall draw up a report on the safety and clinical performance of the device based on the full information collected during the clinical performance study. The manufacturer shall also draw up a summary of that report which shall be written in a way that is easy for a lay person to understand in the language of the country where the device is made available on the market. The draft report shall be part of the documentation to be submitted to and validated by the notified body, and where relevant by the special notified body, involved in the conformity assessment in accordance with Articles 40 and 43a.	1. In the case of devices classified as class C and D, other than devices for performance evaluation, the manufacturer shall draw up a summary of safety and performance. It shall be written in a way that is clear to the intended user and, if relevant, to the patient and shall be available to the public via Eudamed. The draft of this summary shall be part of the documentation to be submitted to the notified body involved in the conformity assessment in accordance with Article 40 and shall be validated by that body. After validation the notified body shall upload this summary report to Eudamed. The manufacturer shall mention on the label or instructions for use where the summary report is available.	**Summary of safety and performance different document for each individual device (!) To be validated and uploaded by the NB, not he manufacturer. IFU or label need to point to this summary.** **Possible inconsistency – manufacturer should upload the info according to document.**
364.		1a. The summary referred to in paragraph 1 shall be made available to the public via Eudamed in accordance with provisions under Article 25(2)(b) and Annex V, Part		

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		A, point 15.		
365.			1a. The summary of safety and performance shall include at least the following aspects: (a) the identification of the device and the manufacturer, including the basic UDI-DI and the single registration number; (b) the intended purpose of the device, including indications, contra-indications and target populations; (c) a description of the device, including a reference to previous generation(s) or variants if such exist, and the description of the differences, as well as a description of the accessories, other in vitro diagnostic medical devices and other products that are not in vitro diagnostic medical devices, which are intended to be used in combination with the in vitro diagnostic medical device; (d) reference to harmonized standards and common (technical) specifications; (e) the summary of the performance evaluation report as referred to in annex XII, and relevant information on the PMPF; (f) the metrological traceability of assigned values; (g) suggested profile and training for users; (h) information on any residual risks and any (indirect) undesirable effects, warnings and precautions.	Note – all of this is covered by the IFU – summary is therefore a subset of IFU information.
366.	2. The Commission may, by means of implementing acts, set out the form and the presentation of the data elements to be included in the summary of safety and	2. The Commission may, by means of implementing acts, set out the format of the presentation of the data elements to be included in both the report and the	2. The Commission may, by means of implementing acts, set out the form and the presentation of the data elements to be included in the summary of safety and	No change

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	performance. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 84(2).	summary referred to in paragraph 1. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 84(2).	performance**.** Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 84(2).	
367.	**Article 25 European databank**	**Article 25 European databank**	**Article 25 European databank**	
368.	The Commission shall develop and manage the European databank on medical devices (Eudamed) in accordance with the conditions and modalities established by Article 27 of Regulation (EU) [Ref. of future Regulation on medical devices]. Eudamed shall include the following as integral parts:	The Commission shall develop and manage the European databank on medical devices (Eudamed) in accordance with the conditions and modalities established by Article 27 of Regulation (EU) [Ref. of future Regulation on medical devices]. Eudamed shall include the following as integral parts:	The Commission, after consulting the MDCG, shall develop and manage the European databank on medical devices (Eudamed) in accordance with the conditions and modalities established by Article 27 of Regulation (EU) [Ref. of future Regulation on medical devices]. Eudamed shall include the following:	Commission needs to consult MDCG on databank.
369.	(a) the electronic system on UDI referred to in Article 22; (b) the electronic system on registration of devices and economic operators referred to in Article 23;	(a) the electronic system on UDI referred to in Article 22; (b) the electronic system on registration of devices and economic operators referred to in Article 23;	(a) the electronic system on UDI referred to in Article 22; (b) the electronic system on registration of economic operators referred to in Article 23;	**UDI is considered to be the registration system for devices.**
370.			(ba) the electronic system on notified bodies referred to in Article 31(9);	How does this work with NANDO?
371.	(c) the electronic system on information on certificates referred to in Article 43(4); (d) the electronic system on interventional clinical performance studies and clinical performance studies involving risks for the subjects set up in Article 51;	(c) the electronic system on information on certificates referred to in Article 43(4); (d) the electronic system on interventional clinical performance studies and clinical performance studies involving risks for the subjects set up in Article 51; (e) the electronic system on vigilance referred to in Article 60;	(c) the electronic system on information on application for conformity assessments and on certificates referred to in Article 41(1)and Article 43(4) and on summaries of safety and clinical performance referred to in Article 24; (d) the electronic system on interventional performance studies and clinical	Additional elements: Summary of safety and performance Conformity assessment routes Post market surveillance system

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	(e) the electronic system on vigilance referred to in Article 60; (f) the electronic system on market surveillance referred to in Article 66.	(f) the electronic system on market surveillance referred to in Article 66.	performance studies involving risks for the subjects set up in Article 51; (e) the electronic system on vigilance and post-market surveillance referred to in Article 64a; (f) the electronic system on market surveillance referred to in Article 73b.	
372.		(fa) the electronic system on registration of subsidiaries and subcontracting referred to in Article 28a.		
373.		(fb) the electronic system on "Special notified bodies" referred to in Article 41 b (new).		
374.	**Chapter IV Notified Bodies**	**Chapter IV Notified Bodies**	**Chapter IV Notified Bodies**	SECTION UNDER ASSESSMENT
375.	**Article 26 National authorities responsible for notified bodies**	**Article 26 National authorities responsible for notified bodies**	**Article 26 National authorities responsible for notified bodies for in vitro diagnostic medical devices**	
376.	1. A Member State that intends to designate a conformity assessment body as a notified body, or has designated a notified body, to carry out third-party conformity assessment tasks under this Regulation shall designate an authority that shall be responsible for setting up and carrying out the necessary procedures for the assessment, designation and notification of conformity assessment bodies and for the monitoring of notified bodies, including subcontractors or subsidiaries of those bodies, hereinafter	1. A Member State that intends to designate a conformity assessment body as a notified body, or has designated a notified body, to carry out third-party conformity assessment tasks under this Regulation shall designate an authority that shall be responsible for setting up and carrying out the necessary procedures for the assessment, designation and notification of conformity assessment bodies and for the monitoring of notified bodies, including subcontractors or subsidiaries of those bodies, hereinafter	1. A Member State that intends to designate a conformity assessment body as a notified body, or has designated a notified body, to carry out conformity assessment activities under this Regulation shall nominate an authority**,** which may consist of separate constituent entities under national law, that shall be responsible for setting up and carrying out the necessary procedures for the assessment, designation and notification of conformity assessment bodies and for the monitoring of notified bodies, including	

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	referred to as the 'national authority responsible for notified bodies'.	referred to as the 'national authority responsible for notified bodies'.	subcontractors and subsidiaries of those bodies, hereinafter referred to as the 'national authority responsible for notified bodies.	
377.	2. The national authority responsible for notified bodies shall be established, organised and operated so as to safeguard the objectivity and impartiality of its activities and to avoid any conflicts of interest with conformity assessment bodies.	2. The national authority responsible for notified bodies shall be established, organised and operated so as to safeguard the objectivity and impartiality of its activities and to avoid any conflicts of interest with conformity assessment bodies.	2. The national authority responsible for notified bodies shall be established, organised and operated so as to safeguard the objectivity and impartiality of its activities and to avoid any conflicts of interests with conformity assessment bodies.	
378.	3. It shall be organised so that each decision relating to notification of a conformity assessment body is taken by personnel different from those who carried out the assessment of the conformity assessment body.	3. It shall be organised so that each decision relating to notification of a conformity assessment body is taken by personnel different from those who carried out the assessment of the conformity assessment body.	3. The national authority responsible for notified bodies shall be organised so that each decision relating to designation or notification is taken by personnel different from those who carried out the assessment.	
379.	4. It shall not perform any activities that conformity assessment bodies perform nor provide consultancy services on a commercial or competitive basis.	4. It shall not perform any activities that conformity assessment bodies perform nor provide consultancy services on a commercial or competitive basis.	4. The national authority responsible for notified bodies It shall not perform any activities that notified bodies perform on a commercial or competitive basis.	
380.	5. The national authority responsible for notified bodies shall safeguard the confidentiality of the information it obtains. However, it shall exchange information on a notified body with other Member States and the Commission.	5. The national authority responsible for notified bodies shall safeguard the confidential aspects of the information it obtains. However, it shall exchange information on a notified body with other Member States and the Commission.	5. The national authority responsible for notified bodies shall safeguard the confidentiality of the information it obtains. However, it shall exchange information on a notified body with other Member States, the Commission and with other regulatory authorities.	
381.	6. The national authority responsible for notified bodies shall have a sufficient number of competent personnel at its disposal for the proper performance of its tasks.	6. The national authority responsible for notified bodies shall have a sufficient number of permanent and competent personnel "in house", for the proper performance of its tasks.	6. The national authority responsible for notified bodies shall have a sufficient number of competent personnel at its disposal for the proper performance of its tasks.	

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382.		Compliance with that requirement shall be assessed in the peer-review referred to in paragraph 8. In particular, the personnel of the national authority responsible for auditing the work of personnel of notified bodies in charge of carrying out product related reviews shall have proven qualifications equivalent to those of the personnel of the notified bodies as laid down in point 3.2.5. of Annex VI. Similarly, the personnel of the national authority responsible for auditing the work of personnel of notified bodies in charge of carrying out audits of the manufacturer's quality management system shall have proven qualifications equivalent to those of the personnel of the notified bodies as laid down in point 3.2.6. of Annex VI.		
383.	Without prejudice to Article 31(3), where a national authority is responsible for the designation of notified bodies in the field of products other than in vitro diagnostic medical devices, the competent authority for in vitro diagnostic medical devices shall be consulted on all aspects specifically related to such devices.	Where a national authority is responsible for the designation of notified bodies in the field of products other than in vitro diagnostic medical devices, the competent authority for in vitro diagnostic medical devices shall be consulted on all aspects specifically related to such devices.	Where the national authority responsible for notified bodies is a different authority than the national competent authority for in vitro diagnostic medical devices, it shall ensure that the authority responsible for in vitro diagnostic medical devices is consulted on relevant aspects.	
384.		7. The ultimate responsibility for the notified bodies and the national authority responsible for notified bodies lies with the Member State in which they are located. The Member State is required to check that the designated national authority responsible for notified bodies performs its work on the assessment, designation and		

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		notification of conformity assessment bodies and for the monitoring of the notified bodies properly and that the designated national authority responsible for notified bodies works impartially and objectively.		
385.	7. Member States shall provide the Commission and the other Member States with information on their procedures for the assessment, designation and notification of conformity assessment bodies and for the monitoring of notified bodies, and of any changes thereto.	Member States shall provide the commission and the other Member States with all information they request on their procedures for the assessment, designation and notification of conformity assessment bodies and for the monitoring of notified bodies, and of any changes thereto. Such information shall be publicly available subject to provisions under Article 80.	7. Member States shall make publicly available general information on their provisions on the assessment, designation and notification of conformity assessment bodies and for the monitoring of notified bodies, and on changes which have a significant impact on these tasks.	
386.	8. The national authority responsible for notified bodies shall be peer-reviewed every second year. The peer-review shall include an on-site visit to a conformity assessment body or a notified body under the responsibility of the reviewed authority. In the case referred to in the second subparagraph of paragraph 6, the competent authority for medical devices shall participate in the peer-review. The Member States shall draw up the annual plan for the peer-review, ensuring an appropriate rotation in respect of reviewing and reviewed authorities, and submit it to the Commission. The Commission may participate in the review. The outcome of the peer-review shall be communicated to all Member States and to the Commission and a summary of the outcome shall be made publicly available.	8. The national authority responsible for notified bodies shall be peer-reviewed every second year. The peer-review shall include an on-site visit to a conformity assessment body or a notified body under the responsibility of the reviewed authority. In the case referred to in the second subparagraph of paragraph 6, the competent authority for medical devices shall participate in the peer-review. The Member States shall draw up the annual plan for the peer-review, ensuring an appropriate rotation in respect of reviewing and reviewed authorities, and submit it to the Commission. The Commission may participate in the review. The outcome of the peer-review shall be communicated to all Member States and to the Commission and a summary of the outcome shall be made publicly available.	**Art 36 2**. The national authorities responsible for notified bodies shall participate in a peer review every third year in accordance with the mechanism agreed in Article 36(1). These reviews shall normally be conducted during on-site joint assessments described in Article 30 but alternatively on a voluntary basis may take place as part of the national authority's monitoring activities in Article 33.	

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387.	**Article 27 Requirements relating to notified bodies**	**Article 27 Requirements relating to notified bodies**	**Article 27 Requirements relating to notified bodies**	
388.	1. Notified bodies shall satisfy the organisational and general requirements and the quality management, resource and process requirements that are necessary to fulfil their tasks for which they are designated in accordance with this Regulation.	1. Notified bodies shall satisfy the organisational and general requirements and the quality management, resource and process requirements that are necessary to fulfil their tasks for which they are designated in accordance with this Regulation.	1. Notified bodies shall satisfy the organisational and general requirements and the quality management,, resource and process requirements that are necessary so they are qualified to fulfil their tasks for which they are designated in accordance with this Regulation.	
389.		In this respect, permanent "in house" administrative, technical and scientific personnel, with medical, technical and where needed pharmacological knowledge shall be ensured. Permanent "in house" personnel shall be used, but notified bodies may hire external experts on an ad hoc and temporary basis as and when needed.		
390.	Minimum requirements to be met by notified bodies are set out in Annex VI.	Minimum requirements to be met by notified bodies are set out in Annex VI. In particular, in accordance with point 1.2. of Annex VI , the notified body shall be organised and operated so as to safeguard the independence, objectivity and impartiality of its activities and avoid conflict of interests.	The requirements to be met by notified bodies are set out in Annex VI.	
391.		The notified body shall publish a list of its staff responsible for the conformity assessment and certification of medical		

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		devices. This list shall at least contain the qualifications, CV and declaration of interests for each member of staff. The list shall be sent to the national authority responsible for notified bodies which shall check that the staff satisfies the requirements of this Regulation. The list shall also be sent to the Commission.		
392.			1a. Notified bodies shall make available and submit upon request, all relevant documentation, including the manufacturer's documentation to the national authority responsible for notified bodies to allow it to conduct its assessment, designation, notification, monitoring and surveillance activities and to facilitate the assessment outlined within this Chapter.	
393.	2. The Commission shall be empowered to adopt delegated acts in accordance with Article 85 amending or supplementing the minimum requirements in Annex VI, in the light of technical progress and considering the minimum requirements needed for the assessment of specific devices, or categories or groups of devices.	2. The Commission shall be empowered to adopt delegated acts in accordance with Article 85 amending or supplementing the minimum requirements in Annex VI, in the light of technical progress and considering the minimum requirements needed for the assessment of specific devices, or categories or groups of devices.	2. In order to ensure the uniform application of the requirements set out in Annex VI, The Commission may adopt implementing acts in accordance with Article 84(3)	
394.	**Article 28 Subsidiaries and subcontracting**	**Article 28 Subsidiaries and subcontracting**	**Article 28 Subsidiaries and subcontracting**	
395.		-1. Notified bodies shall have permanent "in house" competent personnel and expertise, both in technical fields linked with the assessment of the performance of the devices, and in the medical field. They shall have the capacity to evaluate "in		

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		house" the quality of subcontractors. Contracts may be awarded to external experts for the assessment of in vitro diagnostic medical devices or technologies in particular where clinical expertise is limited.		
396.	1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary for specific tasks connected with conformity assessment, it shall verify that the subcontractor or the subsidiary meets the relevant requirements set out in Annex VI and shall inform the national authority responsible for notified bodies accordingly.	1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary for specific tasks connected with conformity assessment, it shall verify that the subcontractor or the subsidiary meets the relevant requirements set out in Annex VI and shall inform the national authority responsible for notified bodies accordingly.	1. Where a notified body subcontracts specific tasks connected with conformity assessment or has recourse to a subsidiary for specific tasks connected with conformity assessment, it shall verify that the subcontractor or the subsidiary meets the applicable requirements set out in Annex VI and shall inform the national authority responsible for notified bodies accordingly.	
397.	2. Notified bodies shall take full responsibility for the tasks performed on their behalf by subcontractors or subsidiaries.	2. Notified bodies shall take full responsibility for the tasks performed on their behalf by subcontractors or subsidiaries.	2. Notified bodies shall take full responsibility for the tasks performed on their behalf by subcontractors or subsidiaries.	
398.		2a. Notified bodies shall make publicly available the list of subcontractors or subsidiaries, the specific tasks for which they are responsible and the declarations of interest of their personnel.		
399.	3. Conformity assessment activities may be subcontracted or carried out by a subsidiary only with the agreement of the legal or natural person that applied for conformity assessment.	3. Conformity assessment activities may be subcontracted or carried out by a subsidiary only with the agreement of the legal or natural person that applied for conformity assessment.	3. Conformity assessment activities may be subcontracted or carried out by a subsidiary only provided that the legal or natural person that applied for conformity assessment has been informed of this.	
400.		4. At least once a year, notified bodies shall submit to the national authority responsible for notified bodies the relevant		

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		documents concerning the verification of the qualifications of the subcontractor or the subsidiary and the work carried out by them under this Regulation.		
401.	4. Notified bodies shall keep at the disposal of the national authority responsible for notified bodies the relevant documents concerning the verification of the qualifications of the subcontractor or the subsidiary and the work carried out by them under this Regulation.	**5.** Notified bodies shall keep at the disposal of the national authority responsible for notified bodies the relevant documents concerning the verification of the qualifications of the subcontractor or the subsidiary and the work carried out by them under this Regulation.	4. Notified bodies shall keep at the disposal of the national authority responsible for notified bodies the relevant documents concerning the verification of the qualifications of the subcontractor or the subsidiary and the work carried out by them under this Regulation.	
402.		4a. The annual assessment of notified bodies as provided for in Article 33(3) shall include verification of the compliance of the subcontractor(s) or the subsidiary(ies) of notified bodies with the requirements set out in Annex VI.		
403.		**Article 28 a** **Electronic system on registration of subsidiaries and subcontractors**		
404.		1. The Commission, in collaboration with the Member States, shall set up and manage an electronic system to collate and process information on subcontractors and subsidiaries, as well as on the specific tasks for which they are responsible.		
405.		2. Before subcontracting can effectively take place, the notified body which intends to subcontract specific tasks connected with conformity assessment or has recourse to a subsidiary for specific tasks connected with conformity assessment,		

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		shall register their name(s) together with their specific tasks.		
406.		3. Within one week of any change occurring in relation to the information referred to in paragraph 1, the relevant economic operator shall update the data in the electronic system.		
407.		4. The data contained in the electronic system shall be accessible to the public.		
408.	**Article 29 Application by a conformity assessment body for notification**	**Article 29 Application by a conformity assessment body for notification**	**Article 29 Application by a conformity assessment body for designation**	
409.	1. A conformity assessment body shall submit an application for notification to the national authority responsible for notified bodies of the Member State in which it is established.	1. A conformity assessment body shall submit an application for notification to the national authority responsible for notified bodies of the Member State in which it is established.	1. A conformity assessment body shall submit an application for designation to the national authority responsible for notified bodies of the Member State in which it is established.	
410.		In case a conformity assessment body wants to be notified for devices referred to in Article 41 a (new) first paragraph, it shall indicate so and submit an application for notification to the European Medicines Agency in accordance with Article 41 a (new)		
411.	2. The application shall specify the conformity assessment activities, the conformity assessment procedures and the devices for which the body claims to be competent, supported by	5. The application shall specify the conformity assessment activities, the conformity assessment procedures and the devices for which the body claims to be competent, supported by	2. The application shall specify the conformity assessment activities as defined in this Regulation and the types of devices for which the body applies to be designated and for which involvement of a	

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	documentation proving compliance with all the requirements set out in Annex VI. In respect of the organisational and general requirements and the quality management requirements set out in Sections 1 and 2 of Annex VI, the relevant documentation may be submitted in form of a valid certificate and the corresponding evaluation report delivered by a national accreditation body in accordance with Regulation (EC) No 765/2008. The conformity assessment body shall be presumed to be in conformity with the requirements covered by the certificate delivered by such accreditation body.	documentation proving compliance with all the requirements set out in Annex VI.	notified body is required, supported by documentation proving compliance with all the requirements set out in Annex VI. In respect of the organisational and general requirements and the quality management requirements set out in Sections 1 and 2 of Annex VI, a valid certificate and the corresponding evaluation report delivered by a national accreditation body in accordance with Regulation (EC) No 765/2008 may be submitted in support of these requirements and shall be taken into consideration during the assessment described in Article 30. However, the applicant shall make available the full documentation to demonstrate conformity with these requirements upon request.	
412.	3. After being designated, the notified body shall update the documentation referred to in paragraph 2 whenever relevant changes occur in order to enable the national authority responsible for notified bodies to monitor and verify continuous compliance with all the requirements set out in Annex VI.	6. After being designated, the notified body shall update the documentation referred to in paragraph 2 whenever relevant changes occur in order to enable the national authority responsible for notified bodies to monitor and verify continuous compliance with all the requirements set out in Annex VI.	3. After being designated, the notified body shall update the documentation referred to in paragraph 2 whenever relevant changes occur in order to enable the national authority responsible for notified bodies to monitor and verify continuous compliance with all the requirements set out in Annex VI.	
413.	**Article 30** **Assessment of the application**	**Article 30** **Assessment of the application**	**Article 30** **Assessment of the application**	
414.	1. The national authority responsible for notified bodies shall check that the application referred to in Article 29 is complete and draw up a preliminary assessment report.	1. The national authority responsible for notified bodies shall check that the application referred to in Article 29 is complete and draw up a preliminary assessment report.	1. The national authority responsible for notified bodies shall within 30 days check that the application referred to in Article 29 is complete and shall request the applicant to provide any missing information. Once the application is complete the national	

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			authority shall send it to the Commission along with a proposed timeframe for preliminary review and an indicative date for an on-site assessment. The national authority shall review the application and supporting documentation in accordance with its own procedures and shall draw up a preliminary assessment report.	
415.	2. It shall submit the preliminary assessment report to the Commission which shall immediately transmit it to the Medical Device Coordination Group ('MDCG') referred to in Article 76. Upon request by the Commission, the report shall be submitted by the authority in up to three official Union languages.	2. It shall submit the preliminary assessment report to the Commission which shall immediately transmit it to the Medical Device Coordination Group ('MDCG') referred to in Article 76. Upon request by the Commission, the report shall be submitted by the authority in up to three official Union languages.	2. It The national authority responsible for notified bodies shall submit the preliminary assessment report to the Commission which shall immediately transmit it to the Medical Device Coordination Group established by Article 76 ('MDCG'). The national authority responsible for notified bodies shall also indicate based on their assessment whether the on-site assessment date proposed in paragraph 1 remains valid. Documents to support the application described in Article 29 shall be made available upon request.	
416.	3. Within 14 days of the submission referred to in paragraph 2, the Commission shall designate a joint assessment team, made up of at least two experts chosen from a list of experts who are qualified in the assessment of conformity assessment bodies. The list shall be drawn up by the Commission in cooperation with the MDCG.	3. 3. Within 14 days of the submission referred to in paragraph 2, the Commission shall designate a joint assessment team made up of at least three experts chosen from a list of experts who are qualified in the assessment of conformity assessment bodies and free of conflicts of interest with the applicant conformity assessment body.. The list shall be drawn up by the Commission in cooperation with the MDCG.	3. Within 14 days of the submission referred to in paragraph 2, the Commission in conjunction with the MDCG shall assign a joint assessment team made up of three experts, unless the specific circumstances require another number of experts, chosen from the list.	

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417.	At least one of these experts shall be a representative of the Commission who shall lead the joint assessment team.	At least one of these experts shall be a representative of the Commission,	One of these experts shall be a representative of the Commission who shall coordinate the activities of the joint assessment team.	
418.		and at least one other shall come from a Member State other than the one in which the applicant conformity assessment body is established. The Commission representative shall lead the joint assessment team. In case the conformity assessment body has asked to be notified for devices referred to in Article 41 a (new) first paragraph, the Agency shall also be part of the joint assessment team.		
419.			3a. The joint assessment team shall be comprised of competent experts which reflect the conformity assessment activities and the types of devices which are subject to the application or, in particular when this procedure is initiated in accordance with Article 35 to ensure that the specific concern can be appropriately assessed.	
420.	4. Within 90 days after designation of the joint assessment team, the national authority responsible for notified bodies and the joint assessment team shall review the documentation submitted with the application in accordance with Article 29 and conduct an on-site assessment of the applicant conformity assessment body and, where relevant, of any subsidiary or sub-contractor, located inside or outside the Union, to be involved in the conformity assessment process. Such on-site	4. Within 90 days after designation of the joint assessment team, the national authority responsible for notified bodies and the joint assessment team shall review the documentation submitted with the application in accordance with Article 29 and conduct an on-site assessment of the applicant conformity assessment body and, where relevant, of any subsidiary or sub-contractor, located inside or outside the Union, to be involved in the conformity assessment process. Such on-site	4. Within 90 days after assignment of the joint assessment team, shall review the documentation submitted with the application in accordance with Article 29. The joint assessment team may feedback to or require clarification from the national authority responsible for notified bodies on the application and on the planned on-site assessment.	

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	assessment shall not cover requirements for which the applicant conformity assessment body has received a certificate delivered by the national accreditation body as referred to in Article 29(2), unless the Commission representative mentioned in Article 30(3) requests the on-site assessment.	assessment shall not cover requirements for which the applicant conformity assessment body has received a certificate delivered by the national accreditation body as referred to in Article 29(2), unless the Commission representative mentioned in Article 30(3) requests the on-site assessment.		
421.	Findings regarding non-compliance of a body with the requirements set out in Annex VI shall be raised during the assessment process and discussed between the national authority responsible for notified bodies and the joint assessment team with a view to finding common agreement with respect to the assessment of the application. Divergent opinions shall be identified in the assessment report of the national authority responsible.	Findings regarding non-compliance of an applicant conformity assessment body with the requirements set out in Annex VI shall be raised during the assessment process and discussed between the national authority responsible for notified bodies and the joint assessment team. The national authority shall set out in the assessment report the measures that the notify body shall take to ensure compliance of that applicant conformity assessment body with the requirements set out in Annex VI. In the event of a disagreement, a separate opinion drawn up by the assessment team setting out its reservations regarding notification shall be appended to the assessment report of the national authority responsible.	4a. Findings regarding non-compliance of a body with the requirements set out in Annex VI shall be raised during the assessment process and discussed between the national authority responsible for notified bodies and the joint assessment team with a view to finding common agreement and resolution of any diverging opinions with respect to the assessment of the application.	
422.			A list of non-compliances resulting from the assessment shall be presented by the national authority responsible for notified bodies to the applicant body at the end of the on-site assessment including a summary of the assessment delivered by the joint assessment team. The national authority shall request a corrective and preventive action plan from the applicant body to be submitted within a	

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			specified timeframe to address the non-compliances.	
423.			4aa. The joint assessment team shall within 30 days of completion of the on-site assessment document any remaining diverging opinions with respect to the assessment and send these to the national authority responsible for notified bodies.	
424.			4b. The national authority responsible for notified bodies shall following receipt of a corrective and preventive action plan from the applicant body assess whether non-compliances identified during the assessment have been appropriately addressed. This plan shall include an indication of the root cause of the finding and a timeframe for implementation of the actions therein. The national authority shall having confirmed the corrective and preventive action plan forward this plan and its opinion on this plan to the joint assessment team. The joint assessment team may request further clarification and modifications from the national authority responsible for notified bodies. The national authority responsible for notified bodies shall draw up its final assessment report which shall include: - the result of the assessment, - confirmation that the corrective and preventive actions have been appropriately addressed and, where	

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			required, implemented, - any remaining diverging opinion with the joint assessment team, and, where applicable, - the recommended scope of designation.	
425.	5. The national authority responsible for notified bodies shall submit its assessment report and its draft notification to the Commission which shall immediately transmit those documents to the MDCG and to the members of the joint assessment team. Upon request by the Commission, those documents shall be submitted by the authority in up to three official Union languages.	5. The national authority responsible for notified bodies shall submit its assessment report and its draft notification to the Commission which shall immediately transmit those documents to the MDCG and to the members of the joint assessment team. If the assessment team draws up a separate opinion, this too shall be submitted to the Commission for forwarding to the MDCG. Upon request by the Commission, those documents shall be submitted by the authority in up to three official Union languages.	5. The national authority responsible for notified bodies shall submit its final assessment report and, if applicable, the draft designation to the Commission, the MDCG and the joint assessment team.	
426.	6. The joint assessment team shall provide its opinion regarding the assessment report and the draft notification within 21 days of receipt of those documents and the Commission shall immediately submit this opinion to the MDCG. Within 21 days after receipt of the opinion of the joint assessment team, the MDCG shall issue a recommendation with regard to the draft notification which the relevant national authority shall duly take into consideration for its decision on the designation of the notified body.	6. The joint assessment team shall provide its final opinion regarding the assessment report, the draft notification and, where appropriate, the separate opinion drawn up by the assessment team, within 21 days of receipt of those documents and the Commission shall immediately submit this opinion to the MDCG. Within 21 days after receipt of the opinion of the joint assessment team, the MDCG shall issue a recommendation with regard to the draft notification.	6. The joint assessment team shall provide its opinion in a final report regarding the assessment report prepared by the national authority responsible for notified bodies and, if applicable, the draft designation within 21 days of receipt of those documents to the Commission, which shall immediately submit this opinion to the MDCG. Within 42 days after receipt of the opinion of the joint assessment team, the MDCG shall issue a recommendation with regard to the draft designation which the national authority shall duly take into consideration for its decision on the designation of the notified body.	

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427.		The relevant national authority shall base its decision on the designation of the notified body on the recommendation by the MDCG. In case where its decision differs from the MDCG recommendation, the relevant national authority shall provide the MDCG in writing with all the necessary justification for its decision.		
428.	7. The Commission may, by means of implementing acts, adopt measures setting out the modalities for the application for notification referred to in Article 29 and the assessment of the application set out in this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).	7. The Commission may, by means of implementing acts, adopt measures setting out the modalities for the application for notification referred to in Article 29 and the assessment of the application set out in this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).	7. The Commission may, by means of implementing acts, adopt measures setting out the modalities specifying procedures and reports for the application for designation referred to in Article 29 and the assessment of the application set out in this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).	
429.			**Article 30a** **Nomination of experts for joint assessment of applications for notification**	
430.			1. The Member States and the Commission shall nominate experts qualified in the assessment of conformity assessment bodies in the field of in vitro diagnostic medical devices to participate in the activities outlined in Article 30 and Article 36. 2. The Commission shall maintain a list of the experts nominated pursuant to paragraph 1, together with information on their specific competence and expertise.	

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			This list shall be made available to Member States competent authorities through the electronic system referred to in Article 25.	
431.			**Article 30b** **Language requirements**	
432.			All documents required pursuant to Articles 29 and 30 shall be drawn up in a language or languages which shall be determined by the Member State concerned. Member States, in applying the first sub-paragraph, shall consider accepting and using a commonly understood language in the medical field, for all or part of the documents concerned. The Commission shall provide necessary translations of the documentation pursuant to Article 29 and 30, or parts of it thereof into an official Union language such that the documents can be readily understood by the joint assessment team designated in accordance with Article 30(3).	
433.	**Article 31** **Notification procedure**	**Article 31** **Notification procedure**	**Article 31** **Designation and notification procedure**	
434.	1. Member States shall notify the Commission and the other Member States of the conformity assessment bodies they have designated, using the electronic notification tool developed and managed by the Commission.	1. Member States shall notify the Commission and the other Member States of the conformity assessment bodies they have designated, using the electronic notification tool developed and managed by the Commission.	1. Member States shall notify the Commission and the other Member States of the conformity assessment bodies they have designated, using the electronic notification tool developed and managed by the Commission.	

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435.	2. Member States may notify only conformity assessment bodies which satisfy the requirements set out in Annex VI.	2. Member States shall notify only conformity assessment bodies which satisfy the requirements set out in Annex VI and for which the application assessment procedure has been completed in accordance with Article 30 .	0. Member States may only designate conformity assessment bodies which satisfy the requirements set out in Annex VI and for which the assessment pursuant to Article 30 was completed.	
436.	3. Where a national authority responsible for notified bodies is responsible for designation of notified bodies in the field of products other than in vitro diagnostic medical devices, the competent authority for in vitro diagnostic medical devices shall provide, prior to the notification, a positive opinion on the notification and its scope.			
437.	4. The notification shall clearly specify the scope of the designation indicating the conformity assessment activities, the conformity assessment procedures and the type of devices which the notified body is authorised to assess.	3. The notification shall clearly specify the scope of the designation indicating the conformity assessment activities, the conformity assessment procedures, the risk class and the type of devices which the notified body is authorised to assess.	4. The notification shall clearly specify the scope of the designation indicating the conformity assessment activities as defined in this Regulation, and the type of devices which the notified body is authorised to assess and, without prejudice to Article 33, any conditions associated with the designation.	
438.	The Commission may, by means of implementing acts, set up a list of codes and the corresponding types of devices to define the scope of the designation of notified bodies which the Member States shall indicate in their notification. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 84(2).	The Commission may, by means of implementing acts, set up a list of codes and the corresponding types of devices to define the scope of the designation of notified bodies which the Member States shall indicate in their notification. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 84(2).	4a. The Commission shall within six months of the entry into force of this Regulation, by means of implementing acts, draw up a list of codes and the corresponding types of devices to describe the scope of the designation of notified bodies which the Member States shall indicate in their notification. Those implementing acts shall be adopted in accordance with the advisory examination procedure referred to in Article 84(3). The Commission, after consulting the MDCG, may update this list inter alia based on	

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			information arising from the coordination activities described in Article 36.	
439.	5. The notification shall be accompanied by the final assessment report of the national authority responsible for notified bodies, the opinion of the joint assessment team and the recommendation of the MDCG. Where the notifying Member State does not follow the recommendation of the MDCG, it shall provide a duly substantiated justification.	4. The notification shall be accompanied by the final assessment report of the national authority responsible for notified bodies, the opinion of the joint assessment team and the recommendation of the MDCG. Where the notifying Member State does not follow the recommendation of the MDCG, it shall provide a duly substantiated justification.	5. The notification shall be accompanied by the final assessment report of the national authority responsible for notified bodies, the final report of the joint assessment team and the recommendation of the MDCG. Where the notifying Member State does not follow the recommendation of the MDCG, it shall provide a duly substantiated justification.	
440.	6. The notifying Member State shall provide the Commission and the other Member States with documentary evidence regarding the arrangements in place to ensure that the notified body will be monitored regularly and will continue to satisfy the requirements set out in Annex VI. It shall furthermore submit evidence of the availability of competent personnel for monitoring the notified body in accordance with Article 26(6).	5. The notifying Member State shall provide the Commission and the other Member States with documentary evidence regarding the arrangements in place to ensure that the notified body will be monitored regularly and will continue to satisfy the requirements set out in Annex VI. It shall furthermore submit evidence of the availability of competent personnel for monitoring the notified body in accordance with Article 26(6).	6. The notifying Member State shall, without prejudice to Article 33, provide the Commission and the other Member States of any conditions associated with the designation and provide documentary evidence regarding the arrangements in place to ensure that the notified body will be monitored regularly and will continue to satisfy the requirements set out in Annex VI.	
441.	7. Within 28 days of a notification, a Member State or the Commission may raise written objections, setting out its arguments, with regard either to the notified body or to its monitoring by the national authority responsible for notified bodies.	6. Within 28 days of a notification, a Member State or the Commission may raise written objections, setting out its arguments, with regard either to the notified body or to its monitoring by the national authority responsible for notified bodies.	7. Within 28 days of a notification, a Member State or the Commission may raise written objections, setting out its arguments, with regard either to the notified body or to its monitoring by the national authority responsible for notified bodies.	
442.	8. When a Member State or the Commission raises objections in accordance with paragraph 7, the effect of the notification shall be suspended. In this case, the Commission shall bring the	7. 7. When a Member State or the Commission raises objections in accordance with paragraph 7, the effect of the notification shall be immediately suspended. In this case, the Commission	8. When a Member State or the Commission raises objections in accordance with paragraph 7, the Commission shall bring the matter before the MDCG within 10 days after expiry of	

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	matter before the MDCG within 15 days after expiry of the period referred to in paragraph 7. After consulting the parties involved, the MDCG shall give its opinion at the latest within 28 days after the matter has been brought before it. If the notifying Member State does not agree with the opinion of the MDCG, it may request the Commission to give its opinion.	shall bring the matter before the MDCG within 15 days after expiry of the period referred to in paragraph 7. After consulting the parties involved, the MDCG shall give its opinion at the latest within 28 days after the matter has been brought before it. If the notifying Member State does not agree with the opinion of the MDCG, it may request the Commission to give its opinion.	the period referred to in paragraph 7. After consulting the parties involved, the MDCG shall give its opinion at the latest within 40 days after the matter has been brought before it.	
443.			8a. Where the MDCG, after having been consulted in accordance with paragraph 8, confirms the existing objection or raises another objection, the notifying Member State shall provide a written response to the MDCG's opinion within 40 days of its receipt. The response shall address the objections raised in the opinion, and set out the reasons for the notifying Member State's decision to designate or not designate the conformity assessment body.	
444.	9. Where no objection is raised in accordance with paragraph 7 or where the MDCG or the Commission, after having been consulted in accordance with paragraph 8, is of the opinion that the notification may be accepted fully or partially, the Commission shall publish the notification accordingly.	8. Where no objection is raised in accordance with paragraph 7 or where the MDCG or the Commission, after having been consulted in accordance with paragraph 8, is of the opinion that the notification may be accepted fully or partially, the Commission shall publish the notification accordingly.	9. Where no objection is raised in accordance with paragraph 7 or where the MDCG, after having been consulted in accordance with paragraph 8, is of the opinion that the notification may be accepted, or where the notifying Member State having responded in accordance with paragraph 8a, decides to designate the conformity assessment body the Commission shall publish the notification accordingly within 14 days of receipt.	
445.		The Commission shall also enter information on the notification of the	When publishing the notification in the database of notified bodies developed and	

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		notified body into the electronic system referred to in Article 25(2). That information shall be accompanied by the final assessment report of the national authority responsible for notified bodies, the opinion of the joint assessment team and the recommendation of the MDCG, as referred to in this article. The full details of the notification, including the class and the typology of devices, as well as the annexes, shall be made publicly available.	managed by the Commission the Commission shall add the information relating to the notification of the notified body to the electronic system referred to in Article 25 along with the documents mentioned in paragraph 5 and the opinion and response referred to in paragraphs 8 and 8a of this Article.	
446.	10. The notification shall become valid the day after its publication in the database of notified bodies developed and managed by the Commission. The published notification shall determine the scope of lawful activity of the notified body.	9. The notification shall become valid the day after its publication in the database of notified bodies developed and managed by the Commission. The published notification shall determine the scope of lawful activity of the notified body.	10. The notification shall become valid the day after its publication in the database of notified bodies developed and managed by the Commission. The published notification shall determine the scope of lawful activity of the notified body.	
447.			11. The conformity assessment body concerned may perform the activities of a notified body only after the notification has become valid in accordance with paragraph 10.	
448.	**Article 32 Identification number and list of notified bodies**	**Article 32 Identification number and list of notified bodies**	**Article 32 Identification number and list of notified bodies**	
449.	1. The Commission shall assign an identification number to each notified body for which the notification is accepted in accordance with Article 31. It shall assign a single identification number even when the body is notified under several Union acts.	1. The Commission shall assign an identification number to each notified body for which the notification is accepted in accordance with Article 31. It shall assign a single identification number even when the body is notified under several Union acts.	1. The Commission shall assign an identification number to each notified body for the notification becomes valid in accordance with Article 31(10). It shall assign a single identification number even when the body is notified under several Union acts.	

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450.	2. The Commission shall make accessible to the public the list of the bodies notified under this Regulation, including the identification numbers that have been assigned to them and the activities for which they have been notified. The Commission shall ensure that the list is kept up to date.	2. The Commission shall make easily accessible to the public the list of the bodies notified under this Regulation, including the identification numbers that have been assigned to them and the activities for which they have been notified and all documents for the notification procedure as referred to in Article 31(5). The Commission shall ensure that the list is kept up to date.	2. The Commission shall make the list of the bodies notified under this Regulation, including the identification numbers that have been assigned to them and the conformity assessment activities as defined in this Regulation and the types of devices for which they have been notified, accessible to the public in the database of notified bodies developed and managed by the Commission. It shall also make this list available on the electronic system referred to in Article 25. The Commission shall ensure that the list is kept up to date.	
451.	**Article 33** **Monitoring of notified bodies**	**Article 33** **Monitoring of notified bodies**	**Article 33** **Monitoring and assessment of notified bodies**	
452.	1. The national authority responsible for notified bodies shall continuously monitor the notified bodies to ensure ongoing compliance with the requirements set out in Annex VI. The notified bodies shall, on request, supply all relevant information and documents required to enable the authority to verify compliance with those criteria.	The national authority responsible for notified bodies, and where applicable EMA, shall continuously monitor the notified bodies to ensure ongoing compliance with the requirements set out in Annex VI. The notified bodies shall, on request, supply all relevant information and documents, required to enable the authority to verify compliance with those criteria.	1. The national authority responsible for notified bodies shall conduct monitoring of the notified bodies based on its territory and of their subsidiaries and subcontractors to ensure ongoing compliance with the requirements and the fulfilment of its obligations set out in this Regulation. The notified bodies shall, on request from the national authority responsible for notified bodies, supply all relevant information and documents, required to enable the authority, the Commission and other Member States to verify compliance with those criteria.	
453.	Notified bodies shall, without delay, inform the national authority responsible for notified bodies of any changes, in particular regarding their personnel, facilities, subsidiaries or subcontractors,	Notified bodies shall, without delay, and within 15 days at the latest inform the national authority responsible for notified bodies of any changes, in particular regarding their personnel, facilities,	**Art. 33 0.** Notified bodies shall, without delay, inform the national authority responsible for notified bodies of relevant changes which may affect their compliance with the requirements set out	

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	which may affect compliance with the requirements set out in Annex VI or their ability to conduct the conformity assessment procedures relating to the devices for which they have been designated.	subsidiaries or subcontractors, which may affect compliance with the requirements set out in Annex VI or their ability to conduct the conformity assessment procedures relating to the devices for which they have been designated.	in Annex VI or their ability to conduct the conformity assessment activities relating to the devices for which they have been designated.	
454.	2. Notified bodies shall respond without delay to requests relating to conformity assessments they have carried out, submitted by their or another Member State's authority or by the Commission. The national authority responsible for notified bodies of the Member State in which the body is established shall enforce requests submitted by authorities of any other Member State or by the Commission unless there is a legitimate reason for not doing so in which case both sides may consult the MDCG.	3. Notified bodies shall respond without delay, and within 15 days at the latest, to requests relating to conformity assessments they have carried out, submitted by their or another Member State's authority or by the Commission. The national authority responsible for notified bodies of the Member State in which the body is established shall enforce requests submitted by authorities of any other Member State or by the Commission. Where there is a legitimate reason for not doing so, the notified bodies shall explain these reasons in writing and shall consult the MDCG, which shall then issue a recommendation. The national authority responsible for notified bodies shall comply with the MDCG's recommendation.	2. The national authority responsible for notified bodies shall receive a copy of all requests submitted by the Commission or by another Member State authority to notified bodies on its territory relating to conformity assessments such notified bodies have carried out. Notified bodies shall respond without delay to such requests. The national authority responsible for notified bodies of the Member State in which the body is established shall ensure that requests submitted by authorities of any other Member State or by the Commission are resolved unless there is a legitimate reason for not doing so in which case both sides may consult the MDCG.	
455.	The notified body or their national authority responsible for notified bodies may request that any information transmitted to the authorities of another Member State or to the Commission shall be treated as confidential.			
456.	3. At least once a year, the national authority responsible for notified bodies shall assess whether each notified body under its responsibility still satisfies the	4. At least once a year, the national authority responsible for notified bodies shall assess whether each notified body under its responsibility still satisfies the	3. At least once a year**,** the national authority responsible for notified bodies shall assess whether each notified body and, when appropriate, the subsidiaries	

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	requirements set out in Annex VI.	requirements set out in Annex VI, including an assessment of whether its subcontractor(s) and subsidiary(-ies) satisfy these requirements.	and subcontractors under its responsibility still satisfy the requirements and fulfil their obligations set out in Annex VI.	
457.	This assessment shall include an on-site visit to each notified body.	This assessment shall include an unannounced inspection through an on-site visit to each notified body, and to each subsidiary or subcontractor within or outside the Union, if relevant. The assessment shall also include a review of samples of the design dossier assessments carried out by the notified body to determine the ongoing competence of the notified body and quality of its assessments, in particular the notified body's ability to evaluate and assess clinical evidence.	This review shall include an on-site visit to each notified body and, when necessary, to its subsidiaries and subcontractors.	
458.			The national authority shall conduct its monitoring, and assessment activities according to an annual assessment plan to ensure that it can effectively monitor the continued compliance of the notified body with the requirements of this Regulation. This plan shall provide a reasoned schedule for the frequency of assessment of the notified body and associated subsidiaries and subcontractors. The authority shall submit its annual plan for monitoring or assessment for each notified body for which it is responsible to the MDCG and to the Commission.	
459.			3a. The national authority's monitoring of notified bodies shall include witnessed audits of the notified body personnel,	

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			including when necessary the personnel from subsidiaries and subcontractors**,** when conducting quality system assessments at a manufacturer's facility.	
460.			3b. The monitoring of notified bodies conducted by national authorities responsible for notified bodies shall consider data arising from market surveillance, vigilance and post-market surveillance systems to help guide its activities. The authority shall provide for a systematic follow-up of complaints, and other information, including from other Member States, which may indicate non-fulfilment of the obligations by a notified body or its deviation from common or best practice The national authority responsible for notified bodies may in addition to regular monitoring or on-site assessments conduct short-notice, unannounced or 'for-cause' reviews if needed to address a particular issue or to verify compliance.	
461.			3c. The national authority responsible for notified bodies shall assess the notified body assessments of manufacturers' technical and clinical documentation as further outlined in Article 33a.	
462.			3d. The national authority responsible for notified bodies shall document and record any findings regarding non-compliance of the notified body with the requirements set	

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			out in Annex VI and shall monitor the timely implementation of relevant corrective and preventative actions.	
463.	4. Three years after notification of a notified body, and again every third year thereafter, the assessment to determine whether the notified body still satisfies the requirements set out in Annex VI shall be conducted by the national authority responsible for notified bodies of the Member State in which the body is established and a joint assessment team designated in accordance with the procedure described in Article 30(3) and (4). At the request of the Commission or of a Member State, the MDCG may initiate the assessment process described in this paragraph at any time when there is reasonable concern about the ongoing compliance of a notified body with the requirements set out in Annex VI.	5. Two years after notification of a notified body, and again every second year thereafter, the assessment to determine whether the notified body and its subsidiaries and subcontractors still satisfy the requirements set out in Annex VI shall be conducted by the national authority responsible for notified bodies of the Member State in which the body is established and a joint assessment team designated in accordance with the procedure described in Article 30(3) and (4). At the request of the Commission or of a Member State, the MDCG may initiate the assessment process described in this paragraph at any time when there is reasonable concern about the ongoing compliance of a notified body, or a subsidiary or subcontractor of a notified body, with the requirements set out in Annex VI. For Special notified bodies under Article 41a, the assessment referred to in this paragraph shall be performed every year. The comprehensive results of the assessments shall be published.	4. Three years after notification of a notified body, and again every fourth year thereafter, the re-assessment to determine whether the notified body still satisfies the requirements set out in Annex VI shall be conducted by the national authority responsible for notified bodies of the Member State in which the body is established and a joint assessment team designated in accordance with the procedure described in Article 29 and 30.	
464.			4a. The Commission may, by means of implementing acts, modify the frequency of complete re-assessment referred to in the previous sub-paragraph. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).	

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465.	5. The Member States shall report to the Commission and to the other Member States, at least once a year, on their monitoring activities. This report shall contain a summary which shall be made publicly available.	5a. Every year, the notified bodies shall forward an annual activity report setting out the information referred to in Annex VI, point 5 to the competent authority and to the Commission, which shall forward it to the MDCG.	5. The Member States shall report to the Commission and to the MDCG, at least once a year, on their monitoring activities regarding their notified bodies and, where applicable, subsidiaries and subcontractors. This report shall provide details of the outcome of the monitoring and surveillance activities. This report shall be treated as confidential by the MDCG and the Commission however it shall contain a summary which shall be made publicly available. The summary report shall be uploaded to the European databank referred to in Article 25.	
466.			**Article 33a** **Review of notified body assessment of technical documentation and performance evaluation documentation**	
467.			1. The national authority responsible for notified bodies, as part of its ongoing monitoring of notified bodies shall assess an appropriate number of notified body assessments of manufacturers' technical documentation and performance evaluations to verify the conclusions drawn by the notified body based on the information presented by the manufacturer. These assessments shall be conducted both off-site and on-site assessments.	
468.			2. The sample of files assessed in accordance with paragraph 1 shall be planned and representative of the types and risk of devices certified by the notified	

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			body and in particular high risk devices appropriately justified and documented in a sampling plan, which shall be available from the national authority responsible for notified bodies upon request of the MDCG.	
469.			3. The national authority responsible for notified bodies shall assess whether the assessment by the notified body was conducted appropriately and verify the procedures used, associated documentation and conclusions drawn by the notified body. This shall include the manufacturer's technical and clinical documentation upon which the notified body has based its assessment. These assessments shall be conducted utilising common technical specifications provided for in Article 7 in the conduct of the assessment.	
470.			4. The assessments shall also form part of the re-assessment of notified bodies in accordance with Article 33(4) and the joint assessment activities referred to in Article 35(2a). These assessment shall be conducted utilising appropriate expertise.	
471.			5. The MDCG may, based on the reports of these assessments by the national authority or joint assessment teams, and inputs from the market surveillance and post-market surveillance activities described in Chapter VII, recommend that the sampling, either by national authority or as part of a joint assessment activity, shall cover a greater or lesser proportion of the performance evaluations and	

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			technical documentation assessed by a notified body.	
472.			6. The Commission may, by means of implementing acts, adopt measures setting out the modalities, associated documents for and coordination of the technical and clinical assessments referred to in this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).	
473.	**Article 34 Changes to notifications**	**Article 34 Changes to notifications**	**Article 34 Changes to designations and notifications**	
474.	1. The Commission and the other Member States shall be notified of any subsequent relevant changes to the notification. The procedures described in Article 30(2) to (6) and in Article 31 shall apply to changes where they entail extension of the scope of the notification. In all other cases, the Commission shall immediately publish the amended notification in the electronic notification tool referred to in Article 31(10).	1. The Commission and the other Member States shall be notified of any subsequent relevant changes to the notification. The procedures described in Article 30(2) to (6) and in Article 31 shall apply to changes where they entail extension of the scope of the notification. In all other cases, the Commission shall immediately publish the amended notification in the electronic notification tool referred to in Article 31(10).	1. The Commission and the other Member States shall be notified of any subsequent relevant changes to the designation by the national authority responsible for notified bodies. The procedures described in Article 30(2) to (6) and in Article 31 shall apply to changes where they entail an extension of the scope of the notification. In all other cases, the Commission shall immediately publish the amended notification in the electronic notification tool referred to in Article 31(10).	
475.			1a. Where a notified body decides to cease its conformity assessment activities it shall inform the national authority responsible for notified bodies and the manufacturers concerned as soon as possible and in case of a planned ceasing its activities. The certificates may remain valid for a temporary period of nine	

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			months after cessation of activities on condition that another notified body has confirmed in writing that it will assume responsibilities for these products. The new notified body shall complete a full assessment of the devices affected by the end of that time period before issuing new certificates for those devices.	
476.	2. Where a national authority responsible for notified bodies has ascertained that a notified body no longer meets the requirements set out in Annex VI, or that it is failing to fulfil its obligations, the authority shall suspend, restrict, or fully or partially withdraw the notification, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. A suspension shall not exceed a period of one year, renewable once for the same period. Where the notified body has ceased its activity, the national authority responsible for notified bodies shall withdraw the notification.	2. 2. Where a national authority responsible for notified bodies has ascertained that a notified body no longer meets the requirements set out in Annex VI, or that it is failing to fulfil its obligations, the authority shall suspend, restrict, or fully or partially withdraw the notification, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. Suspension shall apply until a decision to annul the suspension has been reached by the MDCG, which shall follow an assessment by a joint assessment team designated in accordance with the procedure described in Article 30(3). Where the notified body has ceased its activity, the national authority responsible for notified bodies shall withdraw the notification.	2. Where a national authority responsible for notified bodies has ascertained that a notified body no longer meets the requirements set out in Annex VI, or that it is failing to fulfil its obligations or has not implemented the necessary corrective measures, the authority shall suspend, restrict, or fully or partially withdraw the designation, depending on the seriousness of the failure to meet those requirements or fulfil those obligations. A suspension shall not exceed a period of one year, renewable once for the same period. Where the notified body has ceased its activity, the national authority responsible for notified bodies shall withdraw the notification.	
477.	The national authority responsible for notified bodies shall immediately inform the Commission and the other Member States of any suspension, restriction or withdrawal of a notification.	The national authority responsible for notified bodies shall immediately and within 10 days at the latest, inform the Commission, the other Member States and the relevant manufacturers and health professionals of any suspension, restriction or withdrawal of a notification.	The national authority responsible for notified bodies shall immediately inform the Commission and the other Member States of any suspension, restriction or withdrawal of a notification.	
478.	3. In the event of restriction, suspension or	3. In the event of restriction, suspension or	3. In the event of restriction, suspension or	

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	withdrawal of a notification, the Member State shall take appropriate steps to ensure that the files of the notified body concerned are either processed by another notified body or kept available for the national authorities responsible for notified bodies and for market surveillance at their request.	withdrawal of a notification, the Member State shall inform the Commission and shall take appropriate steps to ensure that the files of the notified body concerned are either processed by another notified body or kept available for the national authorities responsible for notified bodies and for market surveillance at their request.	withdrawal of a notification, the Member State shall take appropriate steps to ensure that the files of the notified body concerned are kept available for the national authorities responsible for notified bodies and national authorities responsible for market surveillance at their request.	
479.	4. The national authority responsible for notified bodies shall	4. The national authority responsible for notified bodies shall	4. The national authority responsible for notified bodies shall:	
480.	assess whether the reasons which gave rise to the change to the notification have an impact on the certificates issued by the notified body	assess whether the reasons which gave rise to the suspension, restriction or withdrawal of the notification have an impact on the certificates issued by the notified body	- assess the impact on the certificates issued by the notified body where there is a change to the notification; and,	
481.	and, within three months after having notified the changes to the notification, shall submit a report on its findings to the Commission and the other Member States.	and, within three months after having notified the changes to the notification, shall submit a report on its findings to the Commission and the other Member States.	- submit a report on its findings to the Commission and the other Member States within three months after having notified the changes to the notification.	
482.	Where necessary to ensure the safety of devices on the market, that authority shall instruct the notified body to suspend or withdraw, within a reasonable period of time determined by the authority, any certificates which were unduly issued. If the notified body fails to do so within the determined period of time, or has ceased its activity, the national authority responsible for notified bodies itself shall suspend or withdraw the certificates unduly issued.	Where necessary to ensure the safety of devices on the market, that authority shall instruct the notified body to suspend or withdraw, within a reasonable period of time determined by the authority, and at the latest 30 days after the publication of the report, any certificates which were unduly issued. If the notified body fails to do so within the determined period of time, or has ceased its activity, the national authority responsible for notified bodies itself shall suspend or withdraw the certificates unduly issued.	- require the notified body to suspend or withdraw, within a reasonable period of time determined by the authority, any certificates which were unduly issued, to ensure the safety of devices on the market.	

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483.		With a view to verifying whether the reasons for the suspension, restriction or withdrawal of the notification have implications for the certificates issued, the national authority responsible shall ask the relevant manufacturers to supply evidence of conformity at notification, and the manufacturers shall have 30 days in which to respond to that request.		
484.			- enter into the electronic system mentioned in Article 43 paragraph 4 all certificates for which it has required suspension or withdrawn.	
485.			- inform the competent authority for in vitro diagnostic medical devices of the Member State where the manufacturer or his authorised representative has his registered place of business through this electronic system referred to in Article 25 of the certificates for which it has required suspension or withdrawal. The competent authority responsible for the manufacturer of the device or his authorised representative shall take the appropriate measures where necessary to avoid a potential risk to the health or safety of patients, users or others.	
486.	5. The certificates, other than those unduly issued, which were issued by the notified body for which the notification has been suspended, restricted or withdrawn shall remain valid in the following circumstances:	5. The certificates, other than those unduly issued, which were issued by the notified body for which the notification has been suspended, restricted or withdrawn shall remain valid in the following circumstances:	5. With the exception of certificates, unduly issued, and where a designation has been suspended, or restricted the certificates shall remain valid in the following circumstances:	

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487.	(a) in the case of suspension of a notification: on condition that, within three months of the suspension, either the competent authority for in vitro diagnostic medical devices of the Member State in which the manufacturer of the device covered by the certificate is established, or another notified body responsible for in vitro diagnostic medical devices confirms in writing that it is assuming the functions of the notified body during the period of suspension;	(a) in the case of suspension of a notification: on condition that, within three months of the suspension, either the competent authority for in vitro diagnostic medical devices of the Member State in which the manufacturer of the device covered by the certificate is established, or another notified body responsible for in vitro diagnostic medical devices confirms in writing that it is assuming the functions of the notified body during the period of suspension;	(a) the national authority responsible for notified bodies has confirmed within one month of the suspension or restriction, that there is no safety issue for certificates affected by the suspension or restriction and the national authority responsible for notified bodies has outlined a timeline and actions anticipated to remedy the suspension or restriction. or:	
488.			(b) The authority responsible for notified bodies has confirmed, that no certificates relevant to the suspension will be issued, amended or re-issued during the course of the suspension/restriction and indicates whether the notified body has the capability of continuing to monitor and remain responsible for existing certificates issued for the period of the suspension or restriction. In case the national authority responsible for notified bodies determines that the notified body does not have the capability to support existing certificates issued, the manufacturer shall provide to the competent authority for devices within three months of the suspension or restriction, the written confirmation that another qualified notified body is temporarily assuming the functions of the notified body to monitor and remain responsible for the certificates during the period of suspension or restriction.	
489.	(b) in the case of restriction or	(b) in the case of restriction or	5a. With the exception of certificates	

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	withdrawal of a notification: for a period of three months after the restriction or withdrawal. The competent authority for in vitro diagnostic medical devices of the Member State in which the manufacturer of the device covered by the certificate is established may extend the validity of the certificates for further periods of three months, which altogether may not exceed twelve months, provided it is assuming the functions of the notified body during this period.	withdrawal of a notification: for a period of three months after the restriction or withdrawal. The competent authority for in vitro diagnostic medical devices of the Member State in which the manufacturer of the device covered by the certificate is established may extend the validity of the certificates for further periods of three months, which altogether may not exceed twelve months, provided it is assuming the functions of the notified body during this period.	unduly issued, and where a notification has been withdrawn, the certificates shall remain valid for a period of nine months in the following circumstances: where the competent authority for in vitro diagnostic medical devices of the Member State in which the manufacturer or the authorised representative of the device covered by the certificate is established has confirmed that there is no safety issue associated with the devices in question, and - another notified body has confirmed in writing that it will assume immediate responsibilities for these products and will have completed assessment of the devices within twelve months, then - the national competent authority of the member state where the manufacturer or authorised representative is established may extend the provisional validity of the certificates for further periods of three months, which altogether may not exceed twelve months.	
490.	The authority or the notified body assuming the functions of the notified body affected by the change of notification shall immediately inform the Commission, the other Member States and the other notified bodies thereof.	The authority or the notified body assuming the functions of the notified body affected by the change of notification shall immediately and within 10 days at the latest, inform the Commission, the other Member States and the other notified bodies thereof.		
491.		The Commission shall immediately and within 10 days at the latest enter information on the changes to the notification of the notified body into the		

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		electronic system referred to in Article 25(2).		
492.	**Article 35 Challenge to the competence of notified bodies**		**Article 35 Challenge to the competence of notified bodies**	
493.	1. The Commission shall investigate all cases where concerns have been brought to its attention regarding the continued fulfilment by a notified body of the requirements set out in Annex VI or the obligations to which it is subject. It may also commence such investigations on its own initiative.	1. The Commission shall investigate all cases where concerns have been brought to its attention regarding the continued fulfilment by a notified body of the requirements set out in Annex VI or the obligations to which it is subject. It may also commence such investigations on its own initiative, including the unannounced inspection of the notified body by a joint assessment team whose composition meets the conditions set out in Article 30(3).	1. The Commission, in conjunction with the MDCG, shall investigate all cases where concerns have been brought to its attention regarding the continued fulfilment by a notified body, or of one or more of its subsidiaries or subcontractors, of the requirements set out in Annex VI or the obligations to which it is subject**.** It shall ensure that the concerned national authority responsible for notified bodies is informed and is given opportunity to investigate these concerns.	
494.	2. The notifying Member State shall provide the Commission, on request, with all information regarding the notification of the notified body concerned.	2. The notifying Member State shall provide the Commission, on request, with all information regarding the notification of the notified body concerned.	2. The notifying Member State shall provide the Commission, on request, with all information regarding the notification of the notified body concerned.	
495.			2a. The Commission in conjunction with the MDCG may initiate, as applicable, the assessment process described in Article 30(3) and (4) when there is reasonable concern about the ongoing compliance of a notified body or a subsidiary or subcontractor of the notified body with the requirements set out in Annex VI and the investigation of the national authority is not deemed to have fully addressed the concerns or upon request of the national authority. The reporting and outcome of this assessment process shall follow the	

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			principles of Article 30(5) and 30(6). Alternatively, depending on the severity of the issue, the Commission in conjunction with the MDCG may request that the national authority responsible for notified bodies allow for participation of up to two experts from the list established pursuant to Article 30a in an on-site assessment as part of the planned monitoring and surveillance activities in accordance with Article 33 and as outlined in the annual plan described in paragraph 3 therein.	
496.	3. Where the Commission ascertains that a notified body no longer meets the requirements for its notification, it shall inform the notifying Member State accordingly and request it to take the necessary corrective measures, including the suspension, restriction or withdrawal of the notification if necessary. Where the Member State fails to take the necessary corrective measures, the Commission may, by means of implementing acts, suspend, restrict or withdraw the notification. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3). It shall notify the Member State concerned of its decision and update the database and list of notified bodies.	3. Where the Commission in consultation with the Medical Devices Coordination Group decides that a notified body no longer meets the requirements for its notification, it shall inform the notifying Member State accordingly and request it to take the necessary corrective measures, including the suspension, restriction or withdrawal of the notification if necessary, in line with Article 34 (2). Where the Member State fails to take the necessary corrective measures, the Commission may, by means of implementing acts, suspend, restrict or withdraw the notification. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3). It shall notify the Member State concerned of its decision and update the database and list of notified bodies.	3. Where the Commission ascertains that a notified body no longer meets the requirements for its notification, it shall inform the notifying Member State accordingly and request it to take the necessary corrective measures, including the suspension, restriction or withdrawal of the designation if necessary. Where the Member State fails to take the necessary corrective measures, the Commission may, by means of implementing acts, suspend, restrict or withdraw the notification. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3). It shall notify the Member State concerned of its decision and update the database and list of notified bodies.	
497.			3a. The Commission shall ensure that all sensitive information obtained in the course of its investigations is treated	

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			confidentially.	
498.	**Article 36 Exchange of experience between national authorities responsible for notified bodies**	**Article 36 Exchange of experience between national authorities responsible for notified bodies**	**Article 36 Peer review and exchange of experience between national authorities responsible for notified bodies**	
499.	The Commission shall provide for the organisation of exchange of experience and coordination of administrative practice between the national authorities responsible for notified bodies under this Regulation.	The Commission shall provide for the organisation of exchange of experience and coordination of administrative practice between the national authorities responsible for notified bodies under this Regulation.	1. The Commission shall provide for the organisation of exchange of experience and coordination of administrative practice between the national authorities responsible for notified bodies under this Regulation. This shall address elements including:	
500.			(a) Development of best practice documents relating to the activities of the national authority responsible for notified bodies; (b) Development of guidance documents for notified bodies in relation to the implementation of this Regulation; (c) Training and qualification of the experts referred to in Article 30a. (d) Monitoring of trends relating to changes to notified body designations and notifications and trends in certificate withdrawals and transfers between notified bodies; (e) Monitoring of the application and applicability of scope codes referred to in Article 31.4a; (f) Development of a mechanism for peer review between authorities and the Commission; (g) Methods of communication to the public on the monitoring and surveillance	

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			activities of authorities and the Commission on notified bodies for in vitro diagnostic medical devices.	
501.			2. The national authorities responsible for notified bodies shall participate in a peer review every third year in accordance with the mechanism agreed in Article 36(1). These reviews shall normally be conducted during on-site joint assessments described in Article 30 but alternatively on a voluntary basis may take place as part of the national authority's monitoring activities in Article 33.	
502.			3. The Commission shall participate in the organisation and implementation of the peer review mechanism, including coordinating peer review. The Commission shall report on the Member States implementation of the requirements in Article 26, taking best practice in the Union into consideration.	
503.			3a. The Commission shall compile a report of the peer review for the national authority being reviewed. The report documenting the outcome of the peer-review shall be communicated to the Member State concerned and, with the consent of the national authority being reviewed, to all other Member States. The Commission shall also compile an annual summary report of the peer review activities which shall be made publicly available.	

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504.			4. The Commission may, by means of implementing acts, adopt measures setting out the modalities and associated documents for the peer review, and training and qualification mechanisms referred to in paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).	
505.	**Article 37 Coordination of notified bodies**	**Article 37 Coordination of notified bodies**	**Article 37 Coordination of notified bodies**	
506.	The Commission shall ensure that appropriate coordination and cooperation between notified bodies is put in place and operated in the form of the coordination group of notified bodies referred to in Article 39 of Regulation [Ref. of future Regulation on medical devices].	The Commission, in consultation with the Medical Devices Coordination Group, shall ensure that appropriate coordination and cooperation between notified bodies is put in place and operated in the form of the coordination group of notified bodies referred to in Article 39 of Regulation [Ref. of future Regulation on medical devices].	The Commission shall ensure that appropriate coordination and cooperation between notified bodies is put in place and operated in the form of a coordination group of notified bodies in the field of medical devices, including in vitro diagnostic medical devices.	
507.		This group shall meet on a regular basis and at least twice a year.		
508.	The bodies notified under this Regulation shall participate in the work of that group.	The bodies notified under this Regulation shall participate in the work of that group. The Commission or the MDCG may request the participation of any notified body.	The bodies notified under this Regulation shall participate in the work of that group.	
509.		The Commission may, by means of implementing acts, adopt measures setting out the modalities for the functioning of the coordination group of		

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		notified bodies as set out in this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).		
510.	Article 38 Fees	Article 38 Fees for the activities of national authorities	Article 82a Funding of notified body designation and monitoring activities	
511.	1. The Member State where the bodies are established shall levy fees on applicant conformity assessment bodies and on notified bodies. These fees shall, wholly or partly, cover the costs relating to the activities exercised by the national authorities responsible for notified bodies in accordance with this Regulation.	1. The Member State where the bodies are established shall levy fees on applicant conformity assessment bodies and on notified bodies. These fees shall, wholly or partly, cover the costs relating to the activities exercised by the national authorities responsible for notified bodies in accordance with this Regulation.	1a. The cost associated with the joint assessment activities shall be covered by the Commission. The Commission shall lay down the scale and structure of recoverable costs and other necessary implementing rules. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).	
512.	2. The Commission shall be empowered to adopt delegated acts in accordance with Article 85 setting out the structure and the level of the fees referred to in paragraph 1,	2. The Commission shall be empowered to adopt delegated acts in accordance with Article 85 setting out the structure and the level of the fees referred to in paragraph 1, These fees shall be proportionate and consistent with national standards of living. The level of fees shall be made public.		
513.	taking into account the objectives of protection of human health and safety, support of innovation and cost-effectiveness. Particular attention shall be paid to the interests of notified bodies that received a certificate delivered by the	3. taking into account the objectives of protection of human health and safety, support of innovation, cost-effectiveness and the need to create a level-playing field across Member States. Particular attention shall be paid to the interests of notified		

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	national accreditation body as referred to in Article 29(2) and notified bodies that are small and medium-sized enterprises as defined by the Commission Recommendation 2003/361/EC.	bodies that submitted a valid certificate delivered by the national accreditation body as referred to in Article 29(2) and notified bodies that are small and mediumsized enterprises as defined by Commission Recommendation 2003/361/EC.		
514.		**Article 38a** **Transparency on fees charged by notified bodies for conformity assessment Activities**		
515.		1. Member States shall adopt regulations on standard fees for notified bodies. 2. Fees shall be comparable across Member States. The Commission shall provide guidelines to facilitate comparability of those fees within 24 months from the date of entry into force of this Regulation. 3. Member States shall transmit their list of standard fees to the Commission. 4. The national authority shall ensure that the notified bodies make the lists of standard fees for the conformity assessment activities publicly available.		
516.	**Chapter V** **Classification and conformity assessment** **SECTION 1 – CLASSIFICATION**	**Chapter III** **Conformity assessment and conformity assessment** **CHAPTER II**	**Chapter V** **Classification and conformity assessment** **Section 1 – Classification**	

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		Classification of in vitro diagnostic medical devices		
517.	**Article 39** **Classification of in vitro diagnostic medical devices**	**Article 39** **Classification of in vitro diagnostic medical devices**	**Article 39** **Classification of in vitro diagnostic medical devices**	
518.	1. Devices shall be divided into class A, B, C and D, taking into account their intended purpose and inherent risks. Classification shall be carried out in accordance with the classification criteria set out in Annex VII.	1. Devices shall be divided into class A, B, C and D, taking into account their intended purpose, novelty, complexity , and inherent risks. Classification shall be carried out in accordance with the classification criteria set out in Annex VII.	1. Devices shall be divided into classes A, B, C and D, taking into account the purpose intended by the manufacturer and inherent risks. Classification shall be carried out in accordance with the classification criteria set out in Annex VII.	No substantial change
519.	2. Any dispute between the manufacturer and the notified body concerned, arising from the application of the classification criteria, shall be referred for a decision to the competent authority of the Member State where the manufacturer has his registered place of business. In cases where the manufacturer has no registered place of business in the Union and has not yet designated an authorised representative, the matter shall be referred to the competent authority of the Member State where the authorised representative referred to in the last indent of point (b) of Section 3.2. of Annex VIII has his registered place of business.	2. Any dispute between the manufacturer and the notified body concerned, arising from the application of the classification criteria, shall be referred for a decision to the competent authority of the Member State where the manufacturer has his registered place of business. In cases where the manufacturer has no registered place of business in the Union and has not yet designated an authorised representative, the matter shall be referred to the competent authority of the Member State where the authorised representative referred to in the last indent of point (b) of Section 3.2. of Annex VIII has his registered place of business.	2. Any dispute between the manufacturer and the notified body concerned, arising from the application of the classification criteria, shall be referred for a decision to the competent authority of the Member State where the manufacturer has his registered place of business. In cases where the manufacturer has no registered place of business in the Union and has not yet designated an authorised representative, the matter shall be referred to the competent authority of the Member State where the authorised representative referred to in the last indent of point (b) of Section 3.2. of Annex VIII has his registered place of business.	No change
520.			Where the notified body concerned is located in a different Member State to the manufacturer, the competent authority shall adopt its decision after consultation with the competent authority of the Member State that designated the notified	**Authority which designated NB becomes more relevant in discussions. Extra consultation – longer classification process. Why is this needed if all authorities will be informed through the**

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			body.	**MDCG?**
521.	At least 14 days prior to any decision, the competent authority shall notify the MDCG and the Commission of its envisaged decision.	At least 14 days prior to any decision, the competent authority shall notify the MDCG and the Commission of its envisaged decision. That decision shall be made publically available in the European databank.	The competent authority of the manufacturer shall notify the MDCG and the Commission of its decision.	**Timeline removed – again longer classification time.**
522.	3. The Commission may, at the request of a Member State or on its own initiative, by means of implementing acts, decide on the application of the classification criteria set out in Annex VII to a given device, or category or group of devices with a view to determining their classification.	3. The Commission may on its own initiative or shall at the request of a Member State or on its own initiative, by means of implementing acts, decide on the application of the classification criteria set out in Annex VII to a given device, or category or group of devices with a view to determining their classification.	3. At a request of a Member State the Commission shall after consulting the MDCG, decide, by means of implementing acts, on the following: (a) application of the classification criteria set out in Annex VII to a given device, or category or group of devices, with a view to determining their classification;	Equivalent text (COM gets right of initiative again in Art 39 3a)
523.		Such a decision shall in particular be taken in order to resolve divergent decisions as regards the classification of devices between Member States.		
524.	Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).	Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).	**Art 39. 3b.** The implementing acts referred to in paragraphs 3 and 3a shall be adopted in accordance with the examination procedure referred to in Article 84(3).	Equivalent text
525.			**Art. 39. 3a.** The Commission may also, on its own initiative and after consulting the MDCG, decide, by means of implementing acts, on the issues referred to in paragraph 3, points (a) and (b).	Commission gets right of initiative
526.	4. In the light of technical progress and any information which becomes available	4. In the light of technical progress and any information which becomes available	4. In order to ensure the uniform application of the classification criteria set	Again confusion between implemented and delegated acts

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	in the course of the vigilance and market surveillance activities described in Articles 59 to 73, the Commission shall be empowered to adopt delegated acts in accordance with Article 85 as regards the following:	in the course of the vigilance and market surveillance activities described in Articles 59 to 73, the Commission , having consulted relevant stakeholders, including healthcare professionals' organisations and manufacturers' associations, shall be empowered to adopt delegated acts in accordance with Article 85 as regards the following:	out in Annex VII, the Commission may adopt implementing acts in accordance with Article 84(3).	(!)
527.	(a) deciding that a device, or category or group of devices, should, by way of derogation from the classification criteria set out in Annex VII, be classified in another class,	(a) deciding that a device, or category or group of devices, should, by way of derogation from the classification criteria set out in Annex VII, be classified in another class,	**Art 39. 3 (b)** that a device, or category or group of devices shall for reasons of public health based on new scientific evidence, or based on any information which becomes available in the course of the vigilance and market surveillance activates by way of derogation from the classification criteria set out in Annex VII, be reclassified.	Equivalent text
528.	(b) amending or supplementing the classification criteria set out in Annex VII.	(b) amending or supplementing the classification criteria set out in Annex VII.		Interestingly classification criteria themselves cannot be changed by the Commission.
529.	**SECTION 2 – CONFORMITY ASSESSMENT**	**SECTION 2 – CONFORMITY ASSESSMENT**	**SECTION 2 – CONFORMITY ASSESSMENT**	
530.	**Article 40 Conformity assessment procedures**	**Article 40 Conformity assessment procedures**	**Article 40 Conformity assessment procedures**	
531.	1. Prior to placing a device on the market, manufacturers shall undertake an assessment of the conformity of that device. The conformity assessment procedures are set out in Annexes VIII to X.	1. Prior to placing a device on the market, manufacturers shall undertake an assessment of the conformity of that device. The conformity assessment procedures are set out in Annexes VIII to X.	1. Prior to placing a device on the market**,** manufacturers shall undertake an assessment of the conformity of that device. The conformity assessment procedures are set out in Annexes VIII to X.	No change

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532.			1a. Prior to putting into service devices that are not placed on the market, with the exception of in-house devices manufactured pursuant to Article 4(5)**,** manufacturers shall undertake an assessment of the conformity of that device. The conformity assessment procedures are set out in Annexes VIII to X.	Explicit call out – prior to putting into service need conformity assessment.
533.	2. Manufacturers of devices classified as class D, other than devices for performance evaluation, shall be subject to a conformity assessment based on full quality assurance, design dossier examination and batch verification, as specified in Annex VIII. Alternatively, the manufacturer may choose to apply a conformity assessment based on type examination as specified in Annex IX, coupled with a conformity assessment based on production quality assurance including batch verification, as specified in Annex X.	2. Manufacturers of devices classified as class D, other than devices for performance evaluation, shall be subject to a conformity assessment based on full quality assurance, design dossier examination and batch verification, as specified in Annex VIII. Alternatively, the manufacturer may choose to apply a conformity assessment based on type examination as specified in Annex IX, coupled with a conformity assessment based on production quality assurance including batch verification, as specified in Annex X.	2. Manufacturers of devices classified as class D, other than devices for performance evaluation, shall be subject to a conformity assessment based on quality management system assurance, and assessment of the technical documentation and batch verification, as specified in Annex VIII. Alternatively, the manufacturer may choose to apply a conformity assessment based on type examination as specified in Annex IX coupled with a conformity assessment based on production quality assurance including batch verification, as specified in Annex X. In addition, where one or more reference laboratories are designated in accordance with Article 78, the notified body performing the conformity assessment shall request one of these reference laboratories to verify by laboratory testing the claimed performance and the compliance of the device with the applicable, when available, or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent, as specified in Section 5.4 of Annex VIII and in Section	**Assessment of technical documentation required for class D (as opposed to design dossier review)** **Reference laboratories to explicitly test devices in class D to verify performance prior to coming to the market.** **CoDx still require consultation with EMA or other medicinal products authority.**

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			3.5 of Annex IX. Laboratory tests performed by a reference laboratory shall in particular focus on analytical sensitivity using reference materials. For companion diagnostics, the notified body shall consult the concerned competent authority designated by Member States in accordance with Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use or the European Medicines Agency (EMA) , as applicable, in accordance with the procedures set out in Section 6.2 of Annex VIII and in Section 3.6 of Annex IX.	
534.	In addition, where a reference laboratory is designated in accordance with Article 78, the notified body performing the conformity assessment shall request that reference laboratory to verify compliance of the device with the applicable CTS, when available, or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent, as specified in Section 5.4 of Annex VIII and in Section 3.5 of Annex IX.	In addition, where a reference laboratory is designated in accordance with Article 78, the notified body performing the conformity assessment shall request that reference laboratory to verify by laboratory testing compliance of the device with the applicable CTS, as specified in Section 5.4 of Annex VIII and in Section 3.5 of Annex IX. Laboratory tests performed by a reference laboratory shall focus on in particular analytic sensitivity and specificity using reference materials and diagnostic sensitivity and specificity using specimens from early and established infection.		
535.	For companion diagnostics intended to be used to assess the patient eligibility for treatment with a specific medicinal product, the notified body shall consult one of the competent authorities designated by	For companion diagnostics intended to be used to assess the patient eligibility for treatment with a specific medicinal product, the notified body shall consult one of the competent authorities designated by		

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	the Member States in accordance with Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use or the European Medicines Agency (EMA) in accordance with the procedures set out in Section 6.2 of Annex VIII and in Section 3.6 of Annex IX.	the Member States in accordance with Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use or the European Medicines Agency (EMA) in accordance with the procedures set out in Section 6.2 of Annex VIII and in Section 3.6 of Annex IX.		
536.	3. Manufacturers of devices classified as class C, other than devices for performance evaluation, shall be subject to a conformity assessment based on full quality assurance, as specified in Annex VIII, with assessment of the design documentation within the technical documentation on a representative basis. Alternatively, the manufacturer may choose to apply a conformity assessment based on type examination, as specified in Annex IX coupled with conformity assessment based on production quality assurance, as specified in Annex X. In addition, for devices for self-testing and near-patient testing, the manufacturer shall fulfil the supplementary requirements set out in Section 6.1 of Annex VIII or in Section 2 of Annex IX. For companion diagnostic intended to be used to assess the patient eligibility to a treatment with a specific medicinal product, the notified body shall consult one of the competent authorities designated by the Member States in accordance with Directive 2001/83/EC or the European	3. Manufacturers of devices classified as class C, other than devices for performance evaluation, shall be subject to a conformity assessment based on full quality assurance, as specified in Annex VIII, with assessment of the design documentation within the technical documentation on a representative basis. Alternatively, the manufacturer may choose to apply a conformity assessment based on type examination, as specified in Annex IX coupled with conformity assessment based on production quality assurance, as specified in Annex X. In addition, for devices for self-testing and near-patient testing, the manufacturer shall fulfil the supplementary requirements set out in Section 6.1 of Annex VIII or in Section 2 of Annex IX. For companion diagnostic intended to be used to assess the patient eligibility to a treatment with a specific medicinal product, the notified body shall consult one of the competent authorities designated by the Member States in accordance with Directive 2001/83/EC or the European	3. Manufacturers of devices classified as class C, other than devices for performance evaluation**,** shall be subject to a conformity assessment based on quality management system assurance as specified in Annex VIII, except for its Chapter II, with assessment of the technical documentation of at least one device representative per generic device group**.** Alternatively, the manufacturer may choose to apply a conformity assessment based on type examination, as specified in Annex IX coupled with a conformity assessment based on production quality assurance, as specified in Annex X. In addition, for devices for self-testing and near-patient testing, the manufacturer shall follow the procedure for technical documentation assessment set out in Section 6.1 of Annex VIII or in Annex IX. In addition, for all companion diagnostics, the notified body shall follow the procedure for technical documentation assessment and shall consult the concerned competent authority designated by the Member States in accordance with	**Requires technical documentation assessment for all self-tests, near patient tests and CoDx in class C.** **Requires technical documentation assessment for representative devices based on generic device group – this is a GMDN concept which is far too detailed for IVDs, thousands of generic device groups!**

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	Medicines Agency (EMA) in accordance with the procedures set out in Section 6.2 of Annex VIII and in Section 3.6 of Annex IX.	Medicines Agency (EMA) in accordance with the procedures set out in Section 6.2 of Annex VIII and in Section 3.6 of Annex IX.	Directive 2001/83/EC or the European Medicines Agency (EMA), as applicable, in accordance with the procedures set out in Section 6.2 of Annex VIII and in Section 3.6 of Annex IX.	
537.	4. Manufacturers of devices classified as class B, other than devices for performance evaluation, shall be subject to a conformity assessment based on full quality assurance, as specified in Annex VIII. In addition, for devices for self-testing and near-patient testing, the manufacturer shall fulfil the supplementary requirements set out in Section 6.1 of Annex VIII.	4. Manufacturers of devices classified as class B, other than devices for performance evaluation, shall be subject to a conformity assessment based on full quality assurance, as specified in Annex VIII. In addition, for devices for self-testing and near-patient testing, the manufacturer shall fulfil the supplementary requirements set out in Section 6.1 of Annex VIII.	4. Manufacturers of devices classified as class B, other than devices for performance evaluation, shall be subject to a conformity assessment based on quality management system assurance**,** as specified in Annex VIII, except for its Chapter II, with assessment of the technical documentation of at least one representative device for each category of devices. In addition, for devices for self-testing and near-patient testing, the manufacturer shall follow the procedure for assessment of the technical documentation set out in Section 6.1 of Annex VIII.	**Includes technical assessment for each category of devices for class B by NB!** **(Good news – IVDs is a device category)**
538.	5. Manufacturers of devices classified as class A, other than devices for performance evaluation, shall declare the conformity of their products by issuing the EU declaration of conformity referred to in Article 15, after drawing up the technical documentation set out in Annex II. However, if the devices are intended for near-patient testing, or if they are placed on the market in sterile condition or have a measuring function, the manufacturer shall apply the procedures set out in Annex VIII or in Annex X. Involvement of the notified body shall be limited:	5. Manufacturers of devices classified as class A, other than devices for performance evaluation, shall declare the conformity of their products by issuing the EU declaration of conformity referred to in Article 15, after drawing up the technical documentation set out in Annex II. However, if the devices are intended for near-patient testing, or if they are placed on the market in sterile condition or have a measuring function, the manufacturer shall apply the procedures set out in Annex VIII or in Annex X. Involvement of the notified body shall be limited:	5. Manufacturers of devices classified as class A, other than devices for performance evaluation, shall declare the conformity of their products by issuing the EU declaration of conformity referred to in Article 15, after drawing up the technical documentation set out in Annex II. However, if the devices are placed on the market in sterile condition, the manufacturer shall apply the procedures set out in Annex VIII or in Annex X. Involvement of the notified body shall be	**Removes requirements for devices with a measuring function (welcome)** **Maintains requirements for assessment by NB for sterile devices (mostly specimen receptacles – remains an issue)**

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	(a) in the case of devices for near-patient testing, to the requirements set out in Section 6.1 of Annex VIII, (b) in the case of devices placed on the market in sterile condition, to the aspects of manufacture concerned with securing and maintaining sterile conditions, (c) in the case of devices with a measuring function, to the aspects of manufacture concerned with the conformity of the devices with the metrological requirements.		limited to the aspects concerned with establishing, securing and maintaining sterile conditions.	
539.	6. Manufacturers may choose to apply a conformity assessment procedure applicable to devices of a higher class than the device in question.	6. Manufacturers may choose to apply a conformity assessment procedure applicable to devices of a higher class than the device in question.		Removed this option
540.	7. Devices for performance evaluation shall be subject to the requirements set out in Articles 48 to 58.	7. Devices for performance evaluation shall be subject to the requirements set out in Articles 48 to 58.	7. Devices intended to be used in l performance evaluation studies, including devices for performance evaluation shall be subject to the requirements set out in Annex XII, and, if applicable, Articles 48 to 58.	(Typo in council text) no substantial change.
541.	8. The Member State in which the notified body is established may determine that all or certain documents, including the technical documentation, audit, assessment and inspection reports, relating to the procedures referred to in paragraphs 1 to 6 shall be available in an official Union language. Otherwise they shall be available in an official Union language acceptable to the notified body.	8. The Member State in which the notified body is established may determine that all or certain documents, including the technical documentation, audit, assessment and inspection reports, relating to the procedures referred to in paragraphs 1 to 6 shall be available in an official Union language. Otherwise they shall be available in an official Union language acceptable to the notified body.	8. The Member State in which the notified body is established may determine that all or certain documents, including the technical documentation, audit, assessment and inspection reports, relating to the procedures referred to in paragraphs 1 to 6 shall be available in an official Union language(s) determined by the Member State concerned. Otherwise they shall be available in an official Union language acceptable to the notified body	**Potentially an issue – technical documentation is available in whatever language the manufacturer uses. Portions of the technical documentation may then be translated upon request of authorities if duly justified.**

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542.	9. The Commission may, by means of implementing acts, specify the modalities and the procedural aspects with a view to ensuring harmonised application of the conformity assessment procedures by the notified bodies, for any of the following aspects: – the frequency and the sampling basis of the assessment of the design documentation within the technical documentation on a representative basis as set out in Sections 3.3.(c) and 4.5 of Annex VIII, in the case of devices classified as class C; – the minimum frequency of unannounced factory inspections and sample checks to be conducted by notified bodies in accordance with Section 4.4 of Annex VIII, taking into account the risk-class and the type of device; – the frequency of samples of the manufactured devices or batches of devices classified as class D to be sent to a reference laboratory designated under Article 78 in accordance with Section 5.7 of Annex VIII and Section 5.1 of Annex X, or – the physical, laboratory or other tests to be carried out by notified bodies in the context of sample checks, design dossier examination and type examination in accordance with Sections 4.4 and 5.3 of Annex VIII and Sections 3.2 and 3.3 of Annex IX.	9. The Commission may, by means of implementing acts, specify the modalities and the procedural aspects with a view to ensuring harmonised application of the conformity assessment procedures by the notified bodies, for any of the following aspects: – the frequency and the sampling basis of the assessment of the design documentation within the technical documentation on a representative basis as set out in Sections 3.3.(c) and 4.5 of Annex VIII, in the case of devices classified as class C; – the minimum frequency of unannounced factory inspections and sample checks to be conducted by notified bodies in accordance with Section 4.4 of Annex VIII, taking into account the risk-class and the type of device; – the frequency of samples of the manufactured devices or batches of devices classified as class D to be sent to a reference laboratory designated under Article 78 in accordance with Section 5.7 of Annex VIII and Section 5.1 of Annex X, or – the physical, laboratory or other tests to be carried out by notified bodies in the context of sample checks, design dossier examination and type examination in accordance with Sections 4.4 and 5.3 of Annex VIII and Sections 3.2 and 3.3 of Annex IX.	9. The Commission may, by means of implementing acts, specify the modalities and the procedural aspects with a view to ensuring harmonised application of the conformity assessment procedures by the notified bodies, for any of the following aspects: – the frequency and the sampling basis of the assessment of the technical documentation on a representative basis as set out in Sections 3.3.(c) and 4.5 of Annex VIII, in the case of devices classified as class C ; – the minimum frequency of unannounced on-site audits and sample checks to be conducted by notified bodies in accordance with Section 4.4 of Annex VIII, taking into account the risk-class and the type of device; – the frequency of samples of the manufactured devices or batches of devices classified as class D to be sent to a reference laboratory designated under Article 78 in accordance with Section 5.7 of Annex VIII and Section 5.1 of Annex X, or – the physical, laboratory or other tests to be carried out by notified bodies in the context of sample checks, assessment of technical documentation and type examination in accordance with Sections 4.4 and 5.3 of Annex VIII and Sections 3.2 and 3.3 of Annex IX. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).	No significant change

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	Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).	Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).		
543.	10. In the light of technical progress and any information which becomes available in the course of the designation or monitoring of notified bodies set out in Articles 26 to 38, or of the vigilance and market surveillance activities described in Articles 59 to 73, the Commission shall be empowered to adopt delegated acts in accordance with Article 85 amending or supplementing the conformity assessment procedures set out in Annexes VIII to X.		10. In the light of technical and scientific progress and any information which becomes available in the course of the designation or monitoring of notified bodies set out in Articles 26 to 38, or of the vigilance and market surveillance activities described in Articles 59 to 73, the Commission shall be empowered to adopt delegated acts in accordance with Article 85 amending or supplementing updating the conformity assessment procedures set out in Annexes VIII to X.	No significant change
544.	**Article 41 Involvement of notified bodies**	**Article 41 Involvement of notified bodies in conformity assessment procedures**	**Article 41 Involvement of notified bodies**	
545.	1. Where the conformity assessment procedure requires the involvement of a notified body, the manufacturer may apply to a notified body of his choice, provided that the body is notified for the conformity assessment activities, the conformity assessment procedures and the devices concerned. An application may not be lodged in parallel with more than one notified body for the same conformity assessment activity.	1. Where the conformity assessment procedure requires the involvement of a notified body, the manufacturer of devices other than those listed in paragraph 1, of Article 41a, may apply to a notified body of his choice, provided that the body is notified for the conformity assessment activities, the conformity assessment procedures and the devices concerned.	1. Where the conformity assessment procedure requires the involvement of a notified body, the manufacturer may apply to a notified body of his choice, provided that the body is notified for the conformity assessment activities**,** the conformity assessment procedures and the devices concerned. An application may not be lodged in parallel with another notified body for the same conformity assessment procedure.	No significant change
546.		Where a manufacturer applies to a notified body located in a Member State other than the one where it is registered, the manufacturer shall inform its national authority responsible for the notified		

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		bodies of the application. An application may not be lodged in parallel with more than one notified body for the same conformity assessment activity.		
547.	2. The notified body concerned shall inform the other notified bodies of any manufacturer who withdraws his application prior to the notified body's decision regarding the conformity assessment.	2. The notified body concerned shall inform the other notified bodies of any manufacturer who withdraws his application prior to the notified body's decision regarding the conformity assessment.	2. The notified body concerned shall inform the other notified bodies of any manufacturer who withdraws his application prior to the notified body's decision regarding the conformity assessment by means of the electronic system referred to in Article 23.	No significant change
548.			2a. Manufacturers shall declare whether they have withdrawn an application with another notified body prior to the decision of that notified body or provide information about any previous application for the same type that has been refused by another notified body.	New requirement – not an issue
549.	3. The notified body may require any information or data from the manufacturer which is necessary in order to properly conduct the chosen conformity assessment procedure.	3. The notified body may require any information or data from the manufacturer which is necessary in order to properly conduct the chosen conformity assessment procedure.	3. The notified body may require any information or data from the manufacturer necessary in order to properly conduct the chosen conformity assessment procedure.	No significant change
550.	4. Notified bodies and the personnel of notified bodies shall carry out their conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgment or the results of their conformity assessment activities, especially as regards persons or groups with an interest	4. Notified bodies and the personnel of notified bodies shall carry out their conformity assessment activities with the highest degree of professional integrity and the requisite technical competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgment or the results of their conformity assessment activities, especially as regards persons or groups with an interest	4. Notified bodies and the personnel of notified bodies shall carry out their conformity assessment activities with the highest degree of professional integrity and the requisite technical and scientific competence in the specific field and shall be free from all pressures and inducements, particularly financial, which might influence their judgement or the results of their conformity assessment activities, especially as regards persons or	No significant change

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	in the results of those activities.	in the results of those activities	groups with an interest in the results of those activities.	
551.		**SECTION 2A (NEW) - ADDITIONAL PROVISIONS FOR THE CONFORMITY ASSESSMENT OF HIGHRISK DEVICES: INVOLVEMENT OF SPECIAL NOTIFIED BODIES**		
552.		**Article 41a Involvement of the Special notified bodies in the conformity assessment procedures of high-risk devices**		
553.		1. Only Special notified bodies (SNB) shall be entitled to conduct conformity assessments for class D devices. 2. Applicant Special notified bodies which consider they fulfil the requirements for Special notified bodies referred to in Annex VI, point 3.6, shall submit their application to the European Medicines Agency (Hereafter, "the Agency"). 3. The application shall be accompanied by the fee payable to the Agency to cover the costs relating to the examination of the application. 4. The Agency shall select the Special notified bodies among applicants, in accordance with requirements listed in Annex VI, and adopt its opinion on the authorisation to perform conformity assessments for devices listed in paragraph 1 within 90 days and send it to		

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		the Commission. 5. The Commission shall then publish the notification accordingly and the names of the Special notified bodies. 6. This notification shall become valid the day after its publication in the database of notified bodies developed and managed by the Commission. The published notification shall determine the scope of lawful activity of the Special notified body. This notification shall be valid for five years and subject to renewal every five years, following a new application to the Agency. 7. The manufacturer of devices specified in paragraph 1 may apply to a Special notified body of his choice, whose name appears in the electronic system of Article 41 b. 8. An application may not be lodged in parallel with more than one Special notified body for the same conformity assessment activity. 9. The Special notified body shall notify the Agency and the Commission of applications for conformity assessments for devices specified in paragraph 1. 10. Article 41, paragraphs 2, 3 and 4 apply to Special notified bodies.		
554.		**Article 41 b**		

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		Electronic system on "Special notified bodies"		
555.		1. The Commission, in collaboration with the Agency, shall establish and regularly update an electronic registration system for: - the registration of applications and granted authorisations to perform conformity assessments as Special notified bodies under this Section and to collate and process information on the name of the Special notified bodies; - the exchange of information with national authorities; - and for the publication of assessment reports; 2. The information collated and processed in the electronic system which relates to Special notified bodies shall be entered into the electronic registration system by the Agency. 3. The information collated and processed In the electronic system and which relates to Special notified bodies shall be accessible to the public.		
556.		**Article 41c** **Network of Special notified bodies**		
557.		11. The Agency shall establish, host, coordinate and manage the network of Special notified bodies. 12. The network shall have the following		

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		objectives: (a) to help realise the potential of European cooperation regarding highly specialised medical technologies in the area of in vitro diagnostic medical devices; (b) to contribute to the pooling of knowledge regarding in vitro diagnostic medical devices; (c) to encourage the development of conformity assessment benchmarks and to help develop and spread best practice within and outside the network; (d) to help identify the experts in innovative fields; (e) to develop and update rules on conflicts of interest; (f) to find common answers to similar challenges concerning the conduct of conformity assessment procedures in innovative technologies; 13. Meetings of the network shall be convened whenever requested by at least two of its members or by the Agency. It shall meet at least twice a year.		
558.	**Article 42** **Mechanism for scrutiny of certain conformity assessments**	**Article 42 a** **Case-by-case assessment procedure for the conformity assessments of certain high-risk devices**	**Article 42** **Mechanism for scrutiny of certain conformity assessments**	
559.	1. Notified bodies shall notify the Commission of applications for conformity assessments for devices classified as class D, with the exception of applications to supplement or renew existing	1. Special notified bodies shall notify the Commission of applications for conformity assessments for Class D devices, with the exception of applications to renew existing certificates. The notification shall be	1. Notified bodies shall notify the competent authorities of certifications they have granted for devices classified as class D, with the exception of applications to supplement or renew existing	Post-market scrutiny model – only if something is found at fault with the NB will action be taken.

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	certificates. The notification shall be accompanied by the draft instructions for use referred to in Section 17.3 of Annex I and the draft summary of safety and performance referred to in Article 24. In its notification the notified body shall indicate the estimated date by which the conformity assessment is to be completed. The Commission shall immediately transmit the notification and the accompanying documents to the MDCG.	accompanied by the draft instructions for use referred to in Section 17.3 of Annex I and the draft summary of safety and clinical performance referred to in Article 24. In its notification the Special notified body shall indicate the estimated date by which the conformity assessment is to be completed. The Commission shall immediately transmit the notification and the accompanying documents to the Coordination Group (CG) of the Assessment Committee for Medical Devices (ACMD), referred to in Article 76a (new). The CG shall immediately transmit the notification and the accompanying documents to the relevant sub-groups.	certificates. Such notification shall take place automatically through the electronic system referred to in Article 25 and shall be accompanied by the instructions for use referred to in Section 17.3 of Annex I, the summary of safety and performance referred to in Article 24, the assessment report by the notified body, and, where applicable, the laboratory tests by the reference laboratory according to Article 40(2) second subparagraph. A competent authority and, where applicable, the Commission may, based on reasonable concerns, apply further procedures according to articles 33, 33a, 34, 35, 67 and, when deemed necessary, take appropriate measures according to Article 68.	Consistent with the fact that there are already multiple layers of checks on class D devices, including testing by reference labs. No exemption for CTS but in this case should not be a problem.
560.	2. Within 28 days of receipt of the information referred to in paragraph 1, the MDCG may request the notified body to submit a summary of the preliminary conformity assessment prior to issuing a certificate. Upon suggestion by any of its members or by the Commission, the MDCG shall decide on making such request in accordance with the procedure set out in Article 78(4) of Regulation [Ref. of future Regulation on medical devices]. In its request the MDCG shall indicate the scientifically valid health reason for having selected the specific file for submission of a summary of the preliminary conformity assessment. When selecting a specific file for submission, the principle of equal treatment shall be duly taken into account.	2. Within 20 days of receipt of the information referred to in paragraph 1, the CG may decide, upon suggestion by at least three of the members of the relevant sub-groups of the ACMD or by the Commission, to request the Special notified body to submit the following documents prior to issuing a certificate: - the summary of the preliminary conformity assessment, - the clinical evidence report and the clinical performance study report as referred to in Annex XII, - data obtained from the post market follow-up referred to in Annex XII, and - any information regarding the marketing or not of the device in third countries and, where available, the results of evaluation		Deleted

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	Within 5 days after receipt of the request by the MDCG, the notified body shall inform the manufacturer thereof.	conducted by competent authorities in those countries.		
561.	3. The MDCG may submit comments on the summary of the preliminary conformity assessment at the latest 60 days after submission of this summary. Within that period and at the latest 30 days after submission, the MDCG may request the submission of additional information that for scientifically valid grounds are necessary for the analysis of the notified body's preliminary conformity assessment. This may include a request for samples or an on-site visit to the manufacturer's premises. Until submission of the additional information requested, the period for comments referred to in the first sentence of this subparagraph shall be suspended. Subsequent requests for additional information from the MDCG shall not suspend the period for the submission of comments.	3. The ACMD, following the consultation of the relevant sub-groups, shall issue an opinion on the documents referred to in paragraph 2 at the latest 60 days after its submission. Within that period and at the latest 30 days after submission, the ACMD may request the submission of additional information that for scientifically valid grounds are necessary for the analysis of the Special notified body's preliminary conformity assessment. This may include a request for samples or an on-site visit to the manufacturer's premises . Until submission of the additional information requested, the period for comments referred to in the first sentence of this paragraph shall be suspended. Subsequent requests for additional information from the ACMD shall not suspend the period for the submission of comments.		Deleted
562.	4. The notified body shall give due consideration to any comments received in accordance with paragraph 3. It shall convey to the Commission an explanation of how they have been taken into consideration, including any due justification for not following the comments received, and its final decision regarding the conformity assessment in question. The Commission shall immediately transmit this information to the MDCG.	4. In its opinion the ACMD may recommend modifications of the documents referred to in paragraph 2. 5. The ACMD shall inform the Commission, the Special notified body and the manufacturer of its opinion within 5 days of its adoption. 6. Within 15 days after receipt of the opinion referred to in paragraph 5, the		Deleted

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		Special notified body shall indicate whether or not it agrees with the opinion of the ACMD. In the latter case, it may give written notice to the ACMD that it wishes to request a re-examination of the opinion. In that case, the Special Notified body shall forward to the ACMD the detailed grounds for the request within 30 days after receipt of the opinion. The ACMD shall immediately transmit this information to the Commission Within 30 days following receipt of the grounds for the request, the ACMD shall re-examine its opinion. The reasons for the conclusion reached shall be annexed to the final opinion. 7. Within 15 days after its adoption, the ACMD shall send its final opinion to the Commission, the Special notified body and the manufacturer. 8. Within 15 days after receipt of the opinion referred to in paragraph 6 in case of agreement by the Special notified body or of the final opinion as referred to in paragraph 7, the Commission shall prepare, on the basis of the opinion, a draft of the decision to be taken in respect of the examined application for conformity assessment. This draft decision shall include or make reference to the opinion referred to in paragraph 6 and 7 as applicable. Where the draft decision is not in accordance with the ACMD opinion, the Commission shall annex a detailed explanation of the reasons for the differences. The draft decision shall be		

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		forwarded to the Member States, the Special notified body and the manufacturer. The Commission shall take a final decision in accordance with, and within 15 days after the end of, the examination procedure referred to in Article 84(3).		
563.	5. Where deemed necessary for the protection of patient safety and public health, the Commission may determine, by means of implementing acts, specific categories or groups of devices, other than devices classified as class D, to which paragraphs 1 to 4 shall apply during a predefined period of time. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3). Measures pursuant to this paragraph may be justified only by one or more of the following criteria:	9. Where deemed necessary for the protection of patient safety and public health, the Commission shall be empowered to adopt delegated acts in accordance with Article 85 to determine, specific categories or groups of devices, other than devices referred to in paragraph 1, to which paragraphs 1 to 8 shall apply during a predefined period of time. Measures pursuant to this paragraph may be justified only by one or more of the criteria referred to in paragraph 2.		Deleted
564.		2. The members of the relevant sub-groups of the ACMD shall decide on making such case-by-case request notably on the basis of the following criteria:		
565.	(a) the novelty of the device or of the technology on which it is based and the significant clinical or public health impact thereof; (b) an adverse change in the risk-benefit profile of a specific category or group of devices due to scientifically valid health concerns in respect of components or source material or in respect of the impact on health in case of failure;	(a) the novelty of the device or of the technology on which it is based and the significant clinical or public health impact thereof; (b) an adverse change in the risk-benefit profile of a specific category or group of devices due to scientifically valid health concerns in respect of components or source material or in respect of the impact on health in case of failure;	(a) the novelty of the device or of the technology on which it is based and the significant clinical or public health impact thereof; (b) an adverse change in the risk-benefit profile of a specific category or group of devices due to scientifically valid health concerns in respect of components or source material or in respect of the impact on health in case of failure;	No change

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	(c) an increased rate of serious incidents reported in accordance with Article 59 in respect of a specific category or group of devices; (d) significant discrepancies in the conformity assessments carried out by different notified bodies on substantially similar devices; (e) public health concerns regarding a specific category or group of devices or the technology on which they are based.	(c) an increased rate of serious incidents reported in accordance with Article 61 in respect of a specific category or group of devices; (d) significant discrepancies in the conformity assessments carried out by different Special notified bodies on substantially similar devices;	(c) an increased rate of serious incidents reported in accordance with Article 59 in respect of a specific category or group of devices; (d) significant discrepancies in the conformity assessments carried out by different notified bodies on substantially similar devices; (e) public health concerns regarding a specific category or group of devices or the technology on which they are based.	
566.		In the light of technical progress and any information which becomes available, the Commission shall be empowered to adopt delegated acts in accordance with Article 89 amending or supplementing these criteria. In its request the ACMD shall indicate the scientifically valid health reason for having selected the specific file. In the absence of request from the ACMD within 20 days of receipt of the information referred to in paragraph 1, the Special notified body shall proceed with the conformity assessment procedure.		
567.	6. The Commission shall make a summary of the comments submitted in accordance with paragraph 3 and the outcome of the conformity assessment procedure accessible to the public. It shall not disclose any personal data or information of commercially confidential nature.	10. The Commission shall make a summary of the opinion referred to in paragraph 6 and 7 accessible to the public. It shall not disclose any personal data or information of commercially confidential nature.	6. The Commission shall make a summary of the comments submitted in accordance with paragraph 3 and the outcome of the conformity assessment procedure accessible to the public. It shall not disclose any personal data or information of commercially confidential nature.	No change
568.	7. The Commission shall set up the technical infrastructure for the data-exchange by an electronic means between	11. The Commission shall set up the technical infrastructure for the data exchange by electronic means between	7. The Commission shall set up the technical infrastructure for the data-exchange by an electronic means between	No change

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	notified bodies and MDCG for the purposes of this Article.	Special notified bodies and the ACMD and between the ACMD and itself for the purposes of this Article.	notified bodies and MDCG for the purposes of this Article.	
569.	8. The Commission, by means of implementing acts, may adopt the modalities and the procedural aspects concerning the submission and analysis of the summary of the preliminary conformity assessment in accordance with paragraphs 2 and 3. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).	12. The Commission, by means of implementing acts, may adopt the modalities and the procedural aspects concerning the submission and analysis of the documentation provided in accordance with this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).	8. The Commission, by means of implementing acts, may adopt the modalities and the procedural aspects concerning the submission and analysis of the summary of the preliminary conformity assessment in accordance with paragraphs 2 and 3. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).	No change
570.		13. Special notified bodies shall notify the Commission of applications for conformity assessment for Class D devices, with the exception of applications to renew existing certificates. The notification shall be accompanied by the draft instructions for use referred to in Section 17.3 of Annex I and the draft summary of safety and clinical performance referred to in Article 24. In its notification the special notified body shall indicate the estimated date by which the conformity assessment is to be completed. The Commission shall immediately transmit the notification and the accompanying documents to the Coordination Group (CG) of the Assessment Committee for Medical Devices (ACMD), referred to in Article 76a. The CG shall immediately transmit the notification and the accompanying documents to the relevant sub-group.		
571.	**Article 43**	**Article 43**	**Article 43**	

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	Certificates	**Certificates**	**Certificates**	
572.	1. The certificates issued by the notified bodies in accordance with Annexes VIII, IX and X shall be in an official Union language determined by the Member State in which the notified body is established or otherwise in an official Union language acceptable to the notified body. The minimum content of the certificates is set out in Annex XI.	1. The certificates issued by the notified bodies in accordance with Annexes VIII, IX and X shall be in an official Union language determined by the Member State in which the notified body is established or otherwise in an official Union language acceptable to the notified body. The minimum content of the certificates is set out in Annex XI.	1. The certificates issued by the notified bodies in accordance with Annexes VIII, IX and X shall be in an official Union language determined by the Member State in which the notified body is established or otherwise in an official Union language acceptable to the notified body**.** The minimum content of the certificates is set out in Annex XI.	No change
573.	2. The certificates shall be valid for the period they indicate, which shall not exceed five years. On application by the manufacturer, the validity of the certificate may be extended for further periods, each not exceeding five years, based on a re-assessment in accordance with the applicable conformity assessment procedures. Any supplement to a certificate shall remain valid as long as the certificate which it supplements is valid.	2. The certificates shall be valid for the period they indicate, which shall not exceed five years. On application by the manufacturer, the validity of the certificate may be extended for further periods, each not exceeding five years, based on a re-assessment in accordance with the applicable conformity assessment procedures. Any supplement to a certificate shall remain valid as long as the certificate which it supplements is valid.	2. The certificates shall be valid for the period they indicate, which shall not exceed five years. On application by the manufacturer, the validity of the certificate may be extended for further periods, each not exceeding five years, based on a re-assessment in accordance with the applicable conformity assessment procedures. Any supplement to a certificate shall remain valid as long as the certificate which it supplements is valid.	No change
574.			2a. Notified bodies may impose restrictions to the intended purpose of a device to certain numbers or groups of patients or require manufacturers to undertake specific post-market performance follow-up studies pursuant to Part B of Annex XII.	NB may require specific restrictions or studies post-market.
575.	3. Where a notified body finds that requirements of this Regulation are no longer met by the manufacturer, it shall, taking account of the principle of proportionality, suspend or withdraw the certificate issued or impose any	3. Where a notified body finds that requirements of this Regulation are no longer met by the manufacturer, it shall, taking account of the principle of proportionality, suspend or withdraw the certificate issued or impose any	3. Where a notified body finds that requirements of this Regulation are no longer met by the manufacturer, it shall, taking account of the principle of proportionality, suspend or withdraw the certificate issued or impose any	No change

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	restrictions on it unless compliance with such requirements is ensured by appropriate corrective measures taken by the manufacturer within an appropriate deadline set by the notified body. The notified body shall give the reasons for its decision.	restrictions on it unless compliance with such requirements is ensured by appropriate corrective measures taken by the manufacturer within an appropriate deadline set by the notified body. The notified body shall give the reasons for its decision.	restrictions on it unless compliance with such requirements is ensured by appropriate corrective action taken by the manufacturer within an appropriate deadline set by the notified body. The notified body shall give the reasons for its decision.	
576.	4. The Commission, in collaboration with the Member States, shall set up and manage an electronic system to collate and process information on certificates issued by notified bodies. The notified body shall enter into the electronic system information regarding certificates issued, including amendments and supplements, and information regarding suspended, reinstated, withdrawn or refused certificates and restrictions imposed on certificates. This information shall be accessible to the public.	4. The Commission, in collaboration with the Member States, shall set up and manage an electronic system to collate and process information on certificates issued by notified bodies. The notified body shall enter into the electronic system information regarding certificates issued, including amendments and supplements, and information regarding suspended, reinstated, withdrawn or refused certificates and restrictions imposed on certificates. This information shall be accessible to the public.	4. The Commission, in collaboration with the Member States, shall set up and manage an electronic system to collate and process information on certificates issued by notified bodies. The notified body shall enter into this electronic system information regarding certificates issued, including amendments and supplements, and regarding suspended, reinstated, withdrawn or refused certificates and restrictions imposed on certificates. This information shall be accessible to the public.	No change
577.	5. In the light of technical progress, the Commission shall be empowered to adopt delegated acts in accordance with Article 85 amending or supplementing the minimum content of the certificates set out in Annex XI.	5. In the light of technical progress, the Commission shall be empowered to adopt delegated acts in accordance with Article 85 amending or supplementing the minimum content of the certificates set out in Annex XI.	5. In the light of technical progress, the Commission shall be empowered to adopt delegated acts in accordance with Article 85 amending or supplementing the minimum content of the certificates set out in Annex XI.	No change
578.	**Article 44** **Voluntary change of notified body**	**Article 44** **Voluntary change of notified body**	**Article 44** **Voluntary change of notified body**	
579.	1. In cases where a manufacturer terminates his contract with a notified body and enters into a contract with another notified body in respect of the conformity assessment of the same device, the modalities of the change of notified body	1. Where a manufacturer decides to terminate his contract with a notified body and enters into a contract with another notified body in respect of the conformity assessment of the same device, it shall inform its national authority responsible for	1. In cases where a manufacturer terminates his contract with a notified body and enters into a contract with another notified body in respect of the conformity assessment of the same device, the modalities of the change of notified body	No significant change

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	shall be clearly defined in an agreement between the manufacturer, the outgoing notified body and the incoming notified body. This agreement shall address at least the following aspects: (a) the date of invalidity of certificates issued by the outgoing notified body; (b) the date until which the identification number of the outgoing notified body may be indicated in the information supplied by the manufacturer, including any promotional material; (c) the transfer of documents, including confidentiality aspects and property rights; (d) the date as of which the incoming notified body assumes full responsibility for the conformity assessment tasks.	the notified bodies of this change, the modalities of the change of notified body shall be clearly defined in an agreement between the manufacturer, the outgoing notified body and the incoming notified body. This agreement shall address at least the following aspects: (a) the date of invalidity of certificates issued by the outgoing notified body; (b) the date until which the identification number of the outgoing notified body may be indicated in the information supplied by the manufacturer, including any promotional material; (c) the transfer of documents, including confidentiality aspects and property rights; (d) the date as of which the incoming notified body assumes full responsibility for the conformity assessment tasks.	shall be clearly defined in an agreement between the manufacturer, the outgoing notified body**,** where practicable, and the incoming notified body. This agreement shall address at least the following aspects: (a) the date of invalidity of certificates issued by the outgoing notified body; (b) the date until which the identification number of the outgoing notified body may be indicated in the information supplied by the manufacturer, including any promotional material; (c) the transfer of documents, including confidentiality aspects and property rights; (e) the date after which the conformity assessment tasks and the full responsibility for the manufacturer's products including products assessed by the outgoing Notified body is assigned to the incoming notified body; (f) the last serial number or batch code/lot number for which the outgoing notified body is responsible.	
580.	2. On their date of invalidity, the outgoing notified body shall withdraw the certificates it has issued for the device concerned.	2. On their date of invalidity, the outgoing notified body shall withdraw the certificates it has issued for the device concerned.	2. On their date of invalidity, the outgoing notified body shall withdraw the certificates it has issued for the device concerned.	No change
581.		**Article 44a** **Additional assessment procedure in extraordinary cases**		
582.		1. Special notified bodies shall notify the Commission applications for conformity assessments for Class D		

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		devices, where no CTS standard exists, with the exception of applications to renew or supplement existing certificates. The notification shall be accompanied by the draft instructions for use referred to in Section 17.3 of Annex I and the draft summary of safety and clinical performance referred to in Article 24. In its notification the Special notified body shall indicate the estimated date by which the conformity assessment is to be completed. The Commission shall immediately transmit the notification and the accompanying documents to the Medical Device Coordination Group (MDCG) for an opinion. In making its opinion, the MDCG may seek a clinical assessment from the relevant experts of the Assessment Committee for Medical Devices (ACMD) referred to in Article 76b.		
583.		2. Within 20 days of receipt of the information referred to in paragraph 1, the MDCG may decide to request the special notifed body to submit the following documents prior to issuing a ceryificate: - The clinical evidence report and the clinical performance study report as referred to in Annex XII, - Data obtained from the post-market follow-up referred to in Annex XII, and - Any information regarding the marketing or not of the device in third countries and, where available, the results of evaluation conducted by comepetent authorities in those countries. The members of the MDCG shall decide		

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		on making such a notably on the basis of the following criteria: (a) the novely of the device with possible major clinical or health impact; (b) an adverse change in the risk-benefit profile of a specific category or group of devices due to scientifically valid health concerns in respect of component or source material or in respect of the impact on health in case of failure; (c) an increased rate of serious incidents is reported in accordance with Article 61 in respect of a specific category or group of devices. In the light of technical progress and any information which becomes available, the Commission shall be empowered to adopt the delegated acts in accordance with Article 89 amending or supplementing these criteria. In its request the MDCG shall indicate the scientifically valid health reason for having selected the specific file. In the absence of a request from the MDCG within 20 days of receipt of the information referred to in paragraph 1, the Special notified body shall proceed with the conformity assessment procedure.		
584.		3. The MDCG, following the consultation of the ACMD shall issue a MDCG opinion on the documents referred to in paragraph 2 at the latest 60 days after its submission. Within that period and at the latest 30 days after submission, the ACMD through the		

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		MDCG may request the submission of additional information that for scientifically valid grounds are necessary for the analysis of the documents referred to in paragraph 2. This may include a request for samples or an on-site visit to the manufacturer's premises. Until submission of the additional information requested, the period for comments referred to in the first sentence of this paragraph shall be suspended. Subsequent requests for additional information from the MDCG shall not suspend the period for the submission of comments.		
585.		4. In its opinion the MDCG shall take into account the clinical assessment of the ACMD. The MDC may recommend modifications of the documents referred to in paragraph 2.		
586.		5. The MDCG shall inform the Commission, the Special notified body and the manufacturer of its opinion.		
587.		6. Within 15 days after receipt of the opinion referred to in paragraph 5, the Special notifed body shall indicate whether or not it agrees with the opinion of the MDCG. In the latter case, it may give written notice to the MDCG that it wishes to request a re-examination of the opinion. In that case, a Special notified body shall forward to the MDCG the detailed grounds for the request within 30 days after receipt of the opinion. The MDCG shall immediately transmit this information the Commission.		

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		Within 30 days following receipt of the grounds for the request, the MDCG shall re-examine its opinion. The reasons for the conclusion reached shall be annexed in the final opinion.		
588.		7. Immediately after its adoption, the MDCG shall send its final opinion to the Commission, the Special notified body and the manufacturer.		
589.		8. In case of a favourable MDCG opinion, the special notified body may proceed with the certification. However if the favourable MDCG opinion is dependent on the application of specific measures (e.g. adaption of the post-market clinical follow-up plan, certification with a time limit), the special notified body shall issue the certificate of conformity only on condition that those measures are fully implemented. Following the adoption of a favourable opinon, the Commission shall always explore the possibility of adopting common technical standards for the device or group of devices concerned and adopt them where possible. In case of an unfavourable MDCG opinion, the special notifed body shall not deliver the certificate of conformity. Nevertheless, the special notified body may submit new information in response to the explanation included in the MDCG assessment. If the new information is substantially different ot that which has been previously submitted, the MDCG shall reassess the application. At the request of the manufacturer, the		

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		Commission shall organise a hearing allowing discussion on the scientifics grounds for the unfavourable scientific assessment and any action that the manufacturer may take or data that may be submitted to address the MDCG concerns.		
590.		9. Where deemed necessary for the protection of patient safety and public health, the Commission shall be empowered to adopt delegated acts in accordance with Article 85 to determine specific categories or groups of devices other than devices referred to in paragraph 1, to which paragraphs 1 to 8 shall apply a predefined period of time. Measures pursuant to this paragraph may be justified only by one or more of the criteria referred to in paragraph 2.		
591.		10. The Commission shall make a summary of the opinion referred to in paragraph 6 and 7 accessible to the public. It shall not disclose any personal data or information of a commercially confidential nature.		
592.		11. The Commission shall set up the technical infrastructure for the data-exchange by electronic means between the MDCG, the Special notified bodies and the ACMD and itself for the purpose of this article.		

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593.		12. The Commission, by means of implementing acts, may adopt the modalities and the procedural aspects concerning the submission and analysis of the documentation provided in accordance with this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).		
594.		13. The company concerned shall not be charged for the additional costs due to this assessment.		
595.	**Article 45** **Derogation from the conformity assessment procedures**	**Article 45** **Derogation from the conformity assessment procedures**	**Article 45** **Derogation from the conformity assessment procedures**	
596.	1. By way of derogation from Article 40, any competent authority may authorise, on duly justified request, the placing on the market or putting into service, within the territory of the Member State concerned, of a specific device for which the procedures referred to in Article 40 have not been carried out and use of which is in the interest of public health or patient safety.	1. By way of derogation from Article 40, any competent authority may authorise, on duly justified request, the placing on the market or putting into service, within the territory of the Member State concerned, of a specific device for which the procedures referred to in Article 40 have not been carried out and use of which is in the interest of public health or patient safety.	1. By way of derogation from Article 40, any competent authority may authorise, justified request**,** the placing on the market or putting into service**,** within the territory of the Member State concerned, of a specific device for which the procedures referred to in Article 40 have not been carried out and use of which is in the interest of public health or patient safety or health.	No significant change
597.	2. The Member State shall inform the Commission and the other Member States of any decision to authorise the placing on the market or putting into service of a device in accordance with paragraph 1 where such authorisation is granted for use other than for a single patient.	2. The Member State shall inform the Commission and the other Member States of any decision to authorise the placing on the market or putting into service of a device in accordance with paragraph 1 where such authorisation is granted for use other than for a single patient.	2. The Member State shall inform the Commission and the other Member States of any decision to authorise the placing on the market or putting into service of a device in accordance with paragraph 1 where such authorisation is granted for use other than for a single patient.	No change

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598.	3. Upon request by a Member State and where this is in the interest of public health or patient safety in more than one Member State, the Commission may, by means of implementing acts, extend for a determined period of time the validity of an authorisation granted by a Member State in accordance with paragraph 1 to the territory of the Union and set the conditions under which the device may be placed on the market or put into service. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3). On duly justified imperative grounds of urgency relating to the health and safety of humans, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 84(4).	3. Upon request by a Member State and where this is in the interest of public health or patient safety in more than one Member State, the Commission may, by means of implementing acts, extend for a determined period of time the validity of an authorisation granted by a Member State in accordance with paragraph 1 to the territory of the Union and set the conditions under which the device may be placed on the market or put into service. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3). On duly justified imperative grounds of urgency relating to the health and safety of humans, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 84(4).	3. Following a notification pursuant to paragraph 2, the Commission, in exceptional cases relating to a public health or patients safety or health, may, by means of implementing acts, extend for a determined period of time the validity of an authorisation granted by a Member State in accordance with paragraph 1 to the territory of the Union and set the conditions under which the device may be placed on the market or put into service. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3). On duly justified imperative grounds of urgency relating to the health and safety of humans, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 84(4).	No significant change
599.	**Article 46** **Certificate of free sale**	**Article 46** **Certificate of free sale**	**Article 46** **Certificate of free sale**	
600.	1. For the purpose of export and upon request by a manufacturer, the Member State in which the manufacturer has its registered place of business shall issue a certificate of free sale declaring that the manufacturer is properly established and that the device in question bearing the CE marking in accordance with this Regulation may be legally marketed in the Union. The certificate of free sale shall be valid for the period indicated on it which shall not exceed five years and shall not exceed the validity of the certificate	1. For the purpose of export and upon request by a manufacturer, the Member State in which the manufacturer has its registered place of business shall issue a certificate of free sale declaring that the manufacturer is properly established and that the device in question bearing the CE marking in accordance with this Regulation may be legally marketed in the Union. The certificate of free sale shall be valid for the period indicated on it which shall not exceed five years and shall not exceed the validity of the certificate	1. For the purpose of export and upon request by a manufacturer or an authorised representative, the Member State in which the manufacturer or the authorised representative has its registered place of business shall issue a certificate of free sale declaring that the manufacturer or the authorised representative, as applicable, is established and that the device in question bearing the CE-marking in accordance with this Regulation may be marketed in the Union. The certificate of free sale shall	**Authorised reps may also request certificates of free sales.**

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	referred to in Article 43 issued for the device in question.	referred to in Article 43 issued for the device in question.	set out the identification of the device in the electronic system set up under Article 25. Where a notified body has issued a certificate referred to in Article 43, the certificate of free sale shall set out the number of the certificate.	
601.	2. The Commission may, by means of implementing acts, establish a model for certificates of free sale taking into account international practice as regards the use of certificates of free sale. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 84(2).	2. The Commission may, by means of implementing acts, establish a model for certificates of free sale taking into account international practice as regards the use of certificates of free sale. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 84(2).	2. The Commission may, by means of implementing acts, establish a model for certificates of free sale taking into account international practice as regards the use of certificates of free sale. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 84(2).	No change
602.	**Chapter VI Clinical evidence**	**Chapter V Clinical evidence**	**Chapter VI Performance evaluation and performance studies**	
603.	**Article 47 General requirements regarding clinical evidence**	**Article 47 General requirements regarding clinical evidence**	**Article 47 Performance evaluation**	**Change from clinical evidence to performance evaluation**
604.	1. The demonstration of conformity with the general safety and performance requirements set out in Annex I, under normal conditions of use, shall be based on clinical evidence.	1. The demonstration of conformity with the general safety and performance requirements set out in Annex I, under normal conditions of use, shall be based on clinical evidence or additional safety data for general safety and performance requirements not covered by clinical evidence.	1. Confirmation of conformity with the requirements, in particular those concerning the performance characteristics referred to in Section I and Section II.6 of Annex I and where applicable relevant requirements of Annex IIa under the normal conditions of the intended use of the device, and the evaluation of the interference(s) and cross-reaction(s) and of the acceptability of the benefit/risk ratio referred to in Sections 1 and 5 of Annex I, shall be based on scientific validity, analytical and	**Performance evaluation (i.e. assessment of data) is always required.** **Manufacturer determines and justifies the level of clinical evidence required.** **Benefit/risk question – what goes into this consideration?**

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			clinical performance data providing sufficient clinical evidence. The manufacturer shall specify and justify the level of the clinical evidence necessary to demonstrate compliance with the relevant essential requirements on safety and performance which shall be appropriate to the characteristics of the device and its intended purpose. To that end, manufacturers shall plan, conduct and document a performance evaluation in accordance with this Article and with Part A of Annex XII.	
605.	2. The clinical evidence shall support the intended purpose of the device as stated by the manufacturer.	2. The clinical evidence shall support the intended purpose of the device as stated by the manufacturer.	2. The clinical evidence shall support the intended purpose of the device as stated by the manufacturer and be based on a continuous process of performance evaluation, following a performance evaluation plan.	**Continuous process – depending on how this is implemented it could be a very high burden.**
606.	3. The clinical evidence shall include all the information supporting the scientific validity of the analyte, the analytical performance and, where applicable, the clinical performance of the device, as described in Section 1 of Part A of Annex XII.	3. The clinical evidence shall include all the information supporting the scientific validity of the analyte, the analytical performance and, where applicable, the clinical performance of the device, as described in Section 1 of Part A of Annex XII.	3. A performance evaluation shall follow a defined and methodologically sound procedure for the demonstration of the following, in accordance with the principles set out in this Article and with Annex XII: (a) scientific validity; (b) analytical performance; (c) clinical performance. The data and conclusions drawn from the assessment of these elements shall constitute the clinical evidence for the device. The clinical evidence shall scientifically demonstrate that the intended	**Reinstates clinical evidence somewhat.** **Problem – concept of clinical benefit (generally clinical benefit are not claimed?)**

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			clinical benefit(s) and safety will be achieved according to the state of the art in medicine. The clinical evidence derived from the performance evaluation shall provide scientifically valid assurance, that the relevant general safety and performance requirements set out in Annex I, under normal conditions of use, are fulfilled.	
607.		3a. Where the manufacturer claims and/or describes a clinical use, evidence attesting to this use shall constitute part of the requirements.		
608.	4. Where demonstration of conformity with the general safety and performance requirements based on clinical performance data or parts thereof is not deemed appropriate, adequate justification for any such exception shall be given based on the results of the manufacturer's risk management and on consideration of the characteristics of the device and, in particular, its intended purpose(s), the intended performance and the claims of the manufacturer. The adequacy of demonstration of conformity with the general safety and performance requirements based on the results of analytical performance evaluation alone shall be duly substantiated in the technical documentation referred to in Annex II.	4. Where demonstration of conformity with the general safety and performance requirements based on clinical performance data or parts thereof is not deemed appropriate, adequate justification for any such exception shall be given based on the results of the manufacturer's risk management and on consideration of the characteristics of the device and, in particular, its intended purpose(s), the intended performance and the claims of the manufacturer. The adequacy of demonstration of conformity with the general safety and performance requirements based on the results of analytical performance evaluation alone shall be duly substantiated in the technical documentation referred to in Annex II.		**Deleted – elements covered elsewhere in the article.**
609.		Exemption from demonstration of conformity with general safety and performance requirements based on clinical data under the first subparagraph		

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		shall be subject to prior approval by the competent authority.		
610.	5. The scientific validity data, the analytical performance data and, where applicable, the clinical performance data shall be summarised as part of a clinical evidence report referred to in Section 3 of Part A of Annex XII. The clinical evidence report shall be included or fully referenced in the technical documentation referred to in Annex II relating to the device concerned.	5. The scientific validity data, the analytical performance data and, where applicable, the clinical performance data shall be summarised as part of a clinical evidence report referred to in Section 3 of Part A of Annex XII. The clinical evidence report shall be included in the technical documentation referred to in Annex II relating to the device concerned.	5. The scientific validity data, the analytical performance data and the clinical performance data and their assessment shall be documented in reports as part of a performance evaluation report referred to in Section 1.4 of Part A of Annex XII, that shall include the clinical evidence derived from it. The performance evaluation report shall be part of the technical documentation referred to in Annex II relating to the device concerned.	**Clinical performance data is always expected.** **Again, performance evaluation report vs clinical evidence report.**
611.	6. The clinical evidence and its documentation shall be updated throughout the life cycle of the device concerned with data obtained from implementation of the manufacturer's post-market surveillance plan referred to in Article 8(6).	6. The clinical evidence and its documentation shall be updated throughout the life cycle of the device concerned with data obtained from implementation of the manufacturer's post-market surveillance plan referred to in Article 8(6).	6. The performance evaluation and its documentation shall be updated throughout the life cycle of the device concerned with data obtained from implementation of the manufacturer's post-market performance follow-up plan, as part of the post-market surveillance plan referred to in Article 8(7).	**Post market follow-up plan introduced as part of performance evaluation.** **Also for all class C and D devices yearly updates to the performance evaluation report.**
612.			The performance evaluation report for devices classified as class C and D shall be updated when necessary, but at least annually with these data. The summary of safety and performance referred to in Article 24(1) shall be updated as soon as possible, where necessary.	
613.	7. The manufacturer shall ensure that the device for performance evaluation complies with the general requirements of this Regulation apart from the aspects covered by the performance evaluation	7. The manufacturer shall ensure that the device for performance evaluation complies with the general requirements of this Regulation apart from the aspects covered by the performance evaluation	7. The manufacturer shall ensure that a device used for performance evaluation complies with the general requirements of this Regulation apart from the aspects covered by the performance	**No significant change**

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	and that, with regard to those aspects, every precaution has been taken to protect the health and safety of the patient, user and other persons.	and that, with regard to those aspects, every precaution has been taken to protect the health and safety of the patient, user and other persons.	evaluation and that, with regard to those aspects, every precaution has been taken to protect the health and safety of the patient, user and other persons.	
614.	The manufacturer shall undertake to keep available to the competent authorities and the EU reference laboratories the documentation allowing an understanding of the design, manufacture and performances of the device, including its expected performance, so as to allow assessment of conformity with the requirements of this Regulation. This documentation shall be kept for at least five years after the performance evaluation of the device in question has ended.	The manufacturer shall undertake to keep available to the competent authorities and the EU reference laboratories the documentation allowing an understanding of the design, manufacture and performances of the device, including its expected performance, so as to allow assessment of conformity with the requirements of this Regulation. This documentation shall be kept for at least five years after the performance evaluation of the device in question has ended.		**Deleted requirements elsewhere**
615.			8. Where necessary to ensure the uniform application of Annex XII the Commission may, having due regard to technical and scientific progress, adopt implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).	**Implementing acts with regards to performance evaluation / clinical evidence (should probably be delegated acts)**
616.	**Article 48 General requirements regarding clinical performance studies**	**Article 48 General requirements regarding clinical performance studies**	**Article 48 General requirements regarding performance studies**	**Rules on article 48 through 58 apply only to interventional or at risk studies – where are the rules for normal studies**
617.	1. Clinical performance studies shall be subject to this Regulation if they are conducted for one or more of the following purposes:	1. Clinical performance studies shall be subject to this Regulation if they are conducted for one or more of the following purposes:	1. Performance studies shall be subject to the provisions of Articles 48 to 58 of this Regulation if they are conducted under for one or more of the following conditions:	

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618.	(a) to verify that, under normal conditions of use, the devices are designed, manufactured and packaged in such a way that they are suitable for one or more of the specific purposes of an in vitro diagnostic medical device referred to in number (2) of Article 2, and achieve the performance intended as specified by the manufacturers;	(a) to verify that, under normal conditions of use, the devices are designed, manufactured and packaged in such a way that they are suitable for one or more of the specific purposes of an in vitro diagnostic medical device referred to in number (2) of Article 2, and achieve the performance intended as specified by the manufacturers or sponsor;	(a) where invasive sample taking is done only for the purpose of the performance study	**Critical – is a normal blood draw covered by this?**
619.	(b) to verify that devices achieve the intended benefits to the patient as specified by the manufacturer;	(b) to verify that devices achieve the intended benefits to the patient as specified by the manufacturer;	(b) where it concerns an interventional clinical performance study as defined in Article 2(37)	**Ok**
620.		to verify the clinical safety and efficacy of the device, including the intended benefits to the patient, when used for the intended purpose, in the target population and in accordance with the instructions of use.		
621.	(c) to determine any limits to the performance of the devices, under normal conditions of use.	(c) to determine any limits to the performance of the devices, under normal conditions of use.	(c) where the conduct of the study involves additional invasive procedures or other risks for the subjects of the studies	**Again – where are normal blood draws in this?**
622.			(d) in case of performance studies involving companion diagnostics.	**Ok**
623.	2. Clinical performance studies shall be performed in circumstances similar to the normal conditions of use of the device.	2. Clinical performance studies shall be performed in circumstances similar to the normal conditions of use of the device.	2. Performance Clinical performance studies shall be performed in circumstances similar to the normal conditions of use of the device.	**No substantial change** **[Typo in Council Text]**
624.	3. Where the sponsor is not established in the Union, he shall ensure that a contact person is established in the Union. That contact person shall be the addressee for	3. Where the sponsor is not established in the Union, he shall ensure that a contact person is established in the Union. That contact person shall be the addressee for	3. Where the sponsor of a performance study is not established in the Union, he that sponsor shall ensure that a natural or legal person is	**Legal rep for sponsors**

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	all communications with the sponsor provided for in this Regulation. Any communication to that contact person shall be considered as communication to the sponsor.	all communications with the sponsor provided for in this Regulation. Any communication to that contact person shall be considered as communication to the sponsor.	established in the Union as its legal representative. Such legal representative shall be responsible for ensuring compliance with the sponsor's obligations pursuant to this Regulation, and shall be the addressee for all communications with the sponsor provided for in this Regulation. Any communication to that legal representative shall be deemed to be a communication to the sponsor.	
625.			Member States may choose not to apply subparagraph above as regards performance studies to be conducted solely on their territory, or on their territory and the territory of a third country, provided that they ensure that the sponsor establishes at least a contact person on their territory in respect of that performance study who shall be the addressee for all communications with the sponsor provided for in this Regulation.	**Derogation for studies in a single member state**
626.	4. All clinical performance studies shall be designed and conducted in a way that the rights, safety and well-being of the subjects participating in such clinical performance studies are protected and that the clinical data generated in the clinical performance study are going to be reliable and robust.	4. All clinical performance studies shall be designed and conducted in a way that the rights, safety and well-being of the subjects participating in such clinical performance studies are protected and that the clinical data generated in the clinical performance study are going to be reliable and robust.	4. All performance studies shall be designed and conducted in a way that the rights, safety, dignity and well-being of the subjects participating in such performance studies are protected and prevail over all other interests and the data generated are going to be scientifically valid, reliable and robust.	**No substantial change**
627.		Such studies shall not be conducted if the risks associated with the investigation are not medically justifiable in terms of the potential benefits of the device.		
628.			Performance studies shall be subject to	**Ethics assessment.**

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			scientific and ethical assessment. The ethical review shall be performed by an ethics committee in accordance with the law of the Member State concerned. Member States shall ensure that the timelines and procedures for the review by the ethics committees are compatible with the timelines and procedures set out in this Regulation for the assessment of the application for authorisation of a performance study.	
629.	5. All clinical performance studies shall be designed, conducted, recorded and reported in accordance with Section 2 of Annex XII.	5. All clinical performance studies shall be designed, conducted, recorded and reported in accordance with Section 2 of Annex XII.	5. All performance studies shall be designed, conducted, recorded and reported in accordance with Section 2 of Annex XII.	**No change**
630.	6. For interventional clinical performance studies, as defined in number (37) of Article 2, and for other clinical performance studies, where the conduct of the study, including specimen collection, involves invasive procedures or other risks for the subjects of the studies, the requirements set out in Articles 49 to 58 and in Annex XIII shall apply, in addition to the obligations laid down in this Article.	6. For interventional clinical performance studies, as defined in number (37) of Article 2, and for other clinical performance studies, where the conduct of the study, including specimen collection, involves invasive procedures or other risks for the subjects of the studies, the requirements set out in Articles 49 to 58 and in Annex XIII shall apply, in addition to the obligations laid down in this Article.		**Deleted as 48-58 all apply only to interventional.**
631.		The Commission shall be empowered to adopt delegated acts in accordance with Article 85 concerning the provision of a list with negligible risks, which allows a derogation to be made from the relevant Article.		
632.			6a. A performance study according to paragraph 1 may be conducted only where all of the following conditions are met:	**Ok**

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633.			(a) the performance study was subject to an authorisation by a Member State(s) concerned, in accordance with this Regulation, unless otherwise stated;	**Ok**
634.			(b) an independent ethics committee, set up according to national law, has issued an opinion on the planned performance study which is not negative and which, in accordance with the law of the Member State concerned, is valid for that entire Member State;	**Ok for interventional**
635.			(c) the sponsor or its legally designated representative or a contact person pursuant to paragraph 3 is established in the Union;	**Ok**
636.			(ca) vulnerable population and subjects are appropriately protected according to relevant national provisions;	**Ok**
637.			(d) the foreseeable risks and inconveniences to the subject are medically justifiable when weighed against the device's potential relevance for the subjects and/or medicine;	**Ok – however how to assess relevance to medicine? Only interventional studies will have relevance to subjects**
638.			(e) the subject or, where the subject is not able to give informed consent, his or her legally designated representative has given informed consent, according to Article 29 of Regulation (EU) no 536/2014 on clinical trials on medicinal products for human use, and repealing directive 2001/20/EC ;	**Ok – for interventional or at risk studies**

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639.			(f) the rights of the subject to physical and mental integrity, to privacy and to the protection of the data concerning him or her in accordance with Directive 95/46/EC are safeguarded;	**Ok**
640.			(h) where appropriate, biological safety testing reflecting the latest scientific knowledge or any other test deemed necessary in the light of the device's intended purpose has been conducted;	**Not relevant for IVDs. No interaction with patients biological safety testing meaningless.**
641.			(i) in case of clinical performance studies, the analytical performance has been demonstrated, taking into consideration the state of the art;	**Ok**
642.			(ia) in case of interventional clinical performance studies, the analytical performance and scientific validity has been demonstrated, taking into consideration the state of the art;	**Not Ok – Interventional studies may be needed to demonstrate scientific validity (e.g. CoDx)**
643.			(j) the technical safety of the device with regard to its use has been proven, taking into consideration the state of the art as well as provisions in the field of occupational safety and accident prevention;	**Ok**
644.			(k) the requirements of Annex XIII are fulfilled.	**Ok**
645.			7. Any subject may, without any resulting detriment, withdraw from the performance study at any time by revoking his or her informed consent. Without prejudice to Directive 95/46/EC, the	**Ok – important that withdrawal does not affect data already gathered.**

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			withdrawal of the informed consent shall not affect the activities already carried out and the use of data obtained based on informed consent before the withdrawal.	
646.			8. The investigator shall be a person, as defined in national law, following a profession which is recognised in the Member State concerned, as qualifying for an investigator because of the necessary scientific knowledge and experience in patient care. Other individuals involved in conducting a performance study shall be suitably qualified by education, training or experience in the relevant medical field and in clinical research methodology, to perform their tasks.	**Medical professionals may not be the ideal investigators for IVD studies.**
647.			9. The facilities where the performance study involving subjects is to be conducted shall be similar to the facilities of the intended use and suitable for the performance study.	**Ok – but may include manufacturer lab if lab is intended use?**
648.			**Article 48b** **Protection of vulnerable subjects; emergency situations**	Under Assessment
649.			In order to specifically protect the rights, safety, dignity and well-being of vulnerable subjects in performance studies, Member States shall take appropriate measures, concerning performance studies (a) on minors, (b) on incapacitated subjects, (c) on pregnant and breastfeeding women,	

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			(d) in emergency situations, and/or (e) on persons in residential care institutions, persons performing mandatory military service, persons deprived of liberty, persons who, due to a judicial decision, cannot take part in performance studies.	
650.			**Article 48c** **Damage compensation**	Under Assessment
651.			1. Member States shall ensure that systems for compensation for any damage suffered by a subject resulting from participation in a performance study conducted on their territory are in place in the form of insurance, a guarantee, or a similar arrangement that is equivalent as regards its purpose and which is appropriate to the nature and the extent of the risk.	
652.			2. The sponsor and the investigator shall make use of the system referred to in paragraph 1 in the form appropriate for the Member State concerned where the performance study is conducted.	
653.	**Article 49** **Application for interventional clinical performance studies and other clinical performance studies involving risks for the subjects of the studies**	**Article 49** **Application for interventional clinical performance studies and other clinical performance studies involving risks for the subjects of the studies**	**Article 49** **Application for interventional performance studies and other performance studies involving risks for the subjects of the studies**	Under Assessment
654.	1. Before making the first application, the sponsor shall procure from the electronic	1. Before making the first application, the sponsor shall procure from the electronic		

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	system referred to in Article 51 a single identification number for a clinical performance study conducted in one site or multiple sites, in one or more than one Member State. The sponsor shall use this single identification number when registering the clinical performance study in accordance with Article 50.	system referred to in Article 51 a single identification number for a clinical performance study conducted in one site or multiple sites, in one or more than one Member State. The sponsor shall use this single identification number when registering the clinical performance study in accordance with Article 50.		
655.	2. The sponsor of a clinical performance study shall submit an application to the Member State(s) in which the study is to be conducted accompanied by the documentation referred to in Annex XIII. Within six days after receipt of the application, the Member State concerned shall notify the sponsor whether the clinical performance study falls within the scope of this Regulation and whether the application is complete.	2. The sponsor of a clinical performance study shall submit an application to the Member State(s) in which the study is to be conducted accompanied by the documentation referred to in Annex XIII. Within 14 days after receipt of the application, the Member State concerned shall notify the sponsor whether the clinical performance study falls within the scope of this Regulation and whether the application is complete.	2. The sponsor of a performance study shall enter and submit by means of the electronic system referred to in Article 51 an application to the Member State(s) in which the study is to be conducted accompanied by the documentation referred to in Chapter I of Annex XII and in Annex XIII. The electronic system referred to in Article 51 shall generate a union wide unique single identification number for this performance study which shall be used for all relevant communication in relation to the performance study concerned. Within ten days after receipt of the application, the Member State concerned shall notify the sponsor whether the performance study falls within the scope of this Regulation and whether the application is complete.	
656.		In case of more than one Member State concerned, where a Member State disagrees with the coordinating Member State on whether the clinical performance study should be approved, on grounds other than intrinsically national, local or ethical concerns, the Member States concerned shall make an attempt to agree on a conclusion. If no conclusion is found,		

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		the commission shall take a decision after having consulted the Member States concerned, and if appropriate, having taken advice from the MDCG.		
657.		In case where the concerned Member States object the clinical performance study for intrinsically national, local or ethical concerns the clinical performance study should not take place in the Member States concerned.		
658.	Where the Member State has not notified the sponsor within the time period referred to in the first subparagraph, the clinical performance study shall be considered as falling within the scope of this Regulation and the application shall be considered complete.	Where the Member State has not notified the sponsor within the time period referred to in the first subparagraph, the clinical performance study shall be considered as falling within the scope of this Regulation and the application shall be considered complete.		
659.	3. Where the Member State finds that the clinical performance study applied for does not fall within the scope of this Regulation or that the application is not complete, it shall inform the sponsor thereof and shall set a maximum of six days for the sponsor to comment or to complete the application.	3. Where the Member State finds that the clinical performance study applied for does not fall within the scope of this Regulation or that the application is not complete, it shall inform the sponsor thereof and shall set a maximum of ten days for the sponsor to comment or to complete the application.	3. Where the Member State finds that the performance study applied for does not fall within the scope of this Regulation or that the application is not complete, it shall inform the sponsor thereof and shall set a maximum of thirty days for the sponsor to comment or to complete the application.	
660.	Where the sponsor has not provided comments nor completed the application within the time-period referred to in the first subparagraph, the application shall be considered as withdrawn.	Where the sponsor has not provided comments nor completed the application within the time-period referred to in the first subparagraph, the application shall be considered as withdrawn.	Where the sponsor has not provided comments nor completed the application within the time-period referred to in the first subparagraph, the application shall be deemed to have lapsed. Where the sponsor considers that the application falls under the scope of the regulation and/or is complete but the competent authority does not agree, the application shall be	

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			considered as rejected. That Member States shall provide for an appeal procedure in respect of such refusal.	
661.	Where the Member State has not notified the sponsor according to paragraph 2 within three days following receipt of the comments or of the completed application, the clinical performance study shall be considered as falling within the scope of this Regulation and the application shall be considered complete.	Where the Member State has not notified the sponsor according to paragraph 2 within seven days following receipt of the comments or of the completed application, the clinical performance study shall be considered as falling within the scope of this Regulation and the application shall be considered complete.	The Member State shall notify the sponsor within five days following receipt of the comments or of the requested additional information, whether the performance study is considered as falling within the scope of this Regulation and the application is complete .	
662.	4. For the purposes of this Chapter, the date on which the sponsor is notified in accordance with paragraph 2 shall be the validation date of the application. Where the sponsor is not notified, the validation date shall be the last day of the time periods referred to in paragraphs 2 and 3.	4. For the purposes of this Chapter, the date on which the sponsor is notified in accordance with paragraph 2 shall be the validation date of the application. Where the sponsor is not notified, the validation date shall be the last day of the time periods referred to in paragraphs 2 and 3.	4. For the purposes of this Chapter, the date on which the sponsor is notified in accordance with paragraphs 2 or 3 shall be the validation date of the application. The concerned Member State may also extend the period referred to in paragraph 2 and 3 each by a further 5 days.	
663.			4a. In the period during which the application is being assessed the Member State may request, additional information from the sponsor. The expiry of the deadline pursuant to the second indent of paragraph 5(b) shall be suspended from the date of the first request until such time as the additional information has been received.	
664.	5. The sponsor may start the clinical performance study in the following circumstances:	5. The sponsor may start the clinical performance study in the following circumstances:	5. The sponsor may start the performance study in the following circumstances:	
665.	(a) in the case of devices for performance evaluation classified as class C or D, as soon as the Member State concerned has	(a) in the case of devices for performance evaluation classified as class C or D, as soon as the Member State concerned has	(a) in the case of performance studies according to Article 48(1)(a) and where the specimen collection does not represent a	

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	notified the sponsor of its approval;	notified the sponsor of its approval;	major clinical risk to the subject of the study, unless otherwise stated by national provisions, immediately after the validation date of application described in paragraph 4, provided that the competent ethics committee in the Member State concerned has issued an opinion which is not negative and which, in accordance with the law of the Member State concerned, is valid for that entire Member State;	
666.	(b) in the case of devices for performance evaluation classified as class A or B immediately after the date of application, provided that the Member State concerned has so decided and that evidence is provided that the rights, safety and well-being of the subjects to the clinical performance study are protected;	(b) in the case of devices for performance evaluation classified as class A or B immediately after the date of application, provided that the Member State concerned has so decided and that evidence is provided that the rights, safety and well-being of the subjects to the clinical performance study are protected;	(b) in case of performance studies according to Article 48(1)(b), (c), (d) and (e) or performance studies other than those referred to in subparagraph (a): - as soon as the Member State concerned has notified the sponsor of its authorisation and provided that the competent ethics committee in the Member State concerned has issued an opinion which is not negative and which, in accordance with the law of the Member State concerned, is valid for that entire Member State; or	
667.	(c) after the expiry of 35 days after the validation date referred to in paragraph 4, unless the Member State concerned has notified the sponsor within that period of its refusal based on considerations of public health, patient safety or public policy.	(c) after the expiry of 60 days after the validation date referred to in paragraph 4, unless the Member State concerned has notified the sponsor within that period of its refusal based on considerations of public health, patient safety or public policy.	**Art. 49 5 (b)** - after the expiry of 45 days after the validation date referred to in paragraph 4, unless the Member State concerned has notified the sponsor within that period of its refusal and provided that the ethics committee in the Member State concerned has issued an opinion which is not negative and which, in accordance with the law of the Member State concerned, is valid for that entire Member State.	
668.		5a. Member States shall ensure that a		

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		clinical performance study is suspended, cancelled or temporarily interrupted if in the light of new facts it would no longer be approved by the competent authority or if it would no longer receive a favourable opinion from the ethics committee.		
669.	6. Member States shall ensure that the persons assessing the application do not have conflicts of interest and that they are independent of the sponsor, the institution of the study site(s) and the investigators involved, as well as free of any other undue influence. Member States shall ensure that the assessment is done jointly by a reasonable number of persons who collectively have the necessary qualifications and experience. In the assessment, the view of at least one person whose primary area of interest is non-scientific shall be taken into account. The view of at least one patient shall be taken into account.	6. Member States shall ensure that the persons assessing the application do not have conflicts of interest and that they are independent of the sponsor, the institution of the study site(s) and the investigators involved, as well as free of any other undue influence. Member States shall ensure that the assessment is done jointly by a reasonable number of persons who collectively have the necessary qualifications and experience. In the assessment, the view of at least one person whose primary area of interest is non-scientific shall be taken into account. The view of at least one patient shall be taken into account.		
670.		6a. Every step in the clinical performance study, from first consideration of the need and justification for the study to the publication of the results, shall be carried out in accordance with recognised ethical principles, such as those laid down in the World Medical Association Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects adopted by the 18th World Medical Assembly in Helsinki in 1964 and last amended by the 59th World Medical Association General Assembly in Seoul in		

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		2008.		
671.		6b. Authorisation by the Member State concerned for conducting a clinical performance study under this Article shall be granted only after examination and approval by an independent ethics committee in accordance with the World Medical Association's Declaration of Helsinki.		
672.		6c. The examination of the Ethics Committee shall cover in particular the medical justification for the study, the consent of the test subjects participating in the clinical performance study following the provision of full information about the clinical performance study and the suitability of the investigators and investigation facilities. The ethics committee shall act in accordance with the respective laws and regulations of the country or countries in which the study is to be conducted and must abide by all relevant international norms and standards. It shall also work with such efficiency as to enable the Member State concerned to comply with the procedural deadlines set out in this Chapter. The ethics committee shall be made up of an appropriate number of members, who together are in possession of the relevant qualifications and experience in order to be able to assess the scientific, medical		

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		and ethical aspects of the clinical investigation under scrutiny. The members of the Ethics Committee assessing the application for a clinical performance study shall be independent from the sponsor, the institution of the performance study site, and the investigators involved, as well as free of any other undue influence. Names, qualifications, and declaration of interest of the assessors of the application shall be made publicly available.		
673.		6d. Member States shall take the necessary measures to establish Ethics Committees in the field of clinical performance studies where such committees do not exist, and to facilitate their work.		
674.		6e. The Commission shall facilitate cooperation of ethics committees and the sharing of best practices on ethical issues including the procedures and principles of ethical assessment. The Commission shall develop guidelines on patient involvement in ethics committees, drawing upon existing good practices.		
675.	7. The Commission shall be empowered to adopt delegated acts in accordance with Article 85 amending or supplementing, in the light of technical progress and global regulatory developments, the requirements for the documentation to be submitted with the application for the	7. The Commission shall be empowered to adopt delegated acts in accordance with Article 85 amending or supplementing, in the light of technical progress and global regulatory developments, the requirements for the documentation to be submitted with the application for the	7. The Commission may adopt implementing acts in accordance with Article 84(3) in order to assure the uniform application of the requirements for the documentation to be submitted with the application for the clinical performance study that is laid down in Chapter I of	

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	clinical performance study that is laid down in Chapter I of Annex XIII.	clinical performance study that is laid down in Chapter I of Annex XIII.	Annex XIII.	
676.		**Article 49a** **Supervision by Member States**	**Article 49a** **Assessment by Member States**	
677.		1. Member States shall appoint inspectors to supervise compliance with this Regulation and shall ensure that those inspectors are adequately qualified and trained.		
678.		2. Inspections shall be conducted under the responsibility of the Member State where the inspection takes place.		
679.		3. Where a Member State intends to carry out an inspection with regard to one or several interventional clinical performance studies which are conducted in more than one Member State, it shall notify its intention to the other Member States concerned, the Commission and the Agency, through the Union portal, and shall inform them of its findings after the inspection.		
680.		4. The MDCG shall coordinate cooperation on inspections between Member States and on inspections conducted by Member States in third countries. 5. Following an inspection, the Member State under whose responsibility the inspection has been conducted shall draw		Under Assessment

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		up an inspection report. That Member State shall make the inspection report available to the sponsor of the relevant clinical trial and shall submit the inspection report through the Union portal to the Union database. When making the inspection report available to the sponsor, the Member State concerned shall ensure that confidentiality is protected. 6. The Commission shall specify the details for the arrangement of the inspection procedures by means of implementing acts in accordance with Article 85.		
681.			1. Member States shall ensure that the persons validating and assessing the application, or deciding on it, do not have conflicts of interest, are independent of the sponsor, the investigators involved and of persons or legal persons financing the performance study, as well as free of any other undue influence.	
682.			2. Member States shall ensure that the assessment is done jointly by a reasonable number of persons who collectively have the necessary qualifications and experience.	
683.			3. Member States shall assess whether the performance study is designed in such a way that potential remaining risks to subjects or third person, after risk minimization, are justified, when weighed against the clinical benefits to be	

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			expected. They shall examine, under consideration of applicable Common Specifications or harmonized standards, in particular: (a) the demonstration of compliance of the device(s) for performance evaluation with the applicable general safety and performance requirements, apart from the aspects covered by the performance study and whether, with regard to these aspects, every precaution has been taken to protect the health and safety of the subjects. This includes, in case of performance studies, the evaluation of the analytical performance, and in case of interventional clinical performance studies, the evaluation of the analytical performance, clinical performance and scientific validity**,** taking into consideration the state of the art; (b) whether the risk-minimisation solutions employed by the sponsor are described in harmonised standards and, in those cases where the sponsor does not use harmonised standards, the equivalence of the level of protection to harmonised standards; (c) the plausibility of the measures planned for the safe installation, putting into service and maintenance of the device for performance evaluation; (d) the reliability and robustness of the data generated in the performance study, taking account of statistical approaches, design of the performance study and methodological aspects (including sample size, and comparator); (da) the requirements of Annex XIII are	

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			met.	
684.			4. Member States may refuse the authorisation of the performance study if: (a) the performance study does not fall within the scope of this Regulation; (b) the application submitted according to Article 49 paragraph 3 remains incomplete; (c) an ethics committee has issued a negative opinion which, in accordance with the law of the Member State concerned, is valid for that entire Member State; (ca) the device or the submitted documents, especially the performance study plan and the investigator's brochure, do not correspond to the state of scientific knowledge**,** and the performance study, in particular, is not suitable to provide evidence for the safety, performance characteristics or benefit of the device on patients, or (d) the requirements of Article 48 are not met, or (e) any assessment according to paragraph 3 is negative.	
685.			**Article 49b** **Conduct of a performance study**	Under Assessment
686.			1. The sponsor and the investigator shall ensure that the performance study is conducted in accordance with the approved performance study plan.	
687.			2. In order to verify that the rights, safety and well-being of subjects are	

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			protected, that the reported data are reliable and robust, and that the conduct of the performance study is in compliance with the requirements of this Regulation, the sponsor shall adequately monitor the conduct of a performance study. The extent and nature of the monitoring shall be determined by the sponsor on the basis of an assessment that takes into consideration all characteristics of the performance study including the following characteristics: (a) the objective and methodology of the performance study and (b) the degree of deviation of the intervention from normal clinical practice.	
688.			3. All performance study information shall be recorded, processed, handled, and stored by the sponsor or investigator, as applicable, in such a way that it can be accurately reported, interpreted and verified while the confidentiality of records and the personal data of the subjects remain protected in accordance with the applicable law on personal data protection.	
689.			4. Appropriate technical and organisational measures shall be implemented to protect information and personal data processed against unauthorised or unlawful access, disclosure, dissemination, alteration, or destruction or accidental loss, in particular where the processing involves the transmission over a network.	
690.			4a. Member States shall inspect on an	

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			appropriate level performance study site(s) to check that performance study are conducted according to the requirements of this Regulation and to the approved investigation plan.	
691.			5. The sponsor shall establish a procedure for emergency situations which enables the immediate identification and, where necessary, an immediate recall of the devices used in the study.	
692.	**Article 50** **Registration of interventional clinical performance studies and other clinical performance studies involving risks for the subjects of the studies**	**Article 50** **Registration of interventional clinical performance studies and other clinical performance studies involving risks for the subjects of the studies**		
693.	1. Before commencing the clinical performance study, the sponsor shall enter in the electronic system referred to in Article 51 the following information regarding the clinical performance study: (a) the single identification number of the clinical performance study; (b) the name and contact details of the sponsor and, if applicable, his contact person established in the Union; (c) the name and contact details of the natural or legal person responsible for the manufacture of the device for performance evaluation, if different from the sponsor; (d) the description of the device for performance evaluation;	1. Before commencing the clinical performance study, the sponsor shall enter in the electronic system referred to in Article 51 the following information regarding the clinical performance study: (a) the single identification number of the clinical performance study; (b) the name and contact details of the sponsor and, if applicable, his contact person established in the Union; (c) the name and contact details of the natural or legal person responsible for the manufacture of the device for performance evaluation, if different from the sponsor; (d) the description of the device for performance evaluation;		

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	(e) the description of the comparator(s), if applicable; (f) the purpose of the clinical performance study; (g) the status of the clinical performance study.	(e) the description of the comparator(s), if applicable; (f) the purpose of the clinical performance study; (g) the status of the clinical performance study.		
694.		(ga) the methodology to be used, the number of subjects involved and the intended result of the study		
695.	2. Within one week of any change occurring in relation to the information referred to in paragraph 1, the sponsor shall update the relevant data in the electronic system referred to in Article 51.	Within one week of any change occurring in relation to the information referred to in paragraph 1, the sponsor shall update the relevant data in the electronic system referred to in Article 51.	**Art 51. 2a.** Within one week of any change occurring in relation to the information referred to in paragraph 1 or in Article 49(2), the sponsor shall update the relevant data in the electronic system referred to in this Article. The Member State concerned shall be notified of the update and the changes to the documents shall be clearly identifiable.	
696.	3. The information shall be accessible to the public, through the electronic system referred to in Article 51, unless, for all or parts of that information, confidentiality of the information is justified on any of the following grounds: (a) protection of personal data in accordance with Regulation (EC) No 45/2001, (b) protection of commercially sensitive information, (c) effective supervision of the conduct of the clinical performance study by the Member State(s) concerned.	2. The information shall be accessible to the public, through the electronic system referred to in Article 51,	**Art. 51. 4.** The information referred to in paragraph 1 shall, except the information referred to in point b, which shall only be accessible to the Member States and the Commission, shall be accessible to the public, through the electronic system referred to in Article 51, unless, for all or parts of that information, confidentiality of the information is justified on any of the following grounds: (a) protection of personal data in accordance with Regulation (EC) No 45/2001, (b) protection of commercially confidential information, especially in the investigators brochure, in particular through taking into account the status of	

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			the conformity assessment for the device, unless there is an overriding public interest in disclosure, (c) effective supervision of the conduct of the clinical performance study by the Member State(s) concerned.	
697.	4. No personal data of subjects participating in the clinical performance study shall be accessible to the public.	3. No personal data of subjects participating in the clinical performance study shall be accessible to the public.	Art. 51 4a. No personal data of subjects participating in interventional clinical performance studies and other performance studies involving risks for the subjects of the studies shall be publicly available.	
698.	**Article 51** **Electronic system on interventional clinical performance studies and other clinical performance studies involving risks for the subjects of the studies**	**Article 51** **Electronic system on interventional clinical performance studies and other clinical performance studies involving risks for the subjects of the studies**	**Article 51** **Electronic system on interventional clinical performance studies and other performance studies involving risks for the subjects of the studies**	Under Assessment
699.	1. The Commission shall, in collaboration with the Member States, set up and manage an electronic system on interventional clinical performance studies and other clinical performance studies involving risks for the subjects of the studies to create the single identification numbers for such clinical performance studies referred to in Article 49(1) and to collate and process the following information: (a) the registration of clinical performance studies in accordance with Article 50; (b) the exchange of information between the Member States and between them and the	1. The Commission shall, in collaboration with the Member States, set up and manage an electronic system on interventional clinical performance studies and other clinical performance studies involving risks for the subjects of the studies to create the single identification numbers for such clinical performance studies referred to in Article 49(1) and to collate and process the following information: (a) the registration of clinical performance studies in accordance with Article 50; (b) the exchange of information between the Member States and between them and the	1. The Commission shall, in collaboration with the Member States, set up, manage and maintain an electronic system on interventional clinical performance studies and other performance studies involving risks for the subjects of the studies: (aa) to create the single identification numbers for such performance studies; (ab) to be used as an entry point for the submission of all applications for performance studies referred to in Article 49(2), 52, 53, 56 and for all other submission of data, or processing of data in this context; (b) for the exchange of information relating to performance studies in	

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	Commission in accordance with Article 54; (c) the information related to clinical performance studies conducted in more than one Member State in case of a single application in accordance with Article 56; (d) the reports on serious adverse events and device deficiencies referred to in Article 57(2) in case of single application in accordance with Article 56.	Commission in accordance with Article 54; (c) the information related to clinical performance studies conducted in more than one Member State in case of a single application in accordance with Article 56; (d) the reports on serious adverse events and device deficiencies referred to in Article 57(2) in case of single application in accordance with Article 56.	accordance with this Regulation between the Member States and between them and the Commission including those according to Article 49 a and 54; (ca) for information by the sponsor according to Article 55; (d) for reporting on serious adverse events and device deficiencies and related updates referred to in Article 57.	
700.		(da) the clinical performance study report and summary submitted by the sponsor in accordance with Article 55(3)		
701.	2. When setting up the electronic system referred in paragraph 1, the Commission shall ensure that it is interoperable with the EU database for clinical trials on medicinal products for human use set up in accordance with Article […] of Regulation (EU) No [Ref. of future Regulation on clinical trials]. With the exception of the information referred to in Article 50, the information collated and processed in the electronic system shall be accessible only to the Member States and to the Commission.	When setting up the electronic system referred in paragraph 1, the Commission shall ensure that it is interoperable with the EU database for clinical trials on medicinal products for human use set up in accordance with Article […] of Regulation (EU) No [Ref. of future Regulation on clinical trials]. With the exception of the information referred to in Article 50 and in points (d) and (da) of Article 51, the information collated and processed in the electronic system shall be accessible only to the Member States and to the Commission. The Commission shall also ensure that healthcare professionals have access to the electronic system.	2. When setting up the electronic system referred in paragraph 1, the Commission shall ensure that it is interoperable with the EU database for clinical trials on medicinal products for human use set up in accordance with Article […] of Regulation (EU) No 536/2014 as concerns performance evaluation studies of companion diagnostics.	
702.		The information referred to in points (d) and (da) of article 51 shall be accessible to the public in accordance with Article 50(3) and (4).		

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703.		2a. Upon a reasoned request, all information on a specific in vitro diagnostic medical device available in the electronic system shall be made accessible to the party requesting it, save where the confidentiality of all or parts of the information is justified in accordance with Article 50(3).		
704.	3. The Commission shall be empowered to adopt delegated acts in accordance with Article 85 determining which other information regarding clinical performance studies collated and processed in the electronic system shall be publicly accessible to allow interoperability with the EU database for clinical trials on medicinal products for human use set up by Regulation (EU) No [Ref. of future Regulation on clinical trials]. Article 50(3) and (4) shall apply.	3. The Commission shall be empowered to adopt delegated acts in accordance with Article 85 determining which other information regarding clinical performance studies collated and processed in the electronic system shall be publicly accessible to allow interoperability with the EU database for clinical trials on medicinal products for human use set up by Regulation (EU) No [Ref. of future Regulation on clinical trials]. Article 50(3) and (4) shall apply.		
705.			4b. The user interface of the electronic system referred to in this Article shall be available in all official languages of the Union.	
706.	**Article 52** **Interventional clinical performance studies and other clinical performance studies involving risks for the subjects of the studies with devices authorised to bear the CE marking**	**Article 52** **Interventional clinical performance studies and other clinical performance studies involving risks for the subjects of the studies with devices authorised to bear the CE marking**	**Article 52** **Interventional clinical performance studies and other performance studies involving risks for the subjects of the studies with devices authorised to bear the CE marking**	Under Assessment
707.	1. Where a clinical performance study is to be conducted to further assess devices which are authorised in accordance with	1. Where a clinical performance study is to be conducted to further assess devices which are authorised in accordance with	1. Where a performance study is to be conducted to further assess devices which are authorised in accordance with	

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	Article 40 to bear the CE marking and within its intended purpose referred to in the relevant conformity assessment procedure, hereinafter referred to as 'post-market follow-up performance study', the sponsor shall notify the Member States concerned at least 30 days prior to their commencement if the study would submit subjects to additionally invasive or burdensome procedures. Articles 48(1) to (5), 50, 53, 54(1) and 55(1), the first subparagraph of Article 55(2) and the relevant provisions of Annexes XII and XIII shall apply.	Article 40 to bear the CE marking and within its intended purpose referred to in the relevant conformity assessment procedure, hereinafter referred to as 'post-market follow-up performance study', the sponsor shall notify the Member States concerned at least 30 days prior to their commencement if the study would submit subjects to additionally invasive or burdensome procedures. Articles 48(1) to (5), 50, 53, 54(1) and 55(1), the first subparagraph of Article 55(2) and the relevant provisions of Annexes XII and XIII shall apply.	Article 40 to bear the CE marking and within its intended purpose referred to in the relevant conformity assessment procedure, hereinafter referred to as 'post-market performance follow-up study', the sponsor shall notify the Member States concerned at least 30 days prior to their commencement if the study would submit subjects to additionally invasive or burdensome procedures. The notification shall be made by means of the electronic system referred to in Article 51. It shall be accompanied by the documentation referred to in Chapter I of Annex XII and in Annex XIII. Article 48 paragraph 6a points (b) to (h) and (k), Articles 53, 54 and 55, Article 57(6) and the relevant provisions of Annexes XII and XIII shall apply.	
708.	2. If the aim of the clinical performance study regarding a device which is authorised in accordance with Article 40 to bear the CE marking is to assess such device for a purpose other than that referred to in the information supplied by the manufacturer in accordance with Section 17 of Annex I and in the relevant conformity assessment procedure, Articles 48 to 58 shall apply.	2. If the aim of the clinical performance study regarding a device which is authorised in accordance with Article 40 to bear the CE marking is to assess such device for a purpose other than that referred to in the information supplied by the manufacturer in accordance with Section 17 of Annex I and in the relevant conformity assessment procedure, Articles 48 to 58 shall apply.	2. If the aim of the performance study regarding a device which is authorised in accordance with Article 40 to bear the CE marking is to assess such device for a purpose other than that referred to in the information supplied by the manufacturer in accordance with Section 17 of Annex I and in the relevant conformity assessment procedure, Articles 48 to 58 shall apply.	
709.	**Article 53** **Substantial modifications to interventional clinical performance studies and other clinical performance studies involving risks for the subjects of the studies**	**Article 53** **Substantial modifications to interventional clinical performance studies and other clinical performance studies involving risks for the subjects of the studies**	**Article 53** **Substantial modifications to interventional clinical performance studies and other performance studies involving risks for the subjects of the studies**	Under Assessment

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710.	1. If the sponsor introduces modifications to a clinical performance study that are likely to have a substantial impact on the safety or rights of the subjects or on the robustness or reliability of the clinical data generated by the study, he shall notify the Member State(s) concerned of the reasons for and the content of those modifications. The notification shall be accompanied by an updated version of the relevant documentation referred to in Annex XIII.	1. If the sponsor introduces modifications to a clinical performance study that are likely to have a substantial impact on the safety or rights of the subjects or on the robustness or reliability of the clinical data generated by the study, he shall notify the Member State(s) concerned of the reasons for and the content of those modifications. The notification shall be accompanied by an updated version of the relevant documentation referred to in Annex XIII.	1. If the sponsor intends to introduces modifications to a performance study that are likely to have a substantial impact on the safety, health or rights of the subjects or on the robustness or reliability of the data generated by the study, he shall notify by means of the electronic system referred to in Article 51 the Member State(s) concerned of the reasons for and the content of those modifications. The notification shall be accompanied by an updated version of the relevant documentation referred to in Annex XIII in which changes shall be clearly identifiable.	
711.	2. The sponsor may implement the modifications referred to in paragraph 1 at the earliest 30 days after notification, unless the Member State concerned has notified the sponsor of its refusal based on considerations of public health, patient safety or public policy.	2. The sponsor may implement the modifications referred to in paragraph 1 at the earliest 30 days after notification, unless the Member State concerned has notified the sponsor of its refusal based on considerations of public health, patient safety or public policy.	2. The sponsor may implement the modifications referred to in paragraph 1 at the earliest 38 days after notification**,** unless the Member State concerned has notified the sponsor of its refusal based on Article 49a paragraph 4 or considerations of public health, subject and user safety or health, of public policy or the ethics committee concerned has issued a negative opinion which is in accordance with the law of that Member State, is valid for that entire Member State.	
712.			3. The Member State(s) concerned may extend the period referred to in paragraph 2 by a further 7 days, for the purpose of consulting with experts.	
713.	**Article 54 Information exchange between Member States on interventional clinical**	**Article 54 Information exchange between Member States on interventional clinical**	**Article 54 Corrective measures to be taken by Member States and information**	Under Assessment

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	performance studies and other clinical performance studies involving risks for the subjects of the studies	**performance studies and other clinical performance studies involving risks for the subjects of the studies**	**exchange between Member States on interventional clinical performance studies and other performance studies involving risks for the subjects of the studies**	
714.			0a. Where a Member State concerned has grounds for considering that the requirements set out in this Regulation are no longer met, it may at least take the following measures on its territory: (a) withdraw or revoke the authorisation of a performance study; (b) suspend, temporary halt or terminate a performance study; (c) require the sponsor to modify any aspect of a performance study.	
715.			0b. Before the Member State concerned takes any of the measures referred to in paragraph 0a it shall, except where immediate action is required, ask the sponsor and/or the investigator for their opinion. That opinion shall be delivered within seven days.	
716.	1. Where a Member State has refused, suspended or terminated a clinical performance study, or has called for a substantial modification or temporary halt of a clinical performance study, or has been notified by the sponsor of the early termination of a clinical performance study on safety grounds, that Member State shall communicate its decision and the grounds therefor to all Member States and the Commission by means of the	1. Where a Member State has refused, suspended or terminated a clinical performance study, or has called for a substantial modification or temporary halt of a clinical performance study, or has been notified by the sponsor of the early termination of a clinical performance study on safety or efficacy grounds, that Member State shall communicate such facts and its decision and the grounds therefor for that decision to all Member States and the	1. Where a Member State has taken a measure referred to in paragraph 0a or has refused, a performance study, or has been notified by the sponsor of the early termination of a performance study on safety grounds, that Member State shall communicate this decision and the grounds therefor to all Member States and the Commission by means of the electronic system referred to in Article 51.	

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	electronic system referred to in Article 51.	Commission by means of the electronic system referred to in Article 51.		
717.	2. Where an application is withdrawn by the sponsor prior to a decision by a Member State that Member State shall inform all the other Member States and the Commission of that fact, by means of the electronic system referred to in Article 51.	2. Where an application is withdrawn by the sponsor prior to a decision by a Member State that Member State shall inform all the other Member States and the Commission of that fact, by means of the electronic system referred to in Article 51.	2. Where an application is withdrawn by the sponsor prior to a decision by a Member State that information shall be available to all the other Member States and the Commission, by means of the electronic system referred to in Article 51.	
718.	**Article 55** **Information by the sponsor in the event of temporary halt or termination of interventional clinical performance studies or of other clinical performance studies involving risks for the subjects of the studies**	**Article 55** **Information by the sponsor in the event of temporary halt or termination of interventional clinical performance studies or of other clinical performance studies involving risks for the subjects of the studies**	**Article 55** **Information by the sponsor in the event of temporary halt or termination of interventional clinical performance studies or of other performance studies involving risks for the subjects of the studies**	Under Assessment
719.	1. If the sponsor has temporarily halted a clinical performance study on safety grounds, he shall inform the Member States concerned within 15 days of the temporary halt.	1. If the sponsor has temporarily halted a clinical performance study on safety or efficacy grounds, he shall inform the Member States concerned within 15 days of the temporary halt.	1. If the sponsor has temporarily halted a performance study or has early terminated a performance study, he shall inform the Member States concerned within 15 days of the temporary halt or early termination, providing a justification. In case the sponsor has temporary halted or early terminated the performance study on safety grounds, he shall inform the Member states concerned thereof within 24 hours.	
720.	2. The sponsor shall notify each Member State concerned of the end of a clinical performance study in relation to that Member State, providing a justification in the event of early termination. That notification shall be made within 15 days from the end of the clinical performance	2. The sponsor shall notify each Member State concerned of the end of a clinical performance study in relation to that Member State, providing a justification in the event of early termination, so that all Member States can inform sponsors conducting similar clinical performance	2. The sponsor shall notify each Member State concerned of the end of a performance study in relation to that Member State. That notification shall be made within 15 days from the end of the performance study in relation to that Member State.	

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	study in relation to that Member State.	studies at the same time within the Union of the results of that clinical performance study. That notification shall be made within 15 days from the end of the clinical performance study in relation to that Member State.		
721.	If the study is conducted in more than one Member State, the sponsor shall notify all Member States concerned of the overall end of the clinical performance study. That notification shall be made within 15 days from the overall end of the clinical performance study.	If the study is conducted in more than one Member State, the sponsor shall notify all Member States concerned of the overall end of the clinical performance study. Information on the reasons for the early termination of the clinical performance study shall also be provided to all Member States, so that all Member States can inform sponsors conducting similar clinical performance studies at the same time within the Union of the results of that the clinical performance study. That notification shall be made within 15 days from the overall end of the clinical performance study.	2a. If the study is conducted in more than one Member State, the sponsor shall notify all Member States concerned of the overall end of the performance study. That notification shall be made within 15 days from the overall end of the performance study.	
722.	3. Within one year from the end of the clinical performance study, the sponsor shall submit to the Member States concerned a summary of the results of the clinical performance study in form of a clinical performance study report referred to in Section 2.3.3 of Part A of Annex XII. Where, for scientific reasons, it is not possible to submit the clinical performance study report within one year, it shall be submitted as soon as it is available. In this case, the clinical performance study protocol referred to in Section 2.3.2 of Part A of Annex XII shall specify when the results of the clinical performance study	3. Irrespective of the outcome of the clinical performance study, within one year from the end of the clinical performance study or from its early termination, the sponsor shall submit to the Member States concerned a summary of the results of the clinical performance study in form of a clinical performance study report referred to in Section 2.3.3 of Part A of Annex XII. It shall be accompanied by a summary presented in terms that are easily understandable to a layperson. Both the report and the summary shall be submitted by the sponsor by means of the electronic system referred to in Article 51.	3. Within one year from the end of the performance study or within three months from the early termination, the sponsor shall submit to the Member States concerned through the electronic system referred to in Article 51 performance study report referred to in Section 2.3.3. of Part A of Annex XII. Where, , it is not possible to submit the clinical performance study report within one year after the completion of the study, it shall be submitted as soon as it is available**.** In this case, the clinical performance study plan referred to in Section 2.3.2. of Part A of Annex XII shall specify when the results of the	

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	are going to be submitted, together with an explanation.	Where, for justified scientific reasons, it is not possible to submit the clinical performance study report within one year, it shall be submitted as soon as it is available. In this case, the clinical performance study protocol referred to in Section 2.3.2 of Part A of Annex XII shall specify when the results of the clinical performance study are going to be submitted, together with a justification.	performance study are going to be submitted, together with an explanation.	
723.		3a. The Commission shall be empowered to adopt delegated acts in accordance with Article 85 in order to define the content and structure of the layperson's summary. The Commission shall be empowered to adopt delegated acts in accordance with Article 85 in order to establish rules for the communication of the clinical performance study report. For cases where the sponsor decides to share raw data on a voluntary basis, the Commission shall produce guidelines for the formatting and sharing of the data.		
724.			4. A summary of the performance study report shall be provided by the sponsor at least within 1 year following the provision of the performance study report according to paragraph 3. the summary of the performance study report shall be written in a way that is readily understood by the intended user of the device.	
725.			5. Submission of information and reports according to paragraphs 1 to 4	

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			shall be accomplished through the electronic system referred to in Article 51. The reports according to paragraphs 3 and 4 shall become publicly accessible through the electronic system, at the latest when the device is CE-marked and before it is placed on the market.	
726.	**Article 56 Interventional clinical performance studies and other clinical performance studies involving risks for the subjects of the studies conducted in more than one Member State**	**Article 56 Interventional clinical performance studies and other clinical performance studies involving risks for the subjects of the studies conducted in more than one Member State**	**Article 56 Interventional clinical performance studies and other performance studies involving risks for the subjects of the studies conducted in more than one Member State**	Under Assessment
727.	1. By means of the electronic system referred to in Article 51, the sponsor of the clinical performance study to be conducted in more than one Member State may submit, for the purpose of Article 49, a single application that, upon receipt, is transmitted electronically to the Member States concerned.	1. By means of the electronic system referred to in Article 51, the sponsor of the clinical performance study to be conducted in more than one Member State may submit, for the purpose of Article 49, a single application that, upon receipt, is transmitted electronically to the Member States concerned.	1. By means of the electronic system referred to in Article 51, the sponsor of the performance study to be conducted in more than one Member State may submit, for the purpose of Article 49, a single application that, upon receipt, is transmitted electronically to the Member States concerned who have voluntarily agreed to that procedure concerning that performance study.	
728.	2. In the single application, the sponsor shall propose one of the Member States concerned as coordinating Member State. If that Member State does not wish to be the coordinating Member State, it shall agree, within six days of submission of the single application, with another Member State concerned that the latter shall be the coordinating Member State. If no other Member State accepts to be the coordinating Member State, the Member	2. Concerned Member States shall agree, within six days of submission of the single application, which Member State shall be the coordinating Member State. Member States and the Commission shall agree, in the framework of the attributions of the Medical Devices Coordination Group, on clear rules for designating the coordinating Member State.	2. In the single application, the sponsor shall propose one of the Member States concerned as coordinating Member State. If that Member State does not wish to be the coordinating Member State, it Concerned Member States shall agree, within six days of submission of the single application, agree on one of them taking the role of with another Member State concerned that the latter shall be the coordinating Member State. If they do not	

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	State proposed by the sponsor shall be the coordinating Member State. If another Member State than the one proposed by the sponsor becomes coordinating Member State, the deadlines referred to in Article 49(2) shall start on the day following the acceptance.		agree on a coordinating Member State, the one proposed by the sponsor shall take that role. The deadlines referred to in Article 49 shall start on the day following the notification of the coordinating Member State to the sponsor (notification date).	
729.	3. Under the direction of the coordinating Member State referred to in paragraph 2, the Member States concerned shall coordinate their assessment of the application, in particular of the documentation submitted in accordance with Chapter I of Annex XIII, except for Sections 4.2, 4.3 and 4.4 thereof which shall be assessed separately by each Member State concerned.	3. Under the direction of the coordinating Member State referred to in paragraph 2, the Member States concerned shall coordinate their assessment of the application, in particular of the documentation submitted in accordance with Chapter I of Annex XIII, except for Sections 4.2, 4.3 and 4.4 thereof which shall be assessed separately by each Member State concerned.	3. Under the direction of the coordinating Member State referred to in paragraph 2, the Member States concerned shall coordinate their assessment of the application, in particular of the documentation submitted in accordance with Chapter I of Annex XIII, except for Sections 1.11a., 4.2, 4.3 and 4.4 and Section 2.3.2.(c) of Part A of Annex XII thereof which shall be assessed separately by each Member State concerned.	
730.	The coordinating Member State shall: (a) within 6 days of receipt of the single application notify the sponsor whether the clinical performance study falls within the scope of this Regulation and whether the application is complete, except for the documentation submitted in accordance with Sections 4.2, 4.3 and 4.4 of Chapter I of Annex XIII for which each Member State shall verify the completeness. Article 49(2) to (4) shall apply to the coordinating Member State in relation to the verification that the clinical performance study falls	The coordinating Member State shall: (a) within 6 days of receipt of the single application notify the sponsor whether the clinical performance study falls within the scope of this Regulation and whether the application is complete, except for the documentation submitted in accordance with Sections 4.2, 4.3 and 4.4 of Chapter I of Annex XIII for which each Member State shall verify the completeness. Article 49(2) to (4) shall apply to the coordinating Member State in relation to the verification that the clinical performance study falls	The coordinating Member State shall: (aa) within 6 days of receipt of the single application notify the sponsor that it is the coordinating Member State (notification date); (a) within 10 days of receipt of the single application notify the sponsor whether the performance study falls within the scope of this Regulation and whether the application is complete, except for the documentation submitted in accordance with Sections 1.11a ., 4.2, 4.3 and 4.4 of Chapter I of Annex XIII and Section 2.3.2.(c) of Part A of Annex XII for which each Member State shall verify the completeness. Article 49(2) to (4) shall apply to the	

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	within the scope of this Regulation and that the application is complete, except for the documentation submitted in accordance with Sections 4.2, 4.3 and 4.4 of Chapter I of Annex XIII. Article 49(2) to (4) shall apply to each Member State in relation to the verification that the documentation submitted in accordance with Sections 4.2, 4.3 and 4.4 of Chapter I of Annex XIII is complete;	within the scope of this Regulation and that the application is complete, except for the documentation submitted in accordance with Sections 4.2, 4.3 and 4.4 of Chapter I of Annex XIII. Article 49(2) to (4) shall apply to each Member State in relation to the verification that the documentation submitted in accordance with Sections 4.2, 4.3 and 4.4 of Chapter I of Annex XIII is complete;	coordinating Member State in relation to the verification that the performance study falls within the scope of this Regulation and that the application is complete, having taken into account considerations expressed by the other Member States concerned, except for the documentation submitted in accordance with Sections 1.11a ., 4.2, 4.3 and 4.4 of Chapter I of Annex XIII and Section 2.3.2.(c) of Part A of Annex XII. Concerned Member States may communicate to the coordinating Member State any considerations relevant to the validation of the application within seven days from the notification date. Article 49(2) to (4) shall apply to each Member State in relation to the verification that the documentation submitted in accordance with Sections 1.11a ., 4.2, 4.3 and 4.4 of Chapter I of Annex XIII and Section 2.3.2.(c) of Part A of Annex XII is complete;	
731.	(b) establish the results of the coordinated assessment in a report to be taken into account by the other Member States concerned when deciding on the sponsor's application in accordance with Article 49(5).	(c) establish the results of the coordinated assessment in a report to be taken into account by the other Member States concerned when deciding on the sponsor's application in accordance with Article 49(5).		
732.			(c) establish the results of its assessment in a draft assessment report to be transmitted within 26 days after the validation date to the concerned Member States. Until day 38 after the validation	

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			date the other concerned Member States shall transmit their comments and proposals on the draft assessment report and the underlying application to the coordinating Member State, which shall take due account of it in the finalization of the final assessment report, to be transmitted within 45 days following the validation date to the sponsor and the concerned Member States. The final assessment report shall be taken into account by the other Member States concerned when deciding on the sponsor's application in accordance with Article 49 (5), except for Sections 1.11a .,4.2, 4.3 and 4.4 of Chapter I of Annex XIII and Section 2.3.2.(c) of Part A of Annex XII, which shall be assessed separately by each Member State concerned. As concerns the assessment of the documentation related to Sections 1.11a ., 4.2, 4.3 and 4.4 of Chapter I of Annex XIII and Section 2.3.2.(c) of Part A of Annex XII, done separately by each Member State, the Member State may request, on a single occasion, additional information from the sponsor. The expiry of the deadline pursuant paragraph 2 shall be suspended from the date of the request until such time as the additional information has been received.	
733.			3a. The coordinating Member State may also extend the periods referred to in paragraph 3 by a further 50 days, for the purpose of consulting with experts. In such case, the periods referred to in paragraphs	

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			3 of this Article shall apply mutatis mutandis.	
734.			3aa. The Commission may, by means of implementing acts, set out the procedures and timescales for a coordinated assessment led by the coordinating Member State, that shall be taken into account by concerned Member States when deciding on the sponsor's application notification. Such implementing acts may also cover the procedures for coordinated assessment in the case of substantial modifications pursuant to paragraph 4 and in the case of reporting of events pursuant to Article 57(4) or in the case of clinical investigations of combination products between medical devices and medicinal products, where the latter are under a concurrent coordinated assessment of a clinical trial under Regulation (EU) 536/2014. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 88(3).	
735.			3b. Where the conclusion of the coordinating Member State is that the conduct of the performance study is acceptable or acceptable subject to compliance with specific conditions, that conclusion shall be deemed to be the conclusion of the Member State(s) concerned. Notwithstanding the previous subparagraph, a Member State concerned may disagree with the conclusion of the	

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			coordinating Member State concerning the area of joint assessment only on the following grounds: (a) when it considers that participation in the performance study would lead to a subject receiving an inferior treatment than in normal clinical practice in the Member State concerned; (b) infringement of national law; (c) considerations as regards subject safety and data reliability and robustness submitted under paragraph 3 point (b). Where a Member State concerned disagrees with the conclusion, it shall communicate its disagreement, together with a detailed justification, through the electronic system referred to in Article 51 to the Commission, to all Member States concerned, and to the sponsor.	
736.			3c. A Member State concerned shall refuse to authorise a performance study if it disagrees with the conclusion of the coordinating Member State as regards any of the grounds referred to in the second subparagraph of paragraph 3b, or if it finds, on duly justified grounds, that the aspects addressed in Sections 1.11a ., 4.2, 4.3 and 4.4 of Chapter I of Annex XIII are not complied with, or where an Ethics committee has issued a negative opinion which in accordance with the law of the Member State concerned is valid for that entire Member State. That Member State shall provide for an appeal procedure in respect of such refusal.	
737.			3ca. Each Member State concerned	

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			shall notify the sponsor through the electronic system referred to in Article 51 as to whether the performance study is authorised, whether it is authorised subject to conditions, or whether authorisation is refused. Notification shall be done by way of one single decision within five days from the reporting date. An authorisation of a performance study subject to conditions is restricted to conditions which by their nature cannot be fulfilled at the time of that authorisation.	
738.			3d. Where the conclusion of the coordinating Member State report is that the clinical performance study is not acceptable, that conclusion shall be deemed to be the conclusion of all Member States concerned.	
739.	4. The substantial modifications referred to in Article 53 shall be notified to the Member States concerned by means of the electronic system referred to in Article 51. Any assessment as to whether there are grounds for refusal as referred to in Article 53 shall be carried out under the direction of the coordinating Member State.	4. The substantial modifications referred to in Article 53 shall be notified to the Member States concerned by means of the electronic system referred to in Article 51. Any assessment as to whether there are grounds for refusal as referred to in Article 53 shall be carried out under the direction of the coordinating Member State.	4. The substantial modifications as referred to in Article 53 shall be notified to the Member States concerned by means of the electronic system referred to in Article 51. Any assessment as to whether there are grounds for refusal as referred to in paragraph 3b shall be carried out under the direction of the coordinating Member State, except for substantial modifications concerning sections 1.11a ., 4.2, 4.3 and 4.4 of Chapter I of Annex XIII and Section 2.3.2.(c) of Part A of Annex XII, which shall be assessed by each concerned Member State on its own.	
740.	5. For the purpose of Article 55(3), the sponsor shall submit the clinical performance study report to the Member	5. For the purpose of Article 55(3), the sponsor shall submit the clinical performance study report to the Member	5. For the purpose of Article 55(3), the sponsor shall submit the performance study report to the Member States	

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	States concerned by means of the electronic system referred to in Article 51.	States concerned by means of the electronic system referred to in Article 51.	concerned by means of the electronic system referred to in Article 51.	
741.	6. The Commission shall provide secretarial support to the coordinating Member State in the accomplishment of its tasks provided for in this Chapter.	6. The Commission shall provide secretarial support to the coordinating Member State in the accomplishment of its tasks provided for in this Chapter.	6. The Commission shall provide administrative support to the coordinating Member State in the accomplishment of its tasks provided for in this Chapter.	
742.			**Article 56a** **Review of performance studies rules**	Under Assessment
743.			Five years after the date referred to in the first paragraph of Article 90, the Commission shall make a report on the application of Article 58 of the present Regulation and propose a review of the provision of Article 56 in order to ensure a coordinated assessment procedure of performance study conducted in more than one Member State.	
744.	**Article 57** **Recording and reporting of events occurring during interventional clinical performance studies and other clinical performance studies involving risks for the subjects of the studies**	**Article 57** **Recording and reporting of events occurring during interventional clinical performance studies and other clinical performance studies involving risks for the subjects of the studies**	**Article 57** **Recording and reporting of events occurring during interventional clinical performance studies and other performance studies involving risks for the subjects of the studies**	Under Assessment
745.	1. The sponsor shall fully record any of the following: (a) an adverse event identified in the clinical performance study protocol as critical to the evaluation of the results of the clinical performance study in view of the purposes referred to in Article 48(1);	1. The sponsor shall fully record any of the following: (a) an adverse event identified in the clinical performance study protocol as critical to the evaluation of the results of the clinical performance study in view of the purposes referred to in Article 48(1);	1. The sponsor shall fully record any of the following: (a) an adverse event identified in the performance study as critical to the evaluation of the results of the performance study according to the clinical performance study plan; (b) a serious adverse event;	

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	(b) a serious adverse event; (c) a device deficiency that might have led to a serious adverse event if suitable action had not been taken, intervention had not occurred, or circumstances had been less fortunate; (d) new findings in relation to any event referred to in points (a) to (c).	(b) a serious adverse event; (c) a device deficiency that might have led to a serious adverse event if suitable action had not been taken, intervention had not occurred, or circumstances had been less fortunate; (d) new findings in relation to any event referred to in points (a) to (c).	(c) a device deficiency that might have led to a serious adverse event if suitable action had not been taken, intervention had not occurred, or circumstances had been less fortunate; (d) new findings in relation to any event referred to in points (a) to (c).	
746.	2. The sponsor shall report to all Member States where a clinical performance study is conducted without delay any of the following: (a) a serious adverse event that has a causal relationship with the device for performance evaluation, the comparator or the study procedure or where such causal relationship is reasonably possible; (b) a device deficiency that might have led to a serious adverse event if suitable action had not been taken, intervention had not occurred, or circumstances had been less fortunate; (c) new findings in relation to any event referred to in points (a) to (b). The time period for reporting shall take account of the severity of the event. Where necessary to ensure timely reporting, the sponsor may submit an initial incomplete report followed up by a complete report.	2. The sponsor shall report to all Member States where a clinical performance study is conducted without delay any of the following: (a) any adverse event that has a causal relationship with the device for performance evaluation, the comparator or the study procedure or where such causal relationship is reasonably possible; (b) a device deficiency that might have led to a serious adverse event if suitable action had not been taken, intervention had not occurred, or circumstances had been less fortunate; (c) new findings in relation to any event referred to in points (a) to (b). The time period for reporting shall take account of the severity of the event. Where necessary to ensure timely reporting, the sponsor may submit an initial incomplete report followed up by a complete report.	2. The sponsor by means of the electronic system referred to in Article 51 shall report to all Member States where a performance study is conducted without delay any of the following: (a) a serious adverse event that has a causal relationship with the device, the comparator or the study procedure or where such causal relationship is reasonably possible; (b) a device deficiency that might have led to a serious adverse event if suitable action had not been taken, intervention had not occurred, or circumstances had been less fortunate; (c) new findings in relation to any event referred to in points (a) to (b). The time period for reporting shall take account of the severity of the event. Where necessary to ensure timely reporting, the sponsor may submit an initial incomplete report followed up by a complete report.	
747.	3. The sponsor shall also report to the	3. The sponsor shall also report to the	3. The sponsor shall also report to	

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	Member States concerned any event referred to in paragraph 2 occurring in third countries in which a clinical performance study is performed under the same clinical performance study protocol as the one applying to a clinical performance study covered by this Regulation.	Member States concerned any event referred to in paragraph 2 occurring in third countries in which a clinical performance study is performed under the same clinical performance study protocol as the one applying to a clinical performance study covered by this Regulation.	the Member States concerned any event referred to in paragraph 2 occurring in third countries in which a performance study is performed under the same performance study plan as the one applying to a performance study covered by this Regulation by means of the electronic system referred to in Article 51.	
748.	4. In the case of a clinical performance study for which the sponsor has used the single application referred to in Article 56, the sponsor shall report any event as referred to in paragraph 2 by means of the electronic system referred to in Article 51. Upon receipt, this report shall be transmitted electronically to all Member States concerned. Under the direction of the coordinating Member State referred to in Article 56(2), the Member States shall coordinate their assessment of serious adverse events and device deficiencies to determine whether a clinical performance study needs to be terminated, suspended, temporarily halted or modified. This paragraph shall not affect the rights of the other Member States to perform their own evaluation and to adopt measures in accordance with this Regulation in order to ensure the protection of public health and patient safety. The coordinating Member State and the Commission shall be kept informed of the outcome of any such evaluation and the adoption of any such measures.	4. In the case of a clinical performance study for which the sponsor has used the single application referred to in Article 56, the sponsor shall report any event as referred to in paragraph 2 by means of the electronic system referred to in Article 51. Upon receipt, this report shall be transmitted electronically to all Member States concerned. Under the direction of the coordinating Member State referred to in Article 56(2), the Member States shall coordinate their assessment of serious adverse events and device deficiencies to determine whether a clinical performance study needs to be terminated, suspended, temporarily halted or modified. This paragraph shall not affect the rights of the other Member States to perform their own evaluation and to adopt measures in accordance with this Regulation in order to ensure the protection of public health and patient safety. The coordinating Member State and the Commission shall be kept informed of the outcome of any such evaluation and the adoption of any such measures.	4. In the case of a performance study for which the sponsor has used the single application referred to in Article 56, the sponsor shall report any event as referred to in paragraph 2 by means of the electronic system referred to in Article 51. Upon receipt, this report shall be transmitted electronically to all Member States concerned. Under the direction of the coordinating Member State referred to in Article 56(2), the Member States shall coordinate their assessment of serious adverse events and device deficiencies to determine whether a performance study needs to be terminated, suspended, temporarily halted or modified. This paragraph shall not affect the rights of the other Member States to perform their own evaluation and to adopt measures in accordance with this Regulation in order to ensure the protection of public health and patient safety. The coordinating Member State and the Commission shall be kept informed of the outcome of any such evaluation and the adoption of any such measures.	

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749.	5. In the case of post-market follow-up performance studies referred to in Article 52(1), the provisions on vigilance contained in Articles 59 to 64 shall apply instead of this Article.	5. In the case of post-market follow-up performance studies referred to in Article 52(1), the provisions on vigilance contained in Articles 59 to 64 shall apply instead of this Article.	5. In the case of post-market performance follow-up studies referred to in Article 52(1), the provisions on vigilance contained in Articles 59 to 64 shall apply instead of this Article.	
750.			6. Notwithstanding paragraph 5**,** this Article shall however apply where a causal relationship between the serious adverse event and the preceding investigational procedure has been established.	
751.	**Article 58** **Implementing acts**	**Article 58** **Implementing acts**	**Article 58** **Implementing acts**	Under Assessment
752.	The Commission may, by means of implementing acts, adopt the modalities and procedural aspects necessary for the implementation of this Chapter, as regards the following: (a) harmonised forms for the application for clinical performance studies and their assessment as referred to in Articles 49 and 56, taking into account specific categories or groups of devices; (b) the functioning of the electronic system referred to in Article 51; (c) harmonised forms for the notification of post-market follow-up performance studies as referred to in Article 52(1), and of substantial modifications as referred to in Article 53; (d) the exchange of information between Member States as referred to in Article 54;	The Commission may, by means of implementing acts, adopt the modalities and procedural aspects necessary for the implementation of this Chapter, as regards the following: (a) harmonised forms for the application for clinical performance studies and their assessment as referred to in Articles 49 and 56, taking into account specific categories or groups of devices; (b) the functioning of the electronic system referred to in Article 51; (c) harmonised forms for the notification of post-market follow-up performance studies as referred to in Article 52(1), and of substantial modifications as referred to in Article 53; (d) the exchange of information between Member States as referred to in Article 54;	The Commission may, by means of implementing acts, adopt the modalities and procedural aspects necessary for the implementation of this Chapter, as regards the following: (a) harmonised electronic forms for the application for performance studies and their assessment as referred to in Articles 49 and 56, taking into account specific categories or groups of devices; (b) the functioning of the electronic system referred to in Article 51; (c) harmonised electronic forms for the notification of post-market performance follow-up studies as referred to in Article 52(1), and of substantial modifications as referred to in Article 53; (d) the exchange of information between Member States as referred to in Article 54;	

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	(e) harmonised forms for the reporting of serious adverse events and device deficiencies as referred to in Article 57; (f) the timelines for the reporting of serious adverse events and device deficiencies, taking into account the severity of the event to be reported as referred to in Article 57. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).	(e) harmonised forms for the reporting of serious adverse events and device deficiencies as referred to in Article 57; (f) the timelines for the reporting of serious adverse events and device deficiencies, taking into account the severity of the event to be reported as referred to in Article 57. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).	(e) harmonised electronic forms for the reporting of serious adverse events and device deficiencies as referred to in Article 57; (f) the timelines for the reporting of serious adverse events and device deficiencies, taking into account the severity of the event to be reported as referred to in Article 57; (g) uniform application of the requirements regarding the clinical evidence/data needed to demonstrate compliance with the general safety and performance requirements specified in Annex I. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).	
753.	**Chapter VII** **Vigilance and market surveillance**	**Chapter VIII** **Vigilance and market surveillance**	**Chapter VII** **Post-market surveillance, vigilance and market surveillance**	
754.			**SECTION 0 – POST-MARKET SURVEILLANCE**	
755.			**Article 58a** **Post-market surveillance system of the manufacturer**	
756.			2. For any device, proportionate to the risk class and appropriate for the type of device, manufacturers shall plan, establish, document, implement, maintain and update a post-market surveillance system which shall be an integral part of	Not new

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			the manufacturer's quality management system according to Article 8(6).	
757.			3. The post-market surveillance system shall be suitable to actively and systematically gather, record and analyse relevant data on the quality, performance and safety of a device throughout its entire lifetime, to draw the necessary conclusions and to determine, implement and monitor any preventive and corrective actions.	No Comment
758.			4. Data gathered by the manufacturer's post-market surveillance system shall in particular be used: (a) to update the benefit risk determination and risk management, the design and manufacturing information, the instructions for use and the labelling; (b) to update the performance evaluation; (c) to update the summary of safety and performance as referred to in Article 24; (d) for the identification of needs for preventive, corrective or field safety corrective action; (e) for the identification of possibilities to improve the usability, performance and safety of the device; (f) when relevant, to contribute to the post-market surveillance of other devices; (g) to detect and report trends in accordance with Article 59a. The technical documentation shall be updated accordingly.	If the device is no longer supported by the manufacturer, providing the same amount of information is unrealistic.

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759.			6. If in the course of the post-market surveillance a need for preventive and corrective action is identified, the manufacturer shall implement the appropriate measures and, where applicable, inform the notified body and the competent authorities concerned. When a serious incident is identified or a field safety corrective action is implemented, this shall be reported in accordance with Article 59.	No comment
760.			**Article 58b** **Post-market surveillance plan**	No Comment
761.			The post-market surveillance system as referred to in Article 58a shall be based on a post-market surveillance plan, the requirements of which are set out in Section 1.1 of Annex IIa. The post-market surveillance plan shall be part of the technical documentation as specified in Annex II.	No Comment
762.			**Article 58c** **Periodic safety update report**	From medicine legislation, this does not make sense for IVDs.
763.			1. Per device and where relevant per category or group of devices, the manufacturer shall prepare a periodic safety update report summarising the results and conclusions of the analyses of the gathered post-market surveillance data according to Annex IIa together with a rationale and description of any preventive and corrective actions taken. Throughout the lifetime of the device	It has no additional benefit for patient safety, only a bureaucratic burden. It is already done for products as part of vigilance reporting, why should it be done for every product systematically? What is “relevant” means? The info should be already available in Eudamed III.

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			concerned this report shall set out: (a) the conclusion of the benefit risk determination; (b) the main findings of the Post Market Performance Follow-up Report and (c) the volume of sales of devices and an estimate of the population that use the device involved and, where practicable, the usage frequency of the device. The report shall be updated at least annually; and be part of the technical documentation as specified in Annex II.	How this relate to ongoing trend reporting? (c) – this is an additional level of check which may not be justified.
764.			2. Manufacturers of devices in class C and D shall submit reports by means of the electronic system referred to in Article 64a to the notified body involved in the conformity assessment in accordance with Article 40. The notified body shall review the report and add its evaluation to the database with details of any action taken. Such reports and the notified body evaluation shall be available to competent authorities through the electronic system.	Periodic safety update report to be prepared for all products in class C and D as part of the technical documentation reviewed by NB annually. It has no additional benefit for patient safety. Immense costs for all manufacturers which could lead to market exit or less R&D.
765.			3. Manufacturers of devices other than those referred to in paragraph 2, shall make reports available to the notified body involved in the assessment and to competent authorities on request.	See 58c 2. Periodic safety update report should be prepared for all classes anyhow due to possible audits (“make reports available to the notified body”)
766.	**SECTION 1 — VIGILANCE**	**SECTION 1 — VIGILANCE**	**SECTION 1 – VIGILANCE**	
767.	**Article 59** **Reporting of incidents and field safety**	**Article 59** **Reporting of incidents and field safety**	**Article 59** **Reporting of serious incidents and field**	No comment

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	corrective actions	**corrective actions**	**safety corrective actions**	
768.	1. Manufacturers of devices, other than devices for performance evaluation, shall report through the electronic system referred to in Article 60 the following:	1. Manufacturers of devices, other than devices for performance evaluation, shall report through the electronic system referred to in Article 60 the following:	1. Manufacturers of devices, made available on the Union market, other than devices for performance evaluation, shall report, through the electronic system referred to in Article 64a, the following:	No comment
769.	(a) any serious incident in respect of devices made available on the Union market;	(a) any incident including date and place of incident, with an indication of whether it is serious in accordance with the definition under Article 2, in respect of devices made available on the Union market; where available, the manufacturer shall include information on the patient or user and healthcare professional involved in the incident;	(a) any serious incident involving devices made available on the Union market, except expected erroneous results which are clearly documented and quantified in the product information and in the technical documentation and are subject to trend reporting pursuant to Article 59a;	No comment
770.	(b) any field safety corrective action in respect of devices made available on the Union market, including any field safety corrective action undertaken in a third country in relation to a device which is also legally made available on the Union market if the reason for the field safety corrective action is not limited to the device made available in the third country.	(b) any field safety corrective action in respect of devices made available on the Union market, including any field safety corrective action undertaken in a third country in relation to a device which is also legally made available on the Union market if the reason for the field safety corrective action is not limited to the device made available in the third country.	(b) any field safety corrective action in respect of devices made available on the Union market, including any field safety corrective action undertaken in a third country in relation to a device which is also legally made available on the Union market, if the reason for the field safety corrective action is not limited to the device made available in the third country.	No comment
771.	Manufacturers shall make the report referred to in the first subparagraph without delay, and no later than 15 days after they have become aware of the event and the causal relationship with their device or that such causal relationship is reasonably possible.	Manufacturers shall make the report referred to in the first subparagraph without delay, and no later than 15 days after they have become aware of the event and the causal relationship with their device or that such causal relationship is reasonably possible.	1b. Manufacturers shall report any serious incident as referred to in point (a) immediately after the manufacturer has established the causal relationship with their device or that such causal relationship is reasonably possible, and not later than 15 days after they have become aware of the event.	Replace event with incident (consistency in text)

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772.	The time period for reporting shall take account of the severity of the incident.	The time period for reporting shall take account of the severity of the incident.	**1a.** As a general rule, the time period for reporting shall take account of the severity of the serious incident.	No significant change
773.	Where necessary to ensure timely reporting, the manufacturer may submit an initial incomplete report followed up by a complete report.	Where necessary to ensure timely reporting, the manufacturer may submit an initial incomplete report followed up by a complete report.	**1e.** Where necessary to ensure timely reporting, the manufacturer may submit an initial incomplete report followed up by a complete report.	
774.			1c. Notwithstanding paragraph 1b, in case of a serious public health threat the report shall be provided immediately, and not later than 2 days after awareness by the manufacturer of this threat.	
775.			1d. Notwithstanding paragraph 1b, in case of death or unanticipated serious deterioration in state of health the report shall be provided immediately after the manufacturer established or suspected a causal relationship between the device and the event but not later than 10 elapsed days following the date of awareness of the event.	Prefer MEDDEV timelines. Replace event with incident.
776.			1f. If after becoming aware of a potentially reportable incident there is still uncertainty about whether the event is reportable, the manufacturer shall submit a report within the timeframe required for that type of incident.	MEDDEV Refers to serious incidents. Replace event with incident.
777.			1g. Except in cases of urgency where the manufacturer need to undertake the field safety corrective action immediately, without undue delay, the manufacturer shall report the field safety corrective action referred to in paragraph 1, point (b)	No comment

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			in advance of the field safety corrective action being undertaken.	
778.	2. For similar serious incidents occurring with the same device or device type and for which the root cause has been identified or the field safety corrective action implemented, manufacturers may provide periodic summary reports instead of individual incident reports, on condition that the competent authorities referred to in points (a), (b) and (c) of Article 60(5) have agreed with the manufacturer on the format, content and frequency of the periodic summary reporting.	2. For similar serious incidents occurring with the same device or device type and for which the root cause has been identified or the field safety corrective action implemented, manufacturers may provide periodic summary reports instead of individual incident reports, on condition that the competent authorities referred to in points (a), (b) and (c) of Article 60(5) have agreed with the manufacturer on the format, content and frequency of the periodic summary reporting.	2. For similar serious incidents occurring with the same device or device type and for which the root cause has been identified or the field safety corrective action implemented or where the incidents are common and well documented, the manufacturers may provide periodic summary reports instead of individual serious incident reports, on condition that the coordinating competent authority referred to in Article 61(6), in consultation with the competent authorities referred to in points (a), and (b) of Article 64a (7), has agreed with the manufacturer on the format, content and frequency of the periodic summary reporting.	Extended to incidents are common and well documented. It is an improvement to the current system. Every CA to agree with the report? Coordinating CA should be consulted? Not understandable - ask for clarification to the last sentence
779.			Where a single competent authority is referred to in points (a), and (b) of Article 64a(7), the manufacturer may provide periodic summary reports on agreement with that competent authority.	
780.	3. The Member States shall take all appropriate measures to encourage healthcare professionals, users and patients to report to their competent authorities suspected serious incidents referred to in point (a) of paragraph 1.	3. The Member States shall take all appropriate measures, including targeted information campaigns, to encourage and enable healthcare professionals, including doctors and pharmacists, users and patients to report to their competent authorities suspected serious incidents referred to in point (a) of paragraph 1.		
781.	They shall record such reports centrally at national level.	They shall inform the Commission of those measures. The competent authorities of the Member		

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		States shall record such reports centrally at national level.		
782.	Where a competent authority of a Member State obtains such reports, it shall take the necessary steps to ensure that the manufacturer of the device concerned is informed of the incident.	Where a competent authority of a Member State obtains such reports, it shall inform the manufacturer of the device concerned without delay. The manufacturer shall ensure the appropriate follow-up. The competent authority of a Member State shall notify the reports referred to in the first subparagraph to the electronic system referred to in Article 60 without delay, unless the same incident has already been reported by the manufacturer.		
783.	The manufacturer shall ensure the appropriate follow-up.			
784.	The Member States shall coordinate between them the development of standard web-based structured forms for reporting of serious incidents by healthcare professionals, users and patients.	The Commission, in cooperation with the Member States and in consultation with the relevant stakeholders, shall develop standard forms for electronic and non-electronic reporting of incidents by healthcare professionals, users and patients		
785.	4. Health institutions manufacturing and using devices referred to in Article 4(4) shall report any serious incidents and field safety corrective actions referred to in paragraph 1 to the competent authority of the Member State in which the health institution is located.	4. Health institutions manufacturing and using devices referred to in Article 4(4) shall immediately report any serious incidents and field safety corrective actions referred to in paragraph 1 to the competent authority of the Member State in which the health institution is located.	Art. 59 3. The manufacturer of the device concerned shall provide to the competent authority of the Member State where the event occurred a report on the serious incident in accordance with paragraph 1 and ensure the appropriate follow-up. If the manufacturer considers that the event is not a serious incident or an increase in expected erroneous results which will be covered by trend reporting according to Article 59.1**,** it shall provide an explanatory	

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			statement. If the competent authority does not agree with the conclusion of the explanatory statement, it may require the manufacturer to provide a report in accordance with this Article and to take or require the manufacturer to take the appropriate corrective action.	
786.	**Article 60** **Electronic system on vigilance**	**Article 60** **Electronic system on vigilance**	**Article 64a** **Electronic system on vigilance**	Under Assessment
787.	1. The Commission shall, in collaboration with the Member States, set up and manage an electronic system to collate and process the following information: (a) the reports by manufacturers on serious incidents and field safety corrective actions referred to in Article 59(1); (b) the periodic summary reports by manufacturers referred to in Article 59(2); (c) the reports by competent authorities on serious incidents referred to in the second subparagraph of Article 61(1); (d) the reports by manufacturers on trends referred to in Article 62; (e) the field safety notices by manufacturers referred to in Article 61(4); (f) the information to be exchanged between the competent authorities of the Member States and between them and the	1. The Commission shall, in collaboration with the Member States, set up and manage an electronic system to collate and process the following information: (a) the reports by manufacturers on serious incidents and field safety corrective actions referred to in Article 59(1); (b) the periodic summary reports by manufacturers referred to in Article 59(2); (c) the reports by competent authorities on serious incidents referred to in the second subparagraph of Article 61(1); (d) the reports by manufacturers on trends referred to in Article 62; (e) the field safety notices by manufacturers referred to in Article 61(4); (f) the information to be exchanged between the competent authorities of the Member States and between them and the	1. The Commission shall, in collaboration with the Member States, collate and process the following information by means of the electronic system set up pursuant to Article 25 including a link to the product information in accordance with Article 22a. (a) the reports by manufacturers on serious incidents and field safety corrective actions referred to in Article 59(1) and Article 61(1); (b) the periodic summary reports by manufacturers referred to in Article 59(2); (d) the reports by manufacturers on trends referred to in Article 59a; (da) the periodic safety update reports referred to in Article 58c; (e) the field safety notices by manufacturers referred to in Article 61(54); (f) the information to be exchanged between the competent authorities of the Member States and between them and the Commission in accordance with Article 61(4) and (7).	

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	Commission in accordance with Article 61(3) and (6).	Commission in accordance with Article 61(3) and (6).		
788.		(fa) the reports by competent authorities on serious incidents and field safety corrective actions taken within health institutions involving devices referred to in Article 4(4)		
789.	2. The information collated and processed by the electronic system shall be accessible to the competent authorities of the Member States, to the Commission and to the notified bodies.	2. The information collated and processed by the electronic system shall be accessible to the competent authorities of the Member States, to the Commission, to the notified bodies, to healthcare professionals and also to manufacturers where the information pertains to their own product.	2. The information collated and processed by the electronic system shall be accessible to the competent authorities of the Member States, to the Commission and to the notified bodies that issued a certificate for the device in question in accordance with Article 41.	
790.	3. The Commission shall ensure that healthcare professionals and the public have appropriate levels of access to the electronic system.	3. The Commission shall ensure that the public has an appropriate level of access to the electronic system. Where the information is requested on a specific in vito diagnostic medical device, that information should be made available without delay and within 15 days at the latest.	3. The Commission shall ensure that healthcare professionals and the public have appropriate levels of access to the electronic system.	FSN would be the appropriate level of disclosure through the electronic system
791.	4. On the basis of arrangements between the Commission and competent authorities of third countries or international organisations, the Commission may grant those competent authorities or international organisations access to the database at the appropriate level. Those arrangements shall be based on reciprocity and make provision for confidentiality and data protection	4. On the basis of arrangements between the Commission and competent authorities of third countries or international organisations, the Commission may grant those competent authorities or international organisations access to the database at the appropriate level. Those arrangements shall be based on reciprocity and make provision for confidentiality and data protection	4. On the basis of arrangements between the Commission and competent authorities of third countries or international organisations, the Commission may grant those competent authorities or international organisations access to the database at the appropriate level. Those arrangements shall be based on reciprocity and make provision for confidentiality and data protection	

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	equivalent to those applicable in the Union.	equivalent to those applicable in the Union.	equivalent to those applicable in the Union.	
792.	5. The reports on serious incidents and field safety corrective actions referred to in points (a) and (b) of Article 59(1), the periodic summary reports referred to in Article 59(2), the reports on serious incidents referred to in the second subparagraph of Article 61(1) and the trend reports referred to in Article 62 shall be automatically transmitted upon receipt via the electronic system to the competent authorities of the following Member States		5. The reports on serious incidents referred to in points (a) of Article 59(1), and the reports on serious incidents referred to in the second subparagraph of Article 61(1) shall be automatically transmitted, upon receipt, via the electronic system, to the competent authority of the Member State where the incident occurred;	
793.	(a) the Member State where the incident occurred;	(a) the Member State where the incident occurred;		
794.			5a. Trend reports on expected erroneous results leading to serious incidents referred to in points (a) of Article 59(1) shall be automatically transmitted upon receipt via the electronic system to the competent authorities of the Member State where the incidents occurred;	
795.			6. The reports on field safety corrective actions referred to in point (b) of Article 59(1) shall be automatically transmitted upon receipt via the electronic system to the competent authority of the following Member States:	
796.	(a) the Member State where the field safety corrective action is being or is to be undertaken;	(b) the Member State where the field safety corrective action is being or is to be undertaken;	(a) the Member State where the field safety corrective action is being or is to be undertaken;	

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797.	(b) the Member State where the manufacturer has his registered place of business;	(c) the Member State where the manufacturer has his registered place of business;	(b) the Member State where the manufacturer or his authorised representative has his registered place of business;	
798.	(d) where applicable, the Member State where the notified body, that issued a certificate in accordance with Article 43 for the device in question, is established.	(d) where applicable, the Member State where the notified body, that issued a certificate in accordance with Article 43 for the device in question, is established.		
799.		5 a. The reports and information referred to in Article 60(5), shall also be automatically transmitted for the device in question via the electronic system to the notified body that issued the certificate in accordance with Article 43.		
800.			7. The periodic summary reports referred to in Article 59(2) shall be automatically transmitted upon receipt via the electronic system to the competent authority of the following Member States: (a) the Member State that agreed on the periodic summary report; (b) the Member State where the manufacturer or his authorised representative has his registered place of business.	
801.			8. The information referred to in paragraphs 5 to 7 shall be automatically transmitted, upon receipt, through the electronic system, to the notified body that issued the certificate for the device in question in accordance with Article 43.	
802.	**Article 61**	**Article 61**	**Article 61**	

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	Analysis of serious incidents and field safety corrective action	**Analysis of serious incidents and field safety corrective action**	**Analysis of serious incidents and field safety corrective actions**	
803.			0. Following the reporting of a serious incident pursuant to Article 59(1), the manufacturer shall without delay perform the necessary investigations of the serious incident and the concerned devices. This shall include risk assessment of the incident and field safety corrective action taking into account criteria outlined in paragraph 2. The manufacturer shall co-operate with the competent authorities and where relevant with the concerned notified body during these investigations and shall not perform any investigation which involves altering the device or a sample of the batch concerned in a way which may affect any subsequent evaluation of the causes of the incident prior to informing the competent authorities of such action.	
804.	1. Member States shall take the necessary steps to ensure that any information regarding a serious incident that has occurred within their territory or a field safety corrective action that has been or is to be undertaken within their territory, and that is brought to their knowledge in accordance with Article 59 is, at national level, evaluated centrally by their competent authority, if possible together with the manufacturer.	1. Member States shall take the necessary steps to ensure that any information regarding a serious incident that has occurred within their territory or a field safety corrective action that has been or is to be undertaken within their territory, and that is brought to their knowledge in accordance with Article 59 is, at national level, evaluated centrally by their competent authority, if possible together with the manufacturer.	1. Member States shall take the necessary steps to ensure that any information regarding a serious incident that has occurred within their territory or a field safety corrective action that has been or is to be undertaken within their territory, and that is brought to their knowledge in accordance with Article 59 is, at national level, evaluated centrally by their competent authority, if possible together with the manufacturer, and, where relevant, with the notified body concerned.	The term “evaluate” suggest that the CA would do more than t would be required to do. Request clarification what MNF should do together with NBs and CAs.
805.		The competent authority shall take into account the views of all relevant		

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		stakeholders, including patients, healthcare professionals' organisations and manufacturers' associations.		
806.			If in the case of reports received in accordance with Article 59(3) the competent authority ascertains that the reports relate to a serious incident it shall notify without delay those reports to the electronic system referred to in Article 60, unless the same incident has already been reported by the manufacturer.	
807.	2. The national competent authorities shall carry out a risk assessment with regard to reported serious incidents or field safety corrective actions, taking into account criteria such as causality, detectability and probability of recurrence of the problem, frequency of use of the device, probability of occurrence of harm and severity of harm, clinical benefit of the device, intended and potential users, and population affected. They shall also evaluate the adequacy of the field safety corrective action envisaged or undertaken by the manufacturer and the need for and kind of any other corrective action.	2. The national competent authorities shall carry out a risk assessment with regard to reported serious incidents or field safety corrective actions, taking into account criteria such as causality, detectability and probability of recurrence of the problem, frequency of use of the device, probability of occurrence of harm and severity of harm, clinical benefit of the device, intended and potential users, and population affected. They shall also evaluate the adequacy of the field safety corrective action envisaged or undertaken by the manufacturer and the need for and kind of any other corrective action.	2. In the context of the evaluation referred to in paragraph 0, the national competent authority shall, assess the risks arising from the reported serious incidents and field safety corrective actions, taking into account the protection of public health and the criteria such as causality, detectability and probability of recurrence of the problem, frequency of use of the device, probability of occurrence of direct or indirect harm and severity of that harm, clinical benefit of the device, intended and potential users, and population affected. It shall also evaluate the adequacy of the field safety corrective action envisaged or undertaken by the manufacturer and the need for and kind of any other corrective action, in particular taking into account the principle of inherent safety laid down in Annex I. Upon request by the national competent authority, the manufacturer shall provide for all documents necessary for the risk assessment.	"probability of occurrence of direct or indirect harm and severity of that harm" – definitions of harm and indirect harm are missing

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808.	They shall monitor the manufacturer's investigation of the incident.	They shall monitor the manufacturer's investigation of the serious incident.	2a. The national competent authorities shall monitor the manufacturer's investigation of a serious incident. Where necessary, a competent authority may intervene in a manufacturer's investigation or initiate an independent investigation.	Concern as to what an authority monitoring the manufacturer's investigation means.
809.			2b. The manufacturer shall provide a final report setting out its findings by means of the electronic system referred to in Article 64a. The report shall set out conclusions and where relevant indicate corrective actions to be taken.	
810.			3. In the case of companion diagnostic, the evaluating competent authority or the coordinating competent authority referred to in paragraph 6 shall inform the relevant competent authority for medicinal products, or the European Medicines Agency (EMA), that was consulted by the notified body in accordance with the procedures set out in Section 6.2 of Annex VIII and Section 3.6 of Annex IX.	
811.	3. After carrying out the assessment, the evaluating competent authority shall, through the electronic system referred to in Article 60, inform without delay the other competent authorities of the corrective action taken or envisaged by the manufacturer or imposed on him to minimise the risk of recurrence of a serious incident, including information on the underlying events and the outcome of its assessment.	3. After carrying out the assessment, the evaluating competent authority shall, through the electronic system referred to in Article 60, inform without delay the other competent authorities of the corrective action taken or envisaged by the manufacturer or imposed on him to minimise the risk of recurrence of a serious incident, including information on the underlying events and the outcome of its assessment.	4. After carrying out the evaluation, the evaluating competent authority shall, through the electronic system referred to in Article 64a, inform without delay the other competent authorities of the corrective action taken or envisaged by the manufacturer or imposed on him to minimise the risk of recurrence of a serious incident, including information on the underlying events and the outcome of its assessment.	

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812.	4. The manufacturer shall ensure that the users of the device in question are informed without delay of the corrective action taken by means of a field safety notice. Except in case of urgency, the content of the draft field safety notice shall be submitted to the evaluating competent authority or, in cases referred to in paragraph 5 of this Article, the coordinating competent authority to allow them to make comments. Unless duly justified by the situation of the individual Member State, the content of the field safety notice shall be consistent in all Member States.	4. The manufacturer shall ensure that the users of the device in question are informed without delay of the corrective action taken by means of a field safety notice. Except in case of urgency, the content of the draft field safety notice shall be submitted to the evaluating competent authority or, in cases referred to in paragraph 5 of this Article, the coordinating competent authority to allow them to make comments. Unless duly justified by the situation of the individual Member State, the content of the field safety notice shall be consistent in all Member States.	5. The manufacturer shall ensure that information about the field safety corrective action taken is brought without delay to the attention of users of the device in question by means of a field safety notice. The field safety notice shall be edited in an official Union language or languages determined by the Member State where the field safety corrective action is taken. Except in case of urgency, the content of the draft field safety notice shall be submitted to the evaluating competent authority or, in cases referred to in paragraph 6 of this Article, the coordinating competent authority to allow them to make comments. Unless duly justified by the situation of the individual Member State, the content of the field safety notice shall be consistent in all Member States.	
813.			The field safety notice shall allow the correct identification of the device or devices involved, including the UDI, and of the manufacturer, including the SRN, that has undertaken the field safety corrective action. The field safety notice shall explain, in a clear manner, without playing down the level of risk, the reasons for field safety corrective action with reference to the device deficiency or malfunction and associated risks for patient, user or other person and shall clearly indicate all the actions to be taken by users.	SRN – this should be a database only issue. FSN should be in a language that is easily understandable by the user, in practice same language as IFU. FSCA in a language understandable by the CA.
814.	The manufacturer shall enter the field safety notice in the electronic system referred to in Article 60 through which that	The manufacturer shall enter the field safety notice in the electronic system referred to in Article 60 through which that	The manufacturer shall enter the field safety notice in the electronic system referred to in Article 64a through which	

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	notice shall be accessible to the public.	notice shall be accessible to the public.	that notice shall be accessible to the public.	
815.	5. The competent authorities shall designate a coordinating competent authority to coordinate their assessments referred to in paragraph 2 in the following cases:	5. The competent authorities shall designate a coordinating competent authority to coordinate their assessments referred to in paragraph 2 in the following cases:	6. The competent authorities shall nominate a coordinating competent authority to coordinate their assessments referred to in paragraph 2 in the following cases:	
816.	(a) where similar serious incidents related to the same device or type of device of the same manufacturer occur in more than one Member State;	(b) where similar serious incidents related to the same device or type of device of the same manufacturer occur in more than one Member State;	(a) where there is concern regarding a particular serious incident or cluster of serious incidents related to the same device or type of device of the same manufacturer in more than one Member State;	
817.	(c) where the field safety corrective action is being or is to be undertaken in more than one Member State.	(d) where the field safety corrective action is being or is to be undertaken in more than one Member State.	(b) where the appropriateness of a field safety corrective action that is proposed by a manufacturer in more than one Member State is in question.	
818.	Unless otherwise agreed between the competent authorities, the coordinating competent authority shall be the one of the Member State where the manufacturer has his registered place of business.	Unless otherwise agreed between the competent authorities, the coordinating competent authority shall be the one of the Member State where the manufacturer has his registered place of business.	Unless otherwise agreed between the competent authorities, the coordinating competent authority shall be the Member State where the manufacturer or the authorised representative has his registered place of business.	
819.			The competent authorities shall actively participate in a coordination procedure. This procedure shall include the following: - designation of a coordinating authority on a case by case basis, when required; - a definition of the coordinated assessment process; - tasks and responsibilities of the coordinating authority and the involvement of other competent authorities.	

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820.	The coordinating competent authority shall inform the manufacturer, the other competent authorities and the Commission that it has assumed the role of coordinating authority.	The coordinating competent authority shall inform the manufacturer, the other competent authorities and the Commission that it has assumed the role of coordinating authority.	The coordinating competent authority shall, through the electronic system referred to in Article 64a, inform the manufacturer, the other competent authorities and the Commission that it has assumed the role of coordinating authority.	
821.	6. The coordinating competent authority shall carry out the following tasks: (a) to monitor the investigation of the serious incident by the manufacturer and the corrective action to be taken; (b) to consult with the notified body that issued a certificate in accordance with Article 43 for the device in question regarding the impact of the serious incident on the certificate; (c) to agree with the manufacturer and the other competent authorities referred to in points (a) to (c) of Article 60(5) on the format, content and frequency of periodic summary reports in accordance with Article 59(2); (d) to agree with the manufacturer and other competent authorities concerned on the implementation of the appropriate field safety corrective action; (e) to inform the other competent authorities and the Commission, through the electronic system referred to in Article 60, of the progress in and the outcome of its assessment.	6. The coordinating competent authority shall carry out the following tasks: (f) to monitor the investigation of the serious incident by the manufacturer and the corrective action to be taken; (g) to consult with the notified body that issued a certificate in accordance with Article 43 for the device in question regarding the impact of the serious incident on the certificate; (h) to agree with the manufacturer and the other competent authorities referred to in points (a) to (c) of Article 60(5) on the format, content and frequency of periodic summary reports in accordance with Article 59(2); (i) to agree with the manufacturer and other competent authorities concerned on the implementation of the appropriate field safety corrective action; (j) to inform the other competent authorities and the Commission, through the electronic system referred to in Article 60, of the progress in and the outcome of its assessment.		

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822.	The designation of a coordinating competent authority shall not affect the rights of the other competent authorities to perform their own assessment and to adopt measures in accordance with this Regulation in order to ensure the protection of public health and patient safety. The coordinating competent authority and the Commission shall be kept informed of the outcome of any such assessment and the adoption of any such measures.	The designation of a coordinating competent authority shall not affect the rights of the other competent authorities to perform their own assessment and to adopt measures in accordance with this Regulation in order to ensure the protection of public health and patient safety. The coordinating competent authority and the Commission shall be kept informed of the outcome of any such assessment and the adoption of any such measures.	The designation of a coordinating competent authority shall not affect the rights of the other competent authorities to perform their own assessment and to adopt measures in accordance with this Regulation in order to ensure the protection of public health and patient safety. The coordinating competent authority and the Commission shall be kept informed of the outcome of any such assessment and the adoption of any such measures.	
823.	7. The Commission shall provide secretarial support to the coordinating competent authority in the accomplishment of its tasks under this Chapter.	7. The Commission shall provide secretarial support to the coordinating competent authority in the accomplishment of its tasks under this Chapter.	8. The Commission shall provide administrative support to the coordinating competent authority in the accomplishment of its tasks under this Chapter.	
824.	**Article 62** **Trend reporting**	**Article 62** **Trend reporting**	**Article 59a** **Trend reporting**	
825.	Manufacturers of devices classified in class C or D shall report to the electronic system referred to in Article 60 any statistically significant increase in the frequency or severity of incidents that are not serious incidents or of expected undesirable effects that have a significant impact on the risk-benefit analysis referred to in Sections 1 and 5 of Annex I and which have led or may lead to unacceptable risks to the health or safety of patients, users or other persons when weighted against the intended benefits. The significant increase shall be established in comparison to the	Manufacturers of devices classified in class C or D shall report to the electronic system referred to in Article 60 any statistically significant increase in the frequency or severity of incidents that are not serious incidents or of expected undesirable effects that have a significant impact on the risk-benefit analysis referred to in Sections 1 and 5 of Annex I and which have led or may lead to unacceptable risks to the health or safety of patients, users or other persons when weighted against the intended benefits. The significant increase shall be established in comparison to the	1. Manufacturers shall report by means of the electronic system referred to in Article 64a any statistically significant increase in the frequency or severity of incidents that are not serious incidents that could have a significant impact on the risk-benefit analysis referred to in Sections I.1 and I.5 of Annex I and which have led or may lead to unacceptable risks to the health or safety of patients, users or other persons or of any significant increase in expected erroneous results established in comparison to the stated performance of the device according to Annex I Section II.6.1 (a) and (b) and specified in the	Council extended trend reporting to all device classes: trend reporting should be required only for class C+D devices, it should be related to the risk class as originally proposed. Trending pilot is only on reportable incidents – the future requirements cover also other incidents. Top of the other reports (incident report, the yearly summary), burdensome admin. The info already submitted to

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	foreseeable frequency or severity of such incidents or expected undesirable effects in respect of the device, or category or group of devices, in question during a specific time period as established in the manufacturer's conformity assessment. Article 61 shall apply.	foreseeable frequency or severity of such incidents or expected undesirable effects in respect of the device, or category or group of devices, in question during a specific time period as established in the manufacturer's conformity assessment. Article 61 shall apply.	technical documentation and product information.	CAs and NBs PSUR is overlapping with trending. One of them should be deleted (synoptic table would help)
826.			The manufacturer shall define how to manage these events and the methodology used for determining any statistically significant increase in the frequency or severity of this these events or change in performance, as well as the observation period, in the post-market surveillance plan pursuant to Article 58b.	
827.			1a. The competent authorities may conduct their own assessments on the trend reports referred to in paragraph 1 and require the manufacturer to adopt appropriate measures in accordance with the present regulation in order to ensure the protection of public health and patient safety. The competent authority shall inform the Commission, the other competent authorities and the notified body that issued the certificate, of the results of such evaluation and of the adoption of such measures.	This would break up harmonisation across Europe in the area of vigilance.
828.	**Article 63** **Documentation of vigilance data**	**Article 63** **Documentation of vigilance data**	**[Deleted]**	
829.	Manufacturers shall update their technical documentation with information on incidents received from healthcare professionals, patients and users, serious	Manufacturers shall update their technical documentation with information on incidents received from healthcare professionals, patients and users, serious		

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	incidents, field safety corrective actions, periodic summary reports referred to in Article 59, trend reports referred to in Article 62 and field safety notices referred to in Article 61(4). They shall make this documentation available to their notified bodies, which shall assess the impact of the vigilance data on the conformity assessment and the certificate issued.	incidents, field safety corrective actions, periodic summary reports referred to in Article 59, trend reports referred to in Article 62 and field safety notices referred to in Article 61(4). They shall make this documentation available to their notified bodies, which shall assess the impact of the vigilance data on the conformity assessment and the certificate issued.		
830.			**Article 63a** **Analysis of vigilance data**	Under Assessment
831.			The Commission shall, in collaboration with the Member States, put in place systems and processes to proactively monitor the data available in the database referred to in Article 64a, in order to identify trends, patterns or signals in the data that may identify new risks or safety concerns. When a previously unknown risk is identified or the frequency of an anticipated risk significantly and adversely changes the risk-benefit determination, the competent authority or, where appropriate, the coordinating competent authority shall inform the manufacturer, or where applicable the authorised representative, who shall take the necessary corrective actions.	
832.	**Article 64** **Implementing acts**	**Article 64** **Implementing acts**	**Article 64** **Implementing acts**	Under Assessment
833.	The Commission may, by means of	The Commission may, by means of	The Commission may**,** by means of	

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	implementing acts, adopt the modalities and procedural aspects necessary for the implementation of Articles 59 to 63 as regards the following: (a) typology of serious incidents and field safety corrective actions in relation to specific devices, or categories or groups of devices; (b) harmonised forms for the reporting of serious incidents and field safety corrective actions, periodic summary reports and trend reports by manufacturers as referred to in Articles 59 and 62; (c) timelines for the reporting of serious incidents and field safety corrective actions, periodic summary reports and trend reports by manufacturers, taking into account the severity of the event to be reported as referred to in Articles 59 and 62; (d) harmonised forms for the exchange of information between competent authorities as referred to in Article 61. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).	implementing acts, adopt the modalities and procedural aspects necessary for the implementation of Articles 59 to 63 as regards the following: (e) typology of serious incidents and field safety corrective actions in relation to specific devices, or categories or groups of devices; (f) harmonised forms for the reporting of serious incidents and field safety corrective actions, periodic summary reports and trend reports by manufacturers as referred to in Articles 59 and 62; (g) timelines for the reporting of serious incidents and field safety corrective actions, periodic summary reports and trend reports by manufacturers, taking into account the severity of the event to be reported as referred to in Articles 59 and 62; (h) harmonised forms for the exchange of information between competent authorities as referred to in Article 61. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).	implementing acts, and after consultation of the MDCG**,** adopt the modalities and procedural aspects necessary for the implementation of Articles 59 61 to 63a and 64a as regards the following: (a) typology of serious incidents and field safety corrective actions in relation to specific devices, or categories or groups of devices; (b) the reporting of serious incidents and field safety corrective actions, field safety notices, periodic summary reports, periodic safety update reports and trend reports by manufacturers as referred to in Articles 58c, 59, 59a and 61; (ba) standard web-based structured forms including a minimum data set for electronic reporting of serious incidents by healthcare professionals, users and patients; (c) timelines for the reporting of field safety corrective actions, periodic summary reports, and trend reports and periodic safety update reports by manufacturers, taking into account the severity of the event to be reported as referred to in Articles 59 and 58c; (d) harmonised forms for the exchange of information between competent authorities as referred to in Article 61. (e) procedures for designation of a coordinating competent authority, the coordinated assessment process, tasks and responsibilities of the coordinating competent	

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			authority and involvement of other competent authorities in this process. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3)	
834.	**SECTION 2 — MARKET SURVEILLANCE**	**SECTION 2 — MARKET SURVEILLANCE**	**SECTION 2 – MARKET SURVEILLANCE**	
835.	**Article 65 Market surveillance activities**	**Article 65 Market surveillance activities**	**Article 65 Market surveillance activities**	Under Assessment
836.	1. The competent authorities shall perform appropriate checks on the characteristics and performance of devices including, where appropriate, review of documentation and physical or laboratory checks on the basis of adequate samples. They shall take account of established principles regarding risk assessment and risk management, vigilance data and complaints.	1. The competent authorities shall perform appropriate checks on the characteristics and performance of devices including, where appropriate, review of documentation and physical or laboratory checks on the basis of adequate samples. They shall take account of established principles regarding risk assessment and risk management, vigilance data and complaints.	1. The competent authorities shall perform appropriate checks on the conformity characteristics and performance of devices including, where appropriate, review of documentation and physical or laboratory checks on the basis of adequate samples. They shall, in particular, take account of established principles regarding risk assessment and risk management, vigilance data and complaints.	
837.			1a. The competent authorities shall draw up annual surveillance activities plans and allocate a sufficient number of competent human and material resources needed to carry out those activities taking into account the European market surveillance program developed by the MDCG according to Article 77 and local circumstances.	
838.	The competent authorities may require	The competent authorities may require	1b. For the purpose referred to in the	

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	economic operators to make available the documentation and information necessary for the purpose of carrying out their activities, and, where necessary and justified, enter the premises of economic operators and take the necessary samples of devices.	economic operators to make available the documentation and information necessary for the purpose of carrying out their activities, and enter and inspect the premises of economic operators and take the necessary samples of devices for analysis by an official laboratory.	paragraph 1, the competent authorities: (a) may, inter alia require economic operators to make available the documentation and information necessary for the purpose of carrying out their activities and, where justified, provide the necessary samples of devices free of charge;	
839.			(b) and shall carry out both announced and, if necessary for control purposes**,** unannounced inspections of the premises of economic operators, as well as suppliers and/or subcontractors, and, where necessary, at the facilities of professional users**..**	
840.			1c. The competent authorities shall prepare annual summary of the results of the surveillance activities and make it accessible to other competent authorities by means of the electronic system referred to in Article 73b.	
841.	They may destroy or otherwise render inoperable devices presenting a serious risk where they deem it necessary.	They may destroy or otherwise render inoperable devices presenting a risk where they deem it necessary.	1d. The competent authorities may confiscate, destroy or otherwise render inoperable devices presenting a serious risk or falsified products where they deem it necessary in the interest of the protection of public health.	
842.		1 a. The competent authorities shall designate inspectors who shall be empowered to carry out the checks referred to in paragraph 1. The checks shall be carried out by the inspectors of the Member State in which the economic operator is located. These inspectors may		

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		be assisted by experts appointed by the competent authorities. 1b. Unannounced inspections may also be carried out. The organisation and implementation of such inspections must always take account of the principle of proportionality, particularly with reference to the hazard potential of a particular product. 1c. Following each inspection carried out under paragraph 1, the competent authority shall draw up a report on compliance by the economic operator inspected with the legal and technical requirements applicable under this Regulation and any corrective actions needed. 1d. The competent authority which carried out the inspection shall communicate the content of this report to the inspected economic operator. Before adopting the report, the competent authority shall give the inspected economic operator the opportunity to submit comments. The final inspection report as referred to in paragraph 1b shall be entered into the electronic system provided for in Article 66. 1e. Without prejudice to any international agreements concluded between the Union and third countries, checks as referred in paragraph 1 can also take place in the premises of an economic operator located in a third country, if the device is intended to be made available on the Union market		
843.	2. The Member States shall periodically review and assess the functioning of their	2. The Member States shall draw up strategic surveillance plans covering their	2. The Member States shall review and assess the functioning of their	

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	surveillance activities. Such reviews and assessments shall be carried out at least every four years and the results thereof shall be communicated to the other Member States and the Commission. The Member State concerned shall make a summary of the results accessible to the public.	planned surveillance activities, as well as the human and material resources needed to carry these activities out. Member States shall periodically review and assess the implementaion of their surveillance plans. Such reviews and assessments shall be carried out at least every two years and the results thereof shall be communicated to the other Member States and the Commission. The Commission may make recommendations for adjustments to the surveillance plans. The Member States shall make a summary of the results and of the Commission's recommendations accessible to the public.	surveillance activities. Such reviews and assessments shall be carried out at least every four years and the results thereof shall be communicated to the other Member States and the Commission. The Member State concerned shall make a summary of the results accessible to the public by means of the electronic system referred to in Article 73b.	
844.	3. The competent authorities of the Member States shall coordinate their market surveillance activities, cooperate with each other and share with each other and with the Commission the results thereof.	3. The competent authorities of the Member States shall coordinate their market surveillance activities, cooperate with each other and share with each other and with the Commission the results thereof.	3. The competent authorities of the Member States shall coordinate their market surveillance activities, cooperate with each other and share with each other and with the Commission the results thereof, to provide for a harmonized high level of market surveillance in all Member States.	
845.	Where appropriate, the competent authorities of the Member States shall agree on work-sharing and specialisation.	Where appropriate, the competent authorities of the Member States shall agree on work-sharing and specialisation.	Where appropriate, the competent authorities of the Member States shall agree on work-sharing, joint market surveillance activities and specialisation.	
846.	4. Where more than one authority in a Member State is responsible for market surveillance and external border controls, those authorities shall cooperate with each other, by sharing information relevant to their role and functions.	4. Where more than one authority in a Member State is responsible for market surveillance and external border controls, those authorities shall cooperate with each other, by sharing information relevant to their role and functions.	4. Where more than one authority in a Member State is responsible for market surveillance and external border controls, those authorities shall cooperate with each other, by sharing information relevant to their role and functions.	
847.	5. The competent authorities of the	The competent authorities of the Member	5. Where appropriate, the competent	

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	Member States shall cooperate with the competent authorities of third countries with a view to exchanging information and technical support and promoting activities relating to market surveillance.	States shall cooperate with the competent authorities of third countries with a view to exchanging information and technical support and promoting activities relating to market surveillance.	authorities of the Member States shall cooperate with the competent authorities of third countries with a view to exchanging information and technical support and promoting activities relating to market surveillance.	
848.	**Article 66** **Electronic system on market surveillance**	**Article 66** **Electronic system on market surveillance**	**Article 73b** **Electronic system on market surveillance**	Under Assessment
849.	1. The Commission, in collaboration with the Member States, shall set up and manage an electronic system to collate and process the following information: (a) information in relation to non-compliant devices presenting a risk to health and safety referred to in Article 68(2), (4) and (6); (b) information in relation to compliant devices presenting a risk to health and safety referred to in Article 70(2); (c) information in relation to formal non-compliance of products referred to in Article 71(2); (d) information in relation to preventive health protection measures referred to in Article 72(2).	1. The Commission, in collaboration with the Member States, shall set up and manage an electronic system to collate and process the following information: (a) information in relation to non-compliant devices presenting a risk to health and safety referred to in Article 68(2), (4) and (6); (b) information in relation to compliant devices presenting a risk to health and safety referred to in Article 70(2); (c) information in relation to formal non-compliance of products referred to in Article 71(2); (d) information in relation to preventive health protection measures referred to in Article 72(2).	1. The Commission, in collaboration with the Member States, shall set up and manage an electronic system to collate and process the following information: . (aa) summaries of the results of the surveillance activities referred to in Article 67(1c); (a) information in relation to non-compliant devices presenting a risk to health and safety referred to in Article 68(2), (4) and (6); (c) information in relation to formal non-compliance of products referred to in Article 71(2); (d) information in relation to preventive health protection measures referred to in Article 72(2); (e) summaries of the results of the reviews and assessments of the surveillance activities of the Member States referred to in Article 65(2).	
850.	2. The information mentioned in paragraph 1 shall be immediately transmitted through the electronic system to all competent authorities concerned and be accessible to	2. The information mentioned in paragraph 1 shall be immediately transmitted through the electronic system to all competent authorities concerned and be accessible to	2. The information mentioned in paragraph 1 shall be immediately transmitted through the electronic system to all competent authorities concerned	

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	the Member States and to the Commission.	the Member States, to the Commission, to the Agency and to healthcare profressionals. The Commission shall also ensure that the public has an appropriate level of access to the electronic system. In particular, it shall ensure that, where information is requested on a specific in vitro diagnostic medical device, it is made available without delay and within 15 days. The Commission in consultation with the Medical Devices Coordination Group, shall provide an overview of this information, every 6 months, for the public and healthcare professionals. This information shall be accessible through the European databank referred to in Article 25.	and, where applicable, to the notified body that issued a certificate in accordance with Article 43 for the device concerned and be accessible to the Member States and to the Commission.	
851.			3. Information exchanged between Member States shall not be made public when this may impair market surveillance activities and co-operation between Member States.	
852.	**Article 67** **Evaluation regarding devices presenting a risk to health and safety at national level**	**Article 67** **Evaluation regarding devices presenting a risk to health and safety at national level**	**Article 67** **Evaluation regarding devices suspected to presenting an unacceptable risk or non-compliance**	Under Assessment
853.	Where the competent authorities of a Member State, based on vigilance data or other information, have sufficient reason to believe that a device presents a risk to the health or safety of patients, users or other persons, they shall carry out an evaluation in relation to the device concerned covering all the requirements laid down in this Regulation that are relevant to the risk	Where the competent authorities of a Member State, based on vigilance data or other information, have sufficient reason to believe that a device presents a risk to the health or safety of patients, users or other persons, they shall carry out an evaluation in relation to the device concerned covering all the requirements laid down in this Regulation that are relevant to the risk	Where the competent authorities of a Member State, based on data obtained by vigilance or market surveillance activities or other information, have reason to believe that a device may presents an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health, or otherwise does not comply with	

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	presented by the device. The relevant economic operators shall cooperate as necessary with the competent authorities.	presented by the device. The relevant economic operators shall cooperate as necessary with the competent authorities.	the requirements laid down in this Regulation, they shall carry out an evaluation in relation to the device concerned covering all the requirements laid down in this Regulation that are relevant to the risk presented by or non-compliance of the device. The relevant economic operators shall cooperate with the competent authorities.	
854.	**Article 68** **Procedure for dealing with non-compliant devices presenting a risk to health and safety**	**Article 68** **Procedure for dealing with non-compliant devices presenting a risk to health and safety**	**Article 68** **Procedure for dealing with devices presenting an unacceptable risk to health and safety**	Under Assessment
855.	1. Where, having performed an evaluation pursuant to Article 67, the competent authorities find that the device, which presents a risk to the health or safety of patients, users or other persons, does not comply with the requirements laid down in this Regulation, they shall without delay require the relevant economic operator to take all appropriate and duly justified corrective action to bring the device into compliance with those requirements, to prohibit or restrict the making available of the device on the market, to subject the making available of the device to specific requirements, to withdraw the device from the market, or to recall it within a reasonable period, proportionate to the nature of the risk.	1. Where, having performed an evaluation pursuant to Article 67, the competent authorities find that the device, which presents a risk to the health or safety of patients, users or other persons, does not comply with the requirements laid down in this Regulation, they shall without delay require the relevant economic operator to take all appropriate and duly justified corrective action to bring the device into compliance with those requirements, to prohibit or restrict the making available of the device on the market, to subject the making available of the device to specific requirements, to withdraw the device from the market, or to recall it within a reasonable period, proportionate to the nature of the risk.	1. Where, having performed an evaluation pursuant to Article 67, the competent authorities find that the device, presents an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health and, they shall without delay require the manufacturer of the devices concerned, his authorised representatives and all other relevant economic operators to take all appropriate and duly justified corrective action to bring the device into compliance with those requirements, to restrict the making available of the device on the market, to subject the making available of the device to specific requirements, to withdraw the device from the market, or to recall it within a reasonable period, proportionate to the nature of the risk or non-compliance.	

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856.	2. Where the competent authorities consider that non-compliance is not restricted to their national territory, they shall inform the Commission and the other Member States of the results of the evaluation and of the actions which they have required the economic operators to take, by means of the electronic system referred to in Article 66.	2. Where the competent authorities consider that non-compliance is not restricted to their national territory, they shall inform the Commission and the other Member States of the results of the evaluation and of the actions which they have required the economic operators to take, by means of the electronic system referred to in Article 66.	2. The competent authorities shall notify the Commission, the other Member States and the notified body that issued a certificate in accordance with Article 43 for the device concerned of the results of the evaluation and of the actions which they have required the economic operators to take, by means of the electronic system referred to in Article 73b.	
857.	3. The economic operators shall ensure that all appropriate corrective action is taken in respect of all the devices concerned that they have made available on the market throughout the Union.	3. The economic operators shall ensure that all appropriate corrective action is taken in respect of all the devices concerned that they have made available on the market throughout the Union.	3. The economic operators shall ensure that all appropriate corrective action is taken in respect of all the devices concerned that they have made available on the market throughout the Union.	
858.	4. Where the relevant economic operator does not take adequate corrective action within the period referred to in paragraph 1, the competent authorities shall take all appropriate provisional measures to prohibit or restrict the device's being made available on their national market, to withdraw the device from that market or to recall it. They shall notify the Commission and the other Member States, without delay, of those measures, by means of the electronic system referred to in Article 66.	4. Where the relevant economic operator does not take adequate corrective action within the period referred to in paragraph 1, the competent authorities shall take all appropriate provisional measures to prohibit or restrict the device's being made available on their national market, to withdraw the device from that market or to recall it. They shall notify the Commission and the other Member States, without delay, of those measures, by means of the electronic system referred to in Article 66.	4. Where the relevant economic operator does not take adequate corrective action within the period referred to in paragraph 1, the competent authorities shall take all appropriate measures to prohibit or restrict the device's being made available on their national market, to withdraw the device from that market or to recall it. They shall notify the Commission, the other Member States and the notified body that issued a certificate in accordance with Article 43 for the device concerned, without delay, of those measures, by means of the electronic system referred to in Article 73b.	
859.	5. The notification referred to in paragraph 4 shall include all available details, in particular the data necessary for the identification of the non-compliant device,	5. The notification referred to in paragraph 4 shall include all available details, in particular the data necessary for the identification of the non-compliant device,	5. The notification referred to in paragraph 4 shall include all available details, in particular the data necessary for the identification and tracing of the non-	

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	the origin of the device, the nature of and the reasons for the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator.	the origin of the device, the nature of and the reasons for the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator.	compliant device, the origin of the device, the nature of and the reasons for the non-compliance alleged and the risk involved, the nature and duration of the national measures taken and the arguments put forward by the relevant economic operator.	
860.	6. Member States other than the Member State initiating the procedure shall without delay inform the Commission and the other Member States of any additional information at their disposal relating to the non-compliance of the device concerned and of any measures adopted by them in relation to the device concerned. In the event of disagreement with the notified national measure, they shall without delay inform the Commission and the other Member States of their objections, by means of the electronic system referred to in Article 66.	6. Member States other than the Member State initiating the procedure shall without delay inform the Commission and the other Member States of any additional information at their disposal relating to the non-compliance of the device concerned and of any measures adopted by them in relation to the device concerned. In the event of disagreement with the notified national measure, they shall without delay inform the Commission and the other Member States of their objections, by means of the electronic system referred to in Article 66.	6. Member States other than the Member State initiating the procedure shall, without delay, inform the Commission and the other Member States, by means of the electronic system referred to in Article 73b, of any additional relevant information at their disposal relating to the non-compliance of the device concerned and of any measures adopted by them in relation to the device concerned. In the event of disagreement with the notified national measure, they shall without delay inform the Commission and the other Member States of their objections, by means of the electronic system referred to in Article 73b.	
861.	7. Where, within two months of receipt of the notification referred to in paragraph 4, no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed justified.	7. Where, within two months of receipt of the notification referred to in paragraph 4, no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed justified.	7. Where, within two months of receipt of the notification referred to in paragraph 4, no objection has been raised by either a Member State or the Commission in respect of any measures taken by a Member State, those measures shall be deemed to be justified.	
862.	8. All Member States shall ensure that appropriate restrictive measures are taken without delay in respect of the device concerned.	8. All Member States shall ensure that appropriate restrictive measures are taken without delay in respect of the device concerned.	8. Where paragraph 7 applies, all Member States shall ensure that appropriate restrictive or prohibitive measures, withdrawing, recalling or limiting the availability of the device on	

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			their national market are taken without delay in respect of the device concerned.	
863.	**Article 69** **Procedure at Union level**	**Article 69** **Procedure at Union level**	**Article 69** **Procedure for evaluating national measures at Union level**	
864.	1. Where, within two months of receipt of the notification referred to in Article 68(4), objections are raised by a Member State against a provisional measure taken by another Member State, or where the Commission considers the measure to be contrary to Union legislation, the Commission shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall decide, by means of implementing acts, whether or not the national measure is justified. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).	1. Where, within two months of receipt of the notification referred to in Article 68(4), objections are raised by a Member State against a provisional measure taken by another Member State, or where the Commission considers the measure to be contrary to Union legislation, the Commission shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall decide, by means of implementing acts, whether or not the national measure is justified. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).	1. Where, within two months of receipt of the notification referred to in Article 68(4), objections are raised by a Member State against a measure taken by another Member State, or where the Commission considers the measure to be contrary to Union legislation, the Commission shall, after consulting the concerned competent authorities and, where necessary, the concerned economic operators, evaluate the national measure. On the basis of the results of that evaluation, the Commission may decide, by means of implementing acts, whether or not the national measure is justified. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 86(3).	
865.	2. If the national measure is considered justified, Article 68(8) shall apply. If the national measure is considered unjustified, the Member State concerned shall withdraw the measure.	2. If the national measure is considered justified, Article 68(8) shall apply. If the national measure is considered unjustified, the Member State concerned shall withdraw the measure.	2. If the national measure is considered justified, Article 68(8) shall apply. If the national measure is considered unjustified, the Member State concerned shall withdraw the measure. In the absence of a Commission decision the national measures shall be considered to be justified.	
866.	Where, in the situations referred to in Articles 68 and 70, a Member State or the	Where, in the situations referred to in Articles 68 and 70, a Member State or the	2a. Where a Member State or the Commission consider that the risk to	

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	Commission consider that the risk to health and safety emanating from a device cannot be contained satisfactorily by means of measures taken by the Member State(s) concerned, the Commission, at the request of a Member State or on its own initiative, may take, by means of implementing acts, the necessary and duly justified measures to ensure the protection of health and safety, including measures restricting or prohibiting the placing on the market and putting into service of the device concerned. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).	Commission consider that the risk to health and safety emanating from a device cannot be contained satisfactorily by means of measures taken by the Member State(s) concerned, the Commission, at the request of a Member State or on its own initiative, may take, by means of implementing acts, the necessary and duly justified measures to ensure the protection of health and safety, including measures restricting or prohibiting the placing on the market and putting into service of the device concerned. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).	health and safety emanating from a device cannot be contained satisfactorily by means of measures taken by the Member State(s) concerned, the Commission, at the request of a Member State or on its own initiative, may take, by means of implementing acts, the necessary and duly justified measures to ensure the protection of health and safety, including measures restricting or prohibiting the placing on the market and putting into service of the device concerned. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).	
867.	3. On duly justified imperative grounds of urgency relating to the health and safety of humans, the Commission shall adopt immediately applicable implementing acts referred to in paragraphs 1 and 2 in accordance with the procedure referred to in Article 84(4).	3. On duly justified imperative grounds of urgency relating to the health and safety of humans, the Commission shall adopt immediately applicable implementing acts referred to in paragraphs 1 and 2 in accordance with the procedure referred to in Article 84(4).		
868.			In the absence of a Commission decision the national measures shall be considered to be justified.	
869.	**Article 70** **Procedure for dealing with compliant devices presenting a risk to health and safety**	**Article 70** **Procedure for dealing with compliant devices presenting a risk to health and safety**		This article is collapsed into article 68 of the council text.
870.	1. Where, having performed an evaluation pursuant to Article 67, a Member State finds that although a device has been	1. Where, having performed an evaluation pursuant to Article 67, a Member State finds that although a device has been		

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	legally placed on the market or put into service, it presents a risk to the health or safety of patients, users or other persons or to other aspects of the protection of public health, it shall require the relevant economic operator or operators to take all appropriate provisional measures to ensure that the device concerned, when placed on the market or put into service, no longer presents that risk, to withdraw the device from the market or to recall it within a reasonable period, proportionate to the nature of the risk.	legally placed on the market or put into service, it presents a risk to the health or safety of patients, users or other persons or to other aspects of the protection of public health, it shall require the relevant economic operator or operators to take all appropriate provisional measures to ensure that the device concerned, when placed on the market or put into service, no longer presents that risk, to withdraw the device from the market or to recall it within a reasonable period, proportionate to the nature of the risk.		
871.	2. The Member State shall immediately notify the Commission and the other Member States of the measures taken, by means of the electronic system referred to in Article 66. That information shall include the data necessary for the identification of the device concerned, the origin and the supply chain of the device, the findings of the Member State's evaluation specifying the nature of the risk involved and the nature and duration of the national measures taken.	2. The Member State shall immediately notify the Commission and the other Member States of the measures taken, by means of the electronic system referred to in Article 66. That information shall include the data necessary for the identification of the device concerned, the origin and the supply chain of the device, the findings of the Member State's evaluation specifying the nature of the risk involved and the nature and duration of the national measures taken.		
872.	3. The Commission shall evaluate the provisional national measures taken. On the basis of the results of that evaluation, the Commission shall decide, by means of implementing acts, whether or not the measure is justified. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3). On duly justified imperative grounds of urgency relating to the health and safety of humans, the Commission	3. The Commission shall evaluate the provisional national measures taken. On the basis of the results of that evaluation, the Commission shall decide, by means of implementing acts, whether or not the measure is justified. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3). On duly justified imperative grounds of urgency relating to the health and safety of humans, the Commission		

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	shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 84(4).	shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 84(4).		
873.	4. Where the national measure is considered justified, Article 68(8) shall apply. If the national measure is considered unjustified, the Member State concerned shall withdraw the measure.	4. Where the national measure is considered justified, Article 68(8) shall apply. If the national measure is considered unjustified, the Member State concerned shall withdraw the measure.		
874.	**Article 71** **Formal non-compliance**	**Article 71** **Formal non-compliance**	**Article 71** **Formal non-compliance**	
875.	1. Without prejudice to Article 68, a Member State shall require the relevant economic operator to put an end to the non-compliance concerned within a reasonable period that is proportionate to the non-compliance where it makes one of the following findings:	1. Without prejudice to Article 68, a Member State shall require the relevant economic operator to put an end to the non-compliance concerned within a reasonable period that is proportionate to the non-compliance where it makes one of the following findings:	1. Where, having performed an evaluation pursuant to Article 67, the competent authorities of a Member State find that a device does not comply with the requirements laid down in this Regulation but does not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health, they shall require the relevant economic operator to put an end to the non-compliance concerned within a reasonable period that is proportionate to the non-compliance.	
876.	(a) that the CE marking has been affixed in violation of the formal requirements laid down in Article 16; (b) that the CE marking has not been affixed to a device contrary to Article 16; (c) that the CE marking has been inappropriately affixed in accordance with procedures in this Regulation on a product that is not	(a) that the CE marking has been affixed in violation of the formal requirements laid down in Article 16; (b) that the CE marking has not been affixed to a device contrary to Article 16; (c) that the CE marking has been inappropriately affixed in accordance with procedures in this Regulation on a product that is not		

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	covered by this Regulation; (d) that the EU declaration of conformity has not been drawn up or is not complete; (e) that the information to be supplied by the manufacturer on the label or in the instructions for use is not available, not complete, or not provided in the language(s) required; that the technical documentation, including the clinical evaluation, is not available or not complete.	covered by this Regulation; (d) that the EU declaration of conformity has not been drawn up or is not complete; (e) that the information to be supplied by the manufacturer on the label or in the instructions for use is not available, not complete, or not provided in the language(s) required; that the technical documentation, including the clinical evaluation, is not available or not complete.		
877.	2. Where the economic operator does not put an end to the non-compliance within the period referred to in paragraph 1, the Member State concerned shall take all appropriate measures to restrict or prohibit the product being made available on the market or to ensure that it is recalled or withdrawn from the market. That Member State shall inform the Commission and the other Member States without delay of those measures, by means of the electronic system referred to in Article 66.	2. Where the economic operator does not put an end to the non-compliance within the period referred to in paragraph 1, the Member State concerned shall take all appropriate measures to restrict or prohibit the product being made available on the market or to ensure that it is recalled or withdrawn from the market. That Member State shall inform the Commission and the other Member States without delay of those measures, by means of the electronic system referred to in Article 66.	2. Where the economic operator does not put an end to the non-compliance within the period referred to in paragraph 1, the Member State concerned shall take all appropriate measures to restrict or prohibit the product being made available on the market or to ensure that it is recalled or withdrawn from the market. That Member State shall inform the Commission and the other Member States without delay of those measures, by means of the electronic system referred to in Article 73b.	
878.			3. The Commission may, by means of implementing acts, elaborate details on the nature of non-compliances and appropriate measures to be taken by competent authorities to ensure the uniform application of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 86(3).	

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879.	**Article 72** **Preventive health protection measures**	**Article 72** **Preventive health protection measures**	**Article 72** **Preventive health protection measures**	
880.	1. Where a Member State, after having performed an evaluation which indicates a potential risk related to a device or a specific category or group of devices considers that the making available on the market or putting into service of such device or specific category or group of devices should be prohibited, restricted or made subject to particular requirements or that such device or, category or group of devices should be withdrawn from the market or recalled in order to protect the health and safety of patients, users or other persons or other aspects of public health, it may take any necessary and justified provisional measures.	1. Where a Member State, after having performed an evaluation which indicates a potential risk related to a device or a specific category or group of devices considers that the making available on the market or putting into service of such device or specific category or group of devices should be prohibited, restricted or made subject to particular requirements or that such device or, category or group of devices should be withdrawn from the market or recalled in order to protect the health and safety of patients, users or other persons or other aspects of public health, it may take any necessary and justified provisional measures.	1. Where a Member State, after having performed an evaluation, which indicates a potential risk related to a device or a specific category or group of devices considers that, in order to protect the health and safety of patients, users or other persons or other aspects of public health, the making available on the market or putting into service of a device or a specific category or group of devices should be prohibited, restricted or made subject to particular requirements or that such device or category or group of devices should be withdrawn from the market or recalled, it may take any necessary and justified measures.	
881.	2. The Member State shall immediately notify the Commission and all other Member States, giving the reasons for its decision, by means of the electronic system referred to in Article 66.	2. The Member State shall immediately notify the Commission and all other Member States, giving the reasons for its decision, by means of the electronic system referred to in Article 66.	2. The Member State shall immediately notify the Commission and all other Member States, giving the reasons for its decision, by means of the electronic system referred to in Article 73b.	
882.	3. The Commission shall assess the provisional national measures taken. The Commission shall decide, by means of implementing acts, whether the national measures are justified or not. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3). On duly justified imperative grounds of urgency relating to the health and safety of humans, the Commission may adopt immediately applicable implementing acts	3. The Commission shall assess the provisional national measures taken. The Commission shall decide, by means of implementing acts, whether the national measures are justified or not. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3). On duly justified imperative grounds of urgency relating to the health and safety of humans, the Commission may adopt immediately applicable implementing acts	3. The Commission, in consultation with the MDCG and, where necessary, the concerned economic operators, shall assess the national measures taken. The Commission may decide, by means of implementing acts, whether the national measures are justified or not. In the absence of a Commission decision the national measures shall be considered to be justified. Those implementing acts shall be adopted in accordance with the examination procedure referred to in	

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	in accordance with the procedure referred to in Article 84(4).	in accordance with the procedure referred to in Article 84(4).	Article 84(3).	
883.	4. Where the assessment referred to in paragraph 3 demonstrates that the making available on the market or putting into service of a device, specific category or group of devices should be prohibited, restricted or made subject to particular requirements or that such device or category or group of devices should be withdrawn from the market or recalled in all Member States in order to protect the health and safety of patients, users or other persons or other aspects of public health, the Commission shall be empowered to adopt delegated acts in accordance with Article 85 to take the necessary and duly justified measures. Where in this case imperative grounds of urgency so require, the procedure provided for in Article 86 shall apply to delegated acts adopted pursuant to this paragraph.	4. Where the assessment referred to in paragraph 3 demonstrates that the making available on the market or putting into service of a device, specific category or group of devices should be prohibited, restricted or made subject to particular requirements or that such device or category or group of devices should be withdrawn from the market or recalled in all Member States in order to protect the health and safety of patients, users or other persons or other aspects of public health, the Commission shall be empowered to adopt delegated acts in accordance with Article 85 to take the necessary and duly justified measures. Where in this case imperative grounds of urgency so require, the procedure provided for in Article 86 shall apply to delegated acts adopted pursuant to this paragraph.	4. Where the assessment referred to in paragraph 3 demonstrates that the making available on the market or putting into service of a device, specific category or group of devices should be prohibited, restricted or made subject to particular requirements or that such device or category or group of devices should be withdrawn from the market or recalled in all Member States in order to protect the health and safety of patients, users or other persons or other aspects of public health, the Commission may adopt implementing acts in accordance with the examination procedure referred to in Article 84(3) to take the necessary and duly justified measures.	
884.	**Article 73** **Good administrative practice**	**Article 73** **Good administrative practice**	**Article 73** **Good administrative practice**	
885.	1. Any measure adopted by the competent authorities of the Member States pursuant to Articles 68 to 72 shall state the exact grounds on which it is based. Where it is addressed to a specific economic operator, it shall be notified without delay to the economic operator concerned, who shall at the same time be informed of the remedies available to him under the law of the Member State concerned and of the	1. Any measure adopted by the competent authorities of the Member States pursuant to Articles 68 to 72 shall state the exact grounds on which it is based. Where it is addressed to a specific economic operator, it shall be notified without delay to the economic operator concerned, who shall at the same time be informed of the remedies available to him under the law of the Member State concerned and of the	1. Any measure adopted by the competent authorities of the Member States pursuant to Articles 68 to 72 shall state the exact grounds on which it is based. Where it is addressed to a specific economic operator, it shall be notified without delay to the economic operator concerned, who shall at the same time be informed of the remedies available to him under the law or the administrative	

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	time limits to which such remedies are subject. Where the measure is of general scope, it shall be appropriately published.	time limits to which such remedies are subject. Where the measure is of general scope, it shall be appropriately published.	practice of the Member State concerned and of the time limits to which such remedies are subject. Where the measure is of general scope, it shall be appropriately published.	
886.	2. Except in cases where immediate action is necessary for reasons of serious risk to human health or safety, the economic operator concerned shall be given the opportunity to make submissions to the competent authority within an appropriate period of time before any measure is adopted. If action has been taken without the economic operator's being heard, he shall be given the opportunity to make submissions as soon as possible and the action taken shall be reviewed promptly thereafter.	2. Except in cases where immediate action is necessary for reasons of serious risk to human health or safety, the economic operator concerned shall be given the opportunity to make submissions to the competent authority within an appropriate period of time before any measure is adopted. If action has been taken without the economic operator's being heard, he shall be given the opportunity to make submissions as soon as possible and the action taken shall be reviewed promptly thereafter.	2. Except in cases where immediate action is necessary for reasons of serious risk to human health or safety, the economic operator concerned shall be given the opportunity to make submissions to the competent authority within an appropriate period of time before any measure is adopted. If action has been taken without the economic operator’s being heard, he shall be given the opportunity to make submissions as soon as possible and the action taken shall be reviewed promptly thereafter.	
887.	3. Any measure adopted shall be immediately withdrawn or amended upon the economic operator's demonstrating that he has taken effective corrective action.	3. Any measure adopted shall be immediately withdrawn or amended upon the economic operator's demonstrating that he has taken effective corrective action.	3. Any measure adopted shall be immediately withdrawn or amended upon the economic operator’s demonstrating that he has taken effective corrective action and that the device is in compliance with the requirements of this Regulation.	
888.	4. Where a measure adopted pursuant to Articles 68 to 72 concerns a product for which a notified body has been involved in the conformity assessment, the competent authorities shall inform the relevant notified body of the measure taken.	4. Where a measure adopted pursuant to Articles 68 to 72 concerns a product for which a notified body has been involved in the conformity assessment, the competent authorities shall inform the relevant notified body of the measure taken.	4. Where a measure adopted pursuant to Articles 68 to 72 concerns a product for which a notified body has been involved in the conformity assessment, the competent authorities shall by means of the electronic system referred to in Article 73b inform the relevant notified body and the authority responsible for the notified body of the measure taken.	
889.	**Chapter VIII**	**Chapter IX**	**Chapter VIII**	

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	Cooperation between Member States, Medical Device Coordination Group, EU reference laboratories, device registers	**Cooperation between Member States, Medical Device Coordination Group, Medical Device Advisory Group, EU reference laboratories, device registers**	**Cooperation between Member States, Medical Device Coordination Group, EU reference laboratories, device registers**	
890.	**Article 74 Competent authorities**	**Article 74 Competent authorities**	**Article 74 Competent authorities**	
891.	1. The Member States shall designate the competent authority or authorities responsible for the implementation of this Regulation. They shall entrust their authorities with the powers, resources, equipment and knowledge necessary for the proper performance of their tasks pursuant to this Regulation. The Member States shall communicate the competent authorities to the Commission which shall publish a list of competent authorities.	1. The Member States shall designate the competent authority or authorities responsible for the implementation of this Regulation. They shall entrust their authorities with the powers, resources, equipment and knowledge necessary for the proper performance of their tasks pursuant to this Regulation. The Member States shall communicate the competent authorities to the Commission which shall publish a list of competent authorities.	1. The Member States shall designate the competent authority or authorities responsible for the implementation of this Regulation. They shall entrust their authorities with the powers, resources, equipment and knowledge necessary for the proper performance of their tasks pursuant to this Regulation. The Member States shall communicate the names and contact details of the competent authorities to the Commission which shall publish a list of competent authorities.	No significant change
892.	2. For the implementation of Articles 48 to 58, the Member States may designate a national contact point other than a national authority. In this case, references to a competent authority in this Regulation shall be understood as including the national contact point.	2. For the implementation of Articles 48 to 58, the Member States may designate a national contact point other than a national authority. In this case, references to a competent authority in this Regulation shall be understood as including the national contact point.		Deleted – MS will not use this provision.
893.	**Article 75 Cooperation**	**Article 75 Cooperation**	**Article 75 Cooperation**	
894.	1. The competent authorities of the Member States shall cooperate with each other and with the Commission and exchange with each other the information	1. The competent authorities of the Member States shall cooperate with each other and with the Commission and exchange with each other the information	1. The competent authorities of the Member States shall cooperate with each other and with the Commission which shall provide for the organisation of exchanges	No significant change

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	necessary to enable this Regulation to be applied uniformly.	necessary to enable this Regulation to be applied uniformly.	of information necessary to enable this Regulation to be applied uniformly.	
895.	2. Member States and the Commission shall participate in initiatives developed at international level with the aim of ensuring cooperation between regulatory authorities in the field of medical devices.	2. Member States and the Commission shall participate in initiatives developed at international level with the aim of ensuring cooperation between regulatory authorities in the field of medical devices.	2. Member States shall with the support of the Commission participate, where appropriate**,** in initiatives developed at international level with the aim of ensuring cooperation between regulatory authorities in the field of medical devices.	
896.	**Article 76** **Medical Device Coordination Group**	**Article 76** **Medical Device Coordination Group**	**Article 76** **Medical Device Coordination Group**	
897.	The Medical Device Coordination Group (MDCG) established in accordance with the conditions and modalities defined in Article 78 of Regulation (EU) [Ref. of future Regulation on medical devices] shall carry out, with the support of the Commission as provided in Article 79 of that Regulation, the tasks assigned to it by this Regulation.	The Medical Device Coordination Group (MDCG) established in accordance with the conditions and modalities defined in Article 78 of Regulation (EU) [Ref. of future Regulation on medical devices] shall carry out, with the support of the Commission as provided in Article 79 of that Regulation, the tasks assigned to it by this Regulation.	The Medical Device Coordination Group (MDCG) established in accordance with the conditions and modalities defined in Article 78 and 82 of Regulation (EU) [Ref. of future Regulation on medical devices] shall carry out, with the support of the Commission as provided in Article 79 of that Regulation, the tasks assigned to it by this Regulation.	No significant change
898.		**Article 76a** **Medical Device Advisory Committee**		

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899.		The Medical Device Advisory Committee (MDAC) established in accordance with the conditions and modalities defined in Article 78a of Regulation EU) [Ref. of future Regulation on medical devices] shall carry out, with the support of the Commission the tasks assigned to it by this Regulation.		
900.		**Article 76b** **Assessment Committee for Medical Devices**		
901.		An ACMD is hereby established, under the priciples of highest scientific competence, impartiality, transparency and to avoid potential conflicts of interest. When undertaking a clinical assessment for a specific device, the ACMD shall be composed of: A minimum of 5 clinical experts in the field of which a clinical assessment and recommendation have been requested; One representative of the EMA; One representative of the Commission;		

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		One representative of patients 'organisation appointed by the Commission in a transparent manner after a call for interest, for a three-year term which may be renewed. The ACMD shall meet on request from the MDCG and Commission, and its meetings shall be chaired by a Commission representative. The Commission shall ensure that the composition of the ACMD corresponds to the expertise needed for the purpose of its clinical assessment and recommendation. The Commission shall be responsible for providing the secretariat of this Committee. 3. The Commission shall establish a pool of clinical experts in the medical fields relevant to in vitro diagnostic medical devices being assessed by the ACMD. In order to undertake the clinical assessment and recommendation procedure, each Member State may propose on expert, following a Union-wide call for expression of interest with a clear definition by the Commission of the requested profile. The publication of the call shall be widely advertised. Each expert shall be approved by the Commission and listed for a three-year		

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		term which may be renewed. The Members of the ACMD shall be chosen for their competence and experience in the corresponding field. They shall perform their tasks with impartiality and objectivity. They shall be completely independent and shall neither seek nor take instructions from any government, notified body or manufacturer. Each member shall draw up a declaration of interests which shall be made publicly available. In the light of technical progress and any information which may become available, the Commission shall be empowered to adopt delegated acts in accordance with Article 85 amending or supplementing the fields referred to in the first subparagraph of this paragraph. 4. The ACMD shall fulfil the tasks defined in Article 44a. When adopting its clinical assessment and recommendation, the members of the ACMD shall use their best endeavours to reach consensus. If consensus cannot be reached, the ACMD shall device by the majority of their members. Any diverging opinion shall be annexed to the ACMD opinion. 5. The ACMD shall establish its rules of procedure which shall, in particular, lay		

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		down procedures for the following: - the adoption of opinions, including in case of urgency; - the delegation of tasks to reporting and co-reporting members		
902.	**Article 77** **Tasks of the MDCG**		**Article 77** **Tasks of the MDCG**	
903.	The MDCG shall have the following tasks:	The MDCG shall have the following tasks:	The MDCG shall have the following tasks:	No significant change
904.		(-a) to provide regulatory opinion on the basis of a scientific assessment on certain types of in vitro diagnostic medical devices pursuant to Article 44a;		
905.	(a) to contribute to the assessment of applicant conformity assessment bodies and notified bodies pursuant to the provisions set out in Chapter IV;	(a) to contribute to the assessment of applicant conformity assessment bodies and notified bodies pursuant to the provisions set out in Chapter IV;	(a) to contribute to the assessment of applicant conformity assessment bodies and notified bodies pursuant to the provisions set out in Chapter IV;	
906.		(aa) to establish and document the high level principles of competence and qualification and procedures for selection and authorisation of persons involved in conformity assessment activities (knowledge, experience and other competence required) and the required training (initial and ongoing). The qualification criteria shall address the various functions within the conformity assessment process as well as the devices, technologies and areas covered by the scope of designation.		

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907.		(ab) to review and approve the criteria of the competent authorities of Member States in respect of Article 77(1)(ab)		
908.		(ac) to oversee the coordination group of Notified Bodies as specified in Article 37;		
909.	(b) to contribute to the scrutiny of certain conformity assessments pursuant to Article 42;	(ad) to support the Commission in providing an overview of vigilance data and market surveillance activities, including any preventive health protection measures taken, on a 6-monthly basis. This information shall be accessible through the European databank in Article 25.	(b) to contribute to the scrutiny of certain conformity assessments pursuant to Article 42;	
910.	(c) to contribute to the development of guidance aimed at ensuring effective and harmonised implementation of this Regulation, in particular regarding the designation and monitoring of notified bodies, application of the general safety and performance requirements and conduct of the clinical evaluation by manufacturers and the assessment by notified bodies;	(c) to contribute to the development of guidance aimed at ensuring effective and harmonised implementation of this Regulation, in particular regarding the designation and monitoring of notified bodies, application of the general safety and performance requirements and conduct of the clinical evaluation by manufacturers and the assessment by notified bodies;	(c) to contribute to the development of guidance aimed at ensuring effective and harmonised implementation of this Regulation, in particular regarding the designation and monitoring of notified bodies, application of the general safety and performance requirements and conduct of the clinical evaluation by manufacturers, the assessment by notified bodies and the vigilance activities;	
911.			(ca) to contribute to the to the continuous monitoring of the technical progress and assessment whether the general safety and performance requirements in this Regulation and Regulation (EU) No […/…] [on medical devices] are appropriate to ensure safety and performance of in vitro diagnostic medical devices and identify the need to amend Annex I;	New requirements CS development (case today) – continuous monitoring of technical progress – complex.

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			(cb) to contribute to the development of in vitro diagnostic medical devices standards and of Common Specifications;	
912.	(a) to assist the competent authorities of the Member States in their coordination activities in the fields of clinical performance studies, vigilance and market surveillance;	(d) to assist the competent authorities of the Member States in their coordination activities in the fields of clinical performance studies, vigilance and market surveillance;	(d) to assist the competent authorities of the Member States in their coordination activities in particular in the fields of classification and regulatory status of in vitro diagnostic medical devices, clinical performance studies, vigilance and market surveillance including the development and maintenance of a framework for a European market surveillance program with the objective of efficiency and harmonisation of market surveillance in the European Union, in accordance with Article 65;	Market surveillance coordination and classification decisions ran by the MDCG.
913.	(b) to provide advice and assist the Commission, at its request, in its assessment of any issue related to the implementation of this Regulation;	(e) to provide advice and assist the Commission, at its request, in its assessment of any issue related to the implementation of this Regulation;	(e) to provide advice, either on its own initiative or at its request of the Commission, in the assessment of any issue related to the implementation of this Regulation;	Own initiative in providing advice
914.	(c) to contribute to harmonised administrative practice with regard to in vitro diagnostic medical devices in the Member States.	(f) to contribute to harmonised administrative practice with regard to in vitro diagnostic medical devices in the Member States.	(f) to contribute to harmonised administrative practice with regard to in vitro diagnostic medical devices in the Member States.	No change
915.	**Article 78 European Union reference laboratories**	**Article 78 European Union reference laboratories**	**Article 78 European Union reference laboratories**	
916.	1. For specific devices, or a category or group of devices, or for specific hazards related to a category or group of devices, the Commission may designate, by means of implementing acts, one or more European Union reference laboratories,	1. For specific devices, or a category or group of devices, or for specific hazards related to a category or group of devices, the Commission may designate, by means of implementing acts, one or more European Union reference laboratories,	1. For specific devices, or a category or group of devices, or for specific hazards related to a category or group of devices, the Commission may designate, by means of implementing acts, one or more European Union reference laboratories,	No change

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	hereinafter referred to as 'EU reference laboratories', that satisfy the criteria set out in paragraph 3. The Commission shall only designate laboratories for which a Member State or the Commission's Joint Research Centre have submitted an application for designation.	hereinafter referred to as 'EU reference laboratories', that satisfy the criteria set out in paragraph 3. The Commission shall only designate laboratories for which a Member State or the Commission's Joint Research Centre have submitted an application for designation.	hereinafter referred to as 'EU reference laboratories', that satisfy the criteria set out in paragraph 3. The Commission shall only designate laboratories for which a Member State or the Commission's Joint Research Centre have submitted an application for designation.	
917.	2. Within the scope of their designation, the EU reference laboratories shall, where appropriate, have the following tasks:	2. Within the scope of their designation, the EU reference laboratories shall, where appropriate, have the following tasks:	2. Within the scope of their designation, the EU reference laboratories shall, where appropriate, have the following tasks:	No change
918.	(a) to verify compliance of class D devices with the applicable CTS, when available, or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent, as provided for in the second subparagraph of Article 40(2);	(a) to verify compliance of class D devices with the applicable CTS, when available, or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent, as provided for in the second subparagraph of Article 40(2);	(a) to verify compliance of class D devices with the applicable CS;	No significant change
919.	(b) to carry out appropriate tests on samples of manufactured class D devices or batches of class D devices, as provided for in the Section 5.7 of Annex VIII and in Section 5.1 of Annex X;	(b) to carry out appropriate laboratory tests on samples of manufactured class D devices on request of competent authorities on samples collected during market surveillance activities under Article 65 and of notified bodies on samples collected during unannounced inspections under Annex VIII section 4.4;	(b) to carry out appropriate tests on samples of manufactured class D devices or batches of class D devices, as provided for in the Section 5.7 of Annex VIII and in Section 5.1 of Annex X;	No change
920.	(c) to provide scientific and technical assistance to the Commission, the Member States and notified bodies in relation to the implementation of this Regulation;	(c) to provide scientific and technical assistance to the Commission, the Member States and notified bodies in relation to the implementation of this Regulation;	(c) to provide scientific and technical assistance to the Commission, the MDCG**,** the Member States and notified bodies in relation to the implementation of this Regulation;	No significant change
921.	(d) to provide scientific advice regarding the state of the art in relation to	(d) to provide scientific advice and technical assistance regarding the	(d) to provide scientific advice regarding the state of the art in relation to	No change

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	specific devices, or a category or group of devices;	definition of the state of the art in relation to specific devices, or a category or group of devices;	specific devices, or a category or group of devices;	
922.	(e) to set up and manage a network of national reference laboratories and publish a list of the participating national reference laboratories and their respective tasks;	(e) to set up and manage a network of national reference laboratories and publish a list of the participating national reference laboratories and their respective tasks;	(e) to set up and manage a network of national reference laboratories after consulting with the national authorities and publish a list of the participating national reference laboratories and their respective tasks;	No significant change
923.	(f) to contribute to the development of appropriate testing and analysis methods to be applied for conformity assessment procedures and market surveillance;	(f) to contribute to the development of appropriate testing and analysis methods to be applied for conformity assessment procedures and in particular for batch verification of class D devices and for market surveillance;	(f) to contribute to the development of appropriate testing and analysis methods to be applied for conformity assessment procedures and market surveillance;	No change
924.	(g) to collaborate with notified bodies in the development of best practices for the performance of conformity assessment procedures;	(g) to collaborate with notified bodies in the development of best practices for the performance of conformity assessment procedures;	(g) to collaborate with notified bodies in the development of best practices for the performance of conformity assessment procedures;	No change
925.	(h) to provide recommendations on suitable reference materials and reference measurement procedures of higher metrological order;	(h) to provide recommendations on suitable reference materials and reference measurement procedures of higher metrological order;	(h) to provide recommendations on suitable reference materials and reference measurement procedures of higher metrological order;	No change
926.	(i) to contribute to the development of standards at international level;	(i) to contribute to the development of standards at international level; to contribute to the development of common technical specifications (CTS) as well as of international standards	(i) to contribute to the development of standards at international level;	No change
927.	(j) to provide scientific opinions in response to consultations by notified bodies in accordance with this Regulation.	(j) to provide scientific opinions in response to consultations by notified bodies in accordance with this Regulation.	(j) to provide scientific opinions in response to consultations by notified bodies in accordance with this Regulation and publish them by electronic means	Opinions of Ref. Labs to be published (similar to SCENHIR?)

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			after consideration of national provisions on the respect of confidentiality.	
928.			2a. At the request of a Member State, the Commission may also designate EU reference laboratories where that Member State wishes to have recourse to such a laboratory to ensure the verification of the compliance of Class C devices with the applicable CS when available, or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent.	Will depend on use of CS for class C devices.
929.	3. EU reference laboratories shall satisfy the following criteria:	3. EU reference laboratories shall satisfy the following criteria:	3. EU reference laboratories shall satisfy the following criteria:	No change
930.	(a) to have appropriately qualified staff with adequate knowledge and experience in the field of the in vitro diagnostic medical devices for which they are designated;	(a) to have appropriately qualified staff with adequate knowledge and experience in the field of the in vitro diagnostic medical devices for which they are designated;	(a) to have adequate and appropriately qualified staff with adequate knowledge and experience in the field of the in vitro diagnostic medical devices for which they are designated;	No significant change
931.		appropriate knowledge and experience shall be based on (i) experience of assessing high-risk IVDs - experience of assessing high-risk IVDs and of carrying out the relevant laboratory tests; (ii) in-depth knowledge of high-risk in-vitro diagnostic medical devices and relevant technologies; (iii) proven laboratory experience in one of the following areas: testing or calibration laboratory, supervisory authority or		

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		institution, national reference laboratory for class D devices, quality control of in- vitro diagnostic medical devices, development of reference materials for IVDs, calibration of diagnostic medical devices; laboratories or blood banks which experimentally assess and use high-risk IVDs or, where applicable, manufacture them in-house (iv) knowledge and experience of product or batch testing, quality checks, design, manufacture and use of IVDs; (v) knowledge of the health risks faced by patients, their partners and recipients of blood/organ/tissue donations/preparations associated with the use and, in particular, malfunctioning of high-risk IVDs; (vi) knowledge of this Regulation and of applicable laws, rules and guidelines, knowledge of the Common Technical Specifications (CTS), applicable harmonized standards, product-specific requirements and relevant guidance documents; (vii) participation in relevant external and internal quality assessment schemes organised by international or national organisations.		
932.	(b) to possess the necessary equipment and reference material to carry out the tasks assigned to them;	(a) to possess the necessary equipment and reference material to carry out the tasks assigned to them;	(b) to possess the necessary equipment and reference material to carry out the tasks assigned to them;	No change
933.	(b) to have the necessary knowledge of international standards and best	(b) to have the necessary knowledge of international standards and best	(c) to have the necessary knowledge of international standards and best	No change

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	practices;	practices;	practices;	
934.	(c) to have an appropriate administrative organisation and structure;	(c) to have an appropriate administrative organisation and structure;	(d) to have an appropriate administrative organisation and structure;	No change
935.	(d) to ensure that their staff observe the confidentiality of the information and data obtained in carrying out their tasks;	(d) to ensure that their staff observe the confidentiality of the information and data obtained in carrying out their tasks;	(e) to ensure that their staff observe the confidentiality of the information and data obtained in carrying out their tasks;	No change
936.	(e) to act in the public interest and in an independent manner;	(e) to act in the public interest and in an independent manner;	(f) to act in the public interest and in an independent manner;	No change
937.	(f) to ensure that their staff do not have financial or other interests in the in vitro diagnostic medical device industry which could affect their impartiality, declare any other direct and indirect interests they may have in the in vitro diagnostic medical device industry and update this declaration whenever a relevant change occurs.	(f) to ensure that their staff do not have financial or other interests in the in vitro diagnostic medical device industry which could affect their impartiality, declare any other direct and indirect interests they may have in the in vitro diagnostic medical device industry and update this declaration whenever a relevant change occurs.	(g) to ensure that their staff do not have financial or other interests in the in vitro diagnostic medical device industry which could affect their impartiality, declare any other direct and indirect interests they may have in the in vitro diagnostic medical device industry and update this declaration whenever a relevant change occurs.	No change
938.			3a. The network of European Union reference laboratories shall satisfy the following criteria and the reference laboratories in the network shall coordinate and harmonise their working methods as regards testing and assessment. This involves: (a) applying coordinated methods, procedures and processes; (b) agreeing on the use of same reference materials and common test samples and seroconversion panels; (c) establishing and common assessment and interpretation criteria; (d) using common testing protocols and assessing the test results using	**New – coordination between reference labs. Important to point out the reassessment of the state of the art.**

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			standardised and coordinated evaluation methods; (e) using standardised and coordinated test reports; (f) developing, applying and maintaining a peer review system; (g) organizing regular quality assessment tests (including mutual checks on the quality and comparability of test results); (h) agreeing on joint guidelines, instructions, procedural instructions or standard operational procedures (SOPs); (i) coordinating the introduction of testing methods for new technologies and according to new or amended CS; (j) reassessing the state of the art on the basis of comparative test results or by further studies, as requested by the Commission or a Member State;	
939.	4. EU reference laboratories may be granted a Union financial contribution. The Commission may adopt, by means of implementing acts, the modalities and the amount of the grant of a Union financial contribution to EU reference laboratories, taking into account the objectives of protection of health and safety, support of innovation and cost-effectiveness. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).	4. EU reference laboratories may be granted a Union financial contribution. The Commission may adopt, by means of implementing acts, the modalities and the amount of the grant of a Union financial contribution to EU reference laboratories, taking into account the objectives of protection of health and safety, support of innovation and cost-effectiveness. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).	4. EU reference laboratories may be granted a Union financial contribution. The Commission may adopt, by means of implementing acts, the modalities and the amount of the grant of a Union financial contribution to EU reference laboratories, taking into account the objectives of protection of health and safety, support of innovation and cost-effectiveness. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 84(3).	No change
940.	5. Where notified bodies or Member States request scientific or technical assistance or a scientific opinion from an EU reference laboratory, they may be	5. Where notified bodies or Member States request scientific or technical assistance or a scientific opinion from an EU reference laboratory, they shall be	5. Where notified bodies or Member States request scientific or technical assistance or a scientific opinion from an EU reference laboratory, they may be	No change

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	required to pay fees to wholly or partially cover the costs incurred by that laboratory in carrying out the requested task according to a set of predetermined and transparent terms and conditions.	required to pay fees to wholly or partially cover the costs incurred by that laboratory in carrying out the requested task according to a set of predetermined and transparent terms and conditions.	required to pay fees to wholly or partially cover the costs incurred by that laboratory in carrying out the requested task according to a set of predetermined and transparent terms and conditions.	
941.	6. The Commission shall be empowered to adopt delegated acts in accordance with Article 85 for the following purposes: (a) amending or supplementing the tasks of EU reference laboratories referred to in paragraph 2 and the criteria to be satisfied by EU reference laboratories referred to in paragraph 3. (b) setting out the structure and the level of the fees referred to in paragraph 5 which may be levied by an EU reference laboratory for providing scientific opinions in response to consultations by notified bodies in accordance with this Regulation, taking into account the objectives of protection of human health and safety, support of innovation and cost-effectiveness.	6. The Commission shall be empowered to adopt delegated acts in accordance with Article 85 for the following purposes: (c) amending or supplementing the tasks of EU reference laboratories referred to in paragraph 2 and the criteria to be satisfied by EU reference laboratories referred to in paragraph 3. (d) setting out the structure and the level of the fees referred to in paragraph 5 which may be levied by an EU reference laboratory for providing scientific opinions in response to consultations by notified bodies in accordance with this Regulation, taking into account the objectives of protection of human health and safety, support of innovation and cost-effectiveness.	6. The Commission shall specify, by means of implementing acts in accordance with Article 84: (a) detailed rules to facilitate the application of paragraph 2 and detailed rules to ensure compliance with the criteria referred to in paragraph 3. (b) setting out the structure and the level of the fees referred to in paragraph 5 which may be levied by an EU Reference Laboratory for providing scientific opinions in response to consultations by notified bodies and Member States in accordance with this Regulation, taking into account the objectives of protection of human health and safety, support of innovation and cost-effectiveness.	No significant change
942.	7. EU reference laboratories shall be subject to controls, including on-site visits and audits, by the Commission to verify compliance with the requirements of this Regulation. If these controls find that a laboratory is not complying with those requirements for which they have been designated, the Commission, by means of implementing acts, shall take appropriate measures, including the withdrawal of the designation.	7. EU reference laboratories shall be subject to controls, including on-site visits and audits, by the Commission to verify compliance with the requirements of this Regulation. If these controls find that a laboratory is not complying with those requirements for which they have been designated, the Commission, by means of implementing acts, shall take appropriate measures, including the withdrawal of the designation.	7. EU reference laboratories shall be subject to controls, including on-site visits and audits, by the Commission to verify compliance with the requirements of this Regulation. If these controls find that a laboratory is not complying with those requirements for which they have been designated, the Commission, by means of implementing acts**,** shall take appropriate measures, including the restriction, suspension or withdrawal of the designation.	No significant change

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943.	**Article 79** **Device registers**	**Article 79** **Device registers**	**Article 79** **Device registers and data banks**	
944.	The Commission and the Member States shall take all appropriate measures to encourage the establishment of registers for specific types of devices to gather post-market experience related to the use of such devices. Such registers shall contribute to the independent evaluation of the long-term safety and performance of devices.	The Commission and the Member States shall take all appropriate measures to ensure the establishment of registers for in vitro diagnostic devices to gather postmarket experience related to the use of such devices. Registers for class C and D shall be systematically established. Such registers shall contribute to the independent evaluation of the long-term safety and performance of devices	The Commission and the Member States shall take all appropriate measures to encourage the establishment of registers and data banks for specific types of devices setting common principles to collect comparable information. Such registers and data banks shall contribute to the independent evaluation of the long-term safety and performance of devices.	Changes are not significant. Registers are still not relevant for IVDs however.
945.	**Chapter IX** **Confidentiality, data protection, funding, penalties**	**Chapter X** **Confidentiality, data protection, funding, penalties**	**Chapter IX** **Confidentiality, data protection, funding, penalties**	
946.	**Article 80** **Confidentiality**	**Article 80** **Confidentiality**	**Article 80** **Confidentiality**	
947.	1. Unless otherwise provided in this Regulation and without prejudice to existing national provisions and practices in the Member States on medical confidentiality, all parties involved in the application of this Regulation shall respect the confidentiality of information and data obtained in carrying out their tasks in order to protect the following: (a) personal data in compliance with Directive 95/46/EC and Regulation (EC) No 45/2001; (b) commercial interests of a natural or legal person, including intellectual property rights; (c) the effective implementation of this	1. Unless otherwise provided in this Regulation and without prejudice to existing national provisions and practices in the Member States on medical confidentiality, all parties involved in the application of this Regulation shall respect the confidentiality of information and data obtained in carrying out their tasks in order to protect the following: (d) personal data in compliance with Directive 95/46/EC and Regulation (EC) No 45/2001; (e) commercial interests of a natural or legal person, including intellectual property rights; (f) the effective implementation of this	1. Unless otherwise provided in this Regulation and without prejudice to existing national provisions and practices in the Member States on confidentiality, all parties involved in the application of this Regulation shall respect the confidentiality of information and data obtained in carrying out their tasks in order to protect the following: (a) personal data in compliance with Article 81; (b) commercial interests and trade secrets of a natural or legal person, including intellectual property rights unless disclosure is necessary for reasons of public health;	Significantly – includes concept of trade secrets (not defined or used in the EU acquis) and disclosure of information for reasons of public health.

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	Regulation, in particular for the purpose of inspections, investigations or audits.	Regulation, in particular for the purpose of inspections, investigations or audits.	(c) the effective implementation of this Regulation, in particular for the purpose of inspections, investigations or audits.	
948.	2. Without prejudice to paragraph 1, information exchanged between competent authorities and between competent authorities and the Commission on condition of confidentiality shall remain confidential unless the originating authority has agreed to its disclosure.	2. Without prejudice to paragraph 1, information exchanged between competent authorities and between competent authorities and the Commission on condition of confidentiality shall remain confidential unless the originating authority has agreed to its disclosure.	2. Without prejudice to paragraph 1, information exchanged between competent authorities and between competent authorities and the Commission on condition of confidentiality shall shall not be disclosed without prior consultation with the originating authority.	No significant change [Typo in Council text]
949.	3. Paragraphs 1 and 2 shall not affect the rights and obligations of the Commission, Member States and notified bodies with regard to exchange of information and the dissemination of warnings, nor the obligations of the persons concerned to provide information under criminal law.	3. Paragraphs 1 and 2 shall not affect the rights and obligations of the Commission, Member States and notified bodies with regard to exchange of information and the dissemination of warnings, nor the obligations of the persons concerned to provide information under criminal law.	3. Paragraphs 1 and 2 shall not affect the rights and obligations of the Commission, Member States and notified bodies with regard to exchange of information and the dissemination of warnings, nor the obligations of the persons concerned to provide information under criminal law.	No change
950.	4. The Commission and Member States may exchange confidential information with regulatory authorities of third countries with which they have concluded bilateral or multilateral confidentiality arrangements.	4. The Commission and Member States may exchange confidential information with regulatory authorities of third countries with which they have concluded bilateral or multilateral confidentiality arrangements.	4. The Commission and Member States may exchange confidential information with regulatory authorities of third countries with which they have concluded bilateral or multilateral confidentiality arrangements.	No change
951.	**Article 81** **Data protection**	**Article 81** **Data protection**	**Article 81** **Data protection**	
952.	1. Member States shall apply Directive 95/46/EC to the processing of personal data carried out in the Member States pursuant to this Regulation.	1. Member States shall apply Directive 95/46/EC to the processing of personal data carried out in the Member States pursuant to this Regulation.	1. Member States shall apply Directive 95/46/EC to the processing of personal data carried out in the Member States pursuant to this Regulation.	No change
953.	2. Regulation (EC) No 45/2001 shall apply	2. Regulation (EC) No 45/2001 shall apply	2. Regulation (EC) No 45/2001 shall	No change

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	to the processing of personal data carried out by the Commission pursuant to this Regulation.	to the processing of personal data carried out by the Commission pursuant to this Regulation.	apply to the processing of personal data carried out by the Commission pursuant to this Regulation.	
954.	**Article 82 Levy of fees**	**Article 82 Levy of fees**	**Article 82 Levy of fees**	
955.	This Regulation shall be without prejudice to the possibility for Member States to levy fees for the activities set out in this Regulation, provided that the level of the fees is set in a transparent manner and on the basis of cost recovery principles.	This Regulation shall be without prejudice to the possibility for Member States to levy fees for the activities set out in this Regulation, provided that the level of the fees is comparable and set in a transparent manner and on the basis of cost recovery principles.	1. This Regulation shall be without prejudice to the possibility for Member States to levy fees for the activities set out in this Regulation, provided that the level of the fees is set in a transparent manner and on the basis of cost recovery principles.	No change
956.	They shall inform the Commission and the other Member States at least three months before the structure and level of fees is to be adopted.		2. Member States shall inform the Commission and the other Member States at least three months before the structure and level of fees is to be adopted.	No significant change
957.	**Article 83 Penalties**	**Article 83 Penalties**	**Article 83 Penalties**	
958.	The Member States shall lay down the provisions on penalties applicable for infringement of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate, and dissuasive. The Member States shall notify those provisions to the Commission by [3 months prior to the date of application of this Regulation] and shall notify it without delay of any subsequent amendment affecting them.	The Member States shall lay down the provisions on penalties applicable for infringement of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate, and dissuasive. The dissuasive nature of the penalty shall be determined in relation to the financial benefit obtained as a result of the infringement .The Member States shall notify those provisions to the Commission by [3 months prior to the date of	The Member States shall lay down the provisions on penalties applicable for infringement of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate, and dissuasive. The Member States shall notify those provisions to the Commission by [3 months prior to the date of application of the Regulation] and shall notify it without delay of any subsequent amendment affecting them.	No change

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		application of this Regulation] and shall notify it without delay of any subsequent amendment affecting them.		
959.	**Chapter X Final provisions**	**Chapter XI Final provisions**	**Chapter X Final provisions**	
960.	**Article 84 Committee procedure**	**Article 84 Committee procedure**	**Article 84 Committee procedure**	
961.	1. The Commission shall be assisted by the Committee on Medical Devices set up by Article 88 of Regulation (EU) [Ref. of future Regulation on medical devices].	1. The Commission shall be assisted by the Committee on Medical Devices set up by Article 88 of Regulation (EU) [Ref. of future Regulation on medical devices].	1. The Commission shall be assisted by the Committee on Medical Devices set up by Article 88 of Regulation (EU) [Ref. of future Regulation on medical devices].	No change
962.	2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.	2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.	2. Where reference is made to this paragraph, Article 4 of Regulation (EU) No 182/2011 shall apply.	No change
963.	3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.	3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.	3. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply. Where the committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.	Blocking power of inaction to the committee…
964.	4. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 4 or Article 5, as appropriate, shall apply.	4. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 4 or Article 5, as appropriate, shall apply.	4. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 4 or Article 5, as appropriate, shall apply.	No change
965.	**Article 85 Exercise of the delegation**	**Article 85 Exercise of the delegation**	**Article 85 Exercise of the delegation**	

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966.	1. The power to adopt the delegated acts referred to in Articles 4(6), 8(2), 15(4), 22(7), 23(7), 27(2), 38(2), 39(4), 40(10), 43(5), 49(7), 51(3), 72(4) and 78(6) is conferred on the Commission subject to the conditions laid down in this Article.	1. The power to adopt the delegated acts referred to in Articles 4(6), 8(2), 15(4), 22(7), 23(7), 27(2), 38(2), 39(4), 40(10), 43(5), 49(7), 51(3), 72(4) and 78(6) is conferred on the Commission subject to the conditions laid down in this Article.	1. The power to adopt the delegated acts referred to in Articles 4(6), 8(2), 15(4), 22(7a), 40(10), 43(5), and 78a(10) is conferred on the Commission subject to the conditions laid down in this Article. When adopting those delegated acts, the Commission shall follow its usual practice and carry out consultations with experts, including Member States' experts.	**Introduces obligation of consultation with experts in the development of delegated acts – include consultation with industry?**
967.	2. The delegation of power referred to in Articles 4(6), 8(2), 15(4), 22(7), 23(7), 27(2), 38(2), 39(4), 40(10), 43(5), 49(7), 51(3), 72(4) and 78(6) shall be conferred on the Commission for an indeterminate period of time from the date of entry into force of this Regulation.	2. The delegation of power referred to in Articles 4(6), 8(2), 15(4), 22(7), 23(7), 27(2), 38(2), 39(4), 40(10), 43(5), 49(7), 51(3), 72(4) and 78(6) shall be conferred on the Commission for an indeterminate period of time from the date of entry into force of this Regulation.	2. The delegation of power referred to in Articles 4(6), 8(2), 15(4), 22(7a), 40(10), 43(5), and 78a(10)shall be conferred on the Commission for a period of five years from the date of entry into force of this Regulation. The Commission shall draw up a report in respect of the delegated powers not later than six months before the end of the five year period. The delegation of powers shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.	**Delegated powers can be revoked by parliament of council?**
968.	3. The delegation of power referred to in Articles 4(6), 8(2), 15(4), 22(7), 23(7), 27(2), 38(2), 39(4), 40(10), 43(5), 49(7), 51(3), 72(4) and 78(6) may be revoked at any time by the European Parliament or by the Council. A decision of revocation shall put an end to the delegation of the power specified in that decision. It shall take effect the day following its publication in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts	3. The delegation of power referred to in Articles 4(6), 8(2), 15(4), 22(7), 23(7), 27(2), 38(2), 39(4), 40(10), 43(5), 49(7), 51(3), 72(4) and 78(6) may be revoked at any time by the European Parliament or by the Council. A decision of revocation shall put an end to the delegation of the power specified in that decision. It shall take effect the day following its publication in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts	3. The delegation of power referred to in Articles 4(6), 8(2), 15(4), 22(7a), 40(10), 43(5), and 78a(10) may be revoked at any time by the European Parliament or by the Council. A decision of revocation shall put an end to the delegation of the power specified in that decision. It shall take effect the day following its publication in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already	No significant change

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	already in force.	already in force.	in force.	
969.	4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.	4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.	4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.	No change
970.	5. A delegated act adopted pursuant to any of the Articles listed in paragraph 1 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period may be extended by two months at the initiative of the European Parliament or the Council.	5. A delegated act adopted pursuant to any of the Articles listed in paragraph 1 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period may be extended by two months at the initiative of the European Parliament or the Council.	5. A delegated act adopted pursuant to any of the Articles listed in paragraph 1 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of three months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period may be extended by three months at the initiative of the European Parliament or the Council.	No significant change – council can extend notification timeline to a total of six months.
971.	**Article 86** **Urgency procedure for delegated acts**	**Article 86** **Urgency procedure for delegated acts**		**Urgency delegated acts deleted – this can be a problem in case of outbreaks.**
972.	1. Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act to the European Parliament and to the Council shall state the reasons for the use of the urgency procedure.	1. Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act to the European Parliament and to the Council shall state the reasons for the use of the urgency procedure.		
973.	2. Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to	2. Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to		

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	in Article 85. In such a case, the Commission shall repeal the act without delay following the notification of the decision to object by the European Parliament or the Council.	in Article 85. In such a case, the Commission shall repeal the act without delay following the notification of the decision to object by the European Parliament or the Council.		
974.			**Article 86a** **Separate delegated acts for different delegated powers**	
975.			The Commission shall adopt a separate delegated act in respect of each power delegated to it pursuant to this Regulation.	No significant change
976.	**Article 87** **Transitional provisions**	**Article 87** **Transitional provisions**	**Article 87** **Transitional provisions**	
977.	1. From the date of application of this Regulation any publication of a notification in respect of a notified body in accordance with Directive 98/79/EC shall become void.	1. From the date of application of this Regulation any publication of a notification in respect of a notified body in accordance with Directive 98/79/EC shall become void.	1. From the date of application of this Regulation any publication of a notification in respect of a notified body in accordance with Directive 98/79/EC shall become void.	No change
978.	2. Certificates issued by notified bodies in accordance with Directive 98/79/EC prior to the entry into force of this Regulation shall remain valid until the end of the period indicated on the certificate, except for certificates issued in accordance with Annex VI of Directive 98/79/EC which shall become void at the latest two years after the date of application of this Regulation. Certificates issued by notified bodies in accordance with Directive 98/79/EC after the entry into force of this Regulation shall become void at the latest two years after the date of application of this Regulation.	2. Certificates issued by notified bodies in accordance with Directive 98/79/EC prior to the entry into force of this Regulation shall remain valid until the end of the period indicated on the certificate, except for certificates issued in accordance with Annex VI of Directive 98/79/EC which shall become void at the latest two years after the date of application of this Regulation. Certificates issued by notified bodies in accordance with Directive 98/79/EC after the entry into force of this Regulation shall become void at the latest two years after the date of application of this Regulation.	2. Certificates issued by notified bodies in accordance with Directive 98/79/EC prior to the entry into force of this Regulation shall remain valid until the end of the period indicated on the certificate, except for certificates issued in accordance with Annex VI of Directive 98/79/EC which shall become void at the latest two years after the date of application of this Regulation. Certificates issued by notified bodies in accordance with Directive 98/79/EC after the entry into force of this Regulation shall become void at the latest two years after	No change

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			the date of application of this Regulation.	
979.	3. By way of derogation from Directive 98/79/EC, devices which comply with this Regulation may be placed on the market before its date of application.	3. By way of derogation from Directive 98/79/EC, devices which comply with this Regulation may be placed on the market before its date of application.	3. By way of derogation from Directive 98/79/EC, devices which comply with this Regulation may be placed on the market before its date of application.	No change
980.	4. By way of derogation from Directive 98/79/EC, conformity assessment bodies which comply with this Regulation may be designated and notified before its date of application. Notified bodies which are designated and notified in accordance with this Regulation may apply the conformity assessment procedures laid down in this Regulation and issue certificates in accordance with this Regulation before its date of application.	4. By way of derogation from Directive 98/79/EC, conformity assessment bodies which comply with this Regulation may be designated and notified before its date of application. Notified bodies which are designated and notified in accordance with this Regulation may apply the conformity assessment procedures laid down in this Regulation and issue certificates in accordance with this Regulation before its date of application.	4. By way of derogation from Directive 98/79/EC, conformity assessment bodies which comply with this Regulation may be designated and notified before its date of application. Notified bodies which are designated and notified in accordance with this Regulation may apply the conformity assessment procedures laid down in this Regulation and issue certificates in accordance with this Regulation before its date of application.	No change
981.	5. By way of derogation from Article 10 and points (a) and (b) of Article 12(1) of Directive 98/79/EC, manufacturers, authorised representatives, importers and notified bodies who, during the period from [date of application] until [18 months after date of application], comply with Article 23(2) and (3) and Article 43(4) of this Regulation shall be considered to comply with the laws and regulations adopted by Member States in accordance with Article 10 and points (a) and (b) of Article 12(1) of Directive 98/79/EC as specified in Commission Decision 2010/227/EU.	5. By way of derogation from Article 10 and points (a) and (b) of Article 12(1) of Directive 98/79/EC, manufacturers, authorised representatives, importers and notified bodies who, during the period from [date of application] until [18 months after date of application], comply with Article 23(2) and (3) and Article 43(4) of this Regulation shall be considered to comply with the laws and regulations adopted by Member States in accordance with Article 10 and points (a) and (b) of Article 12(1) of Directive 98/79/EC as specified in Commission Decision 2010/227/EU.	5. By way of derogation from Article 10 and points (a) and (b) of Article 12(1) of Directive 98/79/EC, manufacturers, authorised representatives, importers and notified bodies who, during the period from [date of application] until [18 months after date of application], comply with Article 23(2) and (3) and Article 43(4) of this Regulation shall be considered to comply with the laws and regulations adopted by Member States in accordance with Article 10 and points (a) and (b) of Article 12(1) of Directive 98/79/EC as specified in Commission Decision 2010/227/EU.	No change
982.	6. Authorisations granted by competent authorities of the Member States in accordance with Article 9(12) of Directive	6. Authorisations granted by competent authorities of the Member States in accordance with Article 9(12) of Directive	6. Authorisations granted by competent authorities of the Member States in accordance with Article 9(12) of	No change

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	98/79/EC shall keep the validity indicated in the authorisation.	98/79/EC shall keep the validity indicated in the authorisation.	Directive 98/79/EC shall keep the validity indicated in the authorisation.	
983.			7. Until the Commission in line with Article 24 (2) has designated the UDI assigning entities, GS1 AISBL, HIBCC and ICCBBA shall be considered as designated UDI assigning entities.	Interesting interim measure in line with GHTF
984.	**Article 88** **Evaluation**	**Article 88** **Evaluation**	**Article 88** **Evaluation**	
985.	No later than five years after the date of application, the Commission shall assess the application of this Regulation and establish an evaluation report on the progress towards achievement of the objectives of this Regulation including an assessment of resources required to implement this Regulation.	No later than five years after the date of application, the Commission shall assess the application of this Regulation and establish an evaluation report on the progress towards achievement of the objectives of this Regulation including an assessment of resources required to implement this Regulation.	No later than five years after the date of application, the Commission shall assess the application of this Regulation and establish an evaluation report on the progress towards achievement of the objectives of the Regulation including an assessment of resources required to implement this Regulation.	No significant change
986.	**Article 89** **Repeal**	**Article 89** **Repeal**	**Article 89** **Repeal**	
987.	Directive 98/79/EC of the European Parliament and of the Council is repealed with effect from [date of application of this Regulation] with the exception of Article 10 and points (a) and (b) of Article 12(1) of Directive 98/79/EC which are repealed with effect from [18 months after date of application]. References to the repealed Directive shall be understood as reference to this Regulation and shall be read in accordance with the correlation table laid	Directive 98/79/EC of the European Parliament and of the Council is repealed with effect from [date of application of this Regulation] with the exception of Article 10 and points (a) and (b) of Article 12(1) of Directive 98/79/EC which are repealed with effect from [18 months after date of application]. References to the repealed Directive shall be understood as reference to this Regulation and shall be read in accordance with the correlation table laid	Directive 98/79/EC of the European Parliament and of the Council is repealed with effect from [date of application of this Regulation] with the exception of Article 10 and points (a) and (b) of Article 12(1) of Directive 98/79/EC which are repealed with effect from [18 months after date of application]. References to the repealed Directive shall be understood as reference to this Regulation and shall be read in accordance with the correlation table laid	No change

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	down in Annex XIV.	down in Annex XIV.	down in Annex XIV.	
988.	**Article 90** **Entry into force and date of application**	**Article 90** **Entry into force and date of application**	**Article 90** **Entry into force and date of application**	
989.	1. This Regulation shall enter into force on the twentieth day after its publication in the Official Journal of the European Union.	1. This Regulation shall enter into force on the twentieth day after its publication in the Official Journal of the European Union.	1. This Regulation shall enter into force on the twentieth day after its publication in the Official Journal of the European Union.	No change
990.	2. It shall apply from [five years after entry into force].	2. It shall apply from [three years after entry into force].	2. It shall apply from [five years after entry into force].	**No change – support of a five year transition**
991.	3. By way of derogation from paragraph 2, the following shall apply:	3. By way of derogation from paragraph 2, the following shall apply:	3. By way of derogation from paragraph 2 the following shall apply:	No change
992.	(a) Article 23(2) and (3) and Article 43(4) shall apply from [18 months after date of application referred to in paragraph 2];	(a) (1) Article 23(1) shall apply from [30 months after entry into force];	(a) Article 23(2) and (3) and Article 43(4) shall apply from [18 months after date of application referred to in paragraph 2];	No change
993.	(b) Articles 26 to 38 shall apply from [six months after entry into force]. However, prior to [date of application as referred to in paragraph 2], the obligations on notified bodies emanating from the provisions in Articles 26 to 38 shall apply only to those bodies which submit an application for notification in accordance with Article 29 of this Regulation.	Articles 26 to 38 shall apply from [six months after entry into force]. However, prior to [date of application as referred to in paragraph 2], the obligations on notified bodies emanating from the provisions in articles 26 to 38 shall apply only to those bodies which submit an application for notification in accordance with Article 29 of this Regulation.	(b) Articles 26 to 38 shall apply from [six months after entry into force]. However, prior to [date of application as referred to in paragraph 2], the obligations on notified bodies emanating from the provisions in Articles 26 to 38 shall apply only to those bodies which submit an application for notification in accordance with Article 29 of this Regulation.	No change
994.	(c)	(ba) Article 74 shall apply from ...*); _____ *OJ: please insert the date: six months		

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		after the entry into force of this Regulation. (bb) Articles 75 to 77 shall apply from...*; _____ * OJ: please insert the date: 12 months after the entry into force of this Regulation. (bc) Article 59 to 64 shall apply from...* ; _____ * OJ: please insert the date: 24 months after the entry into force of this Regulation. (bd) Article 78 shall apply from ...*. _____ * OJ: please insert the date: 24 months after the entry into force of this Regulation 3a. The implementing acts referred to in Articles 31(4), 40(9), 42(8), 46(2) and Articles 58 and 64 shall be adopted within ...* _____ * OJ: please insert the date: 12 months after the entry into force of this Regulation		
995.			(c) For class D devices Article 22(4) shall apply one year after the date of application of this regulation. For class B and class C devices Article 22(4) shall apply three years after the date of application of this regulation. For class A devices Article 22(4) shall apply five years after the date of application of this regulation.	**VERY long timeline for UDI application – this means that registration may be impaired as registration mechanisms will not be in place until ten years after publication of this text!**
996.			(d) Articles 22 to 25, Chapter VI, Article 58c(2), Article 63a and Article 64a shall apply from six months after the publication of the notice referred to in Article 27a(3) of Regulation [future regulation on Medical devices], but in any event no earlier than the period referred to	UDI, Databank, **Summary safety and performance, performance evaluation studies, periodic safety update report, analysis of vigilance and electronic system for vigilance.**

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			in paragraph 2.	
997.	This Regulation shall be binding in its entirety and directly applicable in all Member States.	This Regulation shall be binding in its entirety and directly applicable in all Member States.	This Regulation shall be binding in its entirety and directly applicable in all Member States.	