Analysis of the proposal for IVD Regulation

CONFIDENTIAL – NOT TO BE SHARED OUTSIDE OF EDMA – Draft 20 July 2015

Row	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.	**ANNEXES**	**ANNEXES**	**ANNEXES**	
2.	I General safety and performance requirements	I General safety and performance requirements	I General safety and performance requirements	---
3.	II Technical documentation	II Technical documentation	II Technical documentation	---
4.			*IIa Technical documentation on post-market surveillance*	New Annex
5.	III EU Declaration of conformity	III EU Declaration of conformity	III EU Declaration of conformity	---
6.	IV CE marking of conformity	IV CE marking of conformity	IV CE marking of conformity	---
7.	V Information to be submitted with the registration of devices and economic operators in accordance with Article 23 and data elements of the UDI device identifier in accordance with Article 22	V Information to be submitted with the registration of devices and economic operators in accordance with Article 23 and data elements of the UDI device identifier in accordance with Article 22	V Information to be submitted with the registration of devices and economic operators in accordance with Article 23 and data elements of the UDI device identifier in accordance with Article 22	---
8.	VI Minimum requirements to be met by Notified Bodies	VI Minimum requirements to be met by Notified Bodies	VI Minimum requirements to be met by Notified Bodies	---
9.	VII Classification criteria	VII Classification criteria	VII Classification criteria	---
10.	VIII Conformity assessment based on full quality assurance and design examination	VIII Conformity assessment based on full quality assurance and design examination	VIII Conformity assessment based on full quality assurance and design examination	---
11.	IX Conformity assessment based on type examination	IX Conformity assessment based on type examination	IX Conformity assessment based on type examination	---

Row	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
12.	X Conformity assessment based on production quality assurance	X Conformity assessment based on production quality assurance	X Conformity assessment based on production quality assurance	---
13.	XI Minimum content of certificates issued by a notified body	XI Minimum content of certificates issued by a notified body	XI Minimum content of certificates issued by a notified body	---
14.	XII Clinical evidence and post-market follow-up	XII Clinical evidence and post-market follow-up	XII Clinical evidence and post-market follow-up	---
15.	XIII Interventional clinical performance studies and other clinical performance studies involving risks for the subjects of the studies	XIII Interventional clinical performance studies and other clinical performance studies involving risks for the subjects of the studies	XIII Interventional clinical performance studies and other clinical performance studies involving risks for the subjects of the studies	---
16.	XIV Correlation table	XIV Correlation table	XIV Correlation table	---
17.	**ANNEX I** **GENERAL SAFETY AND PERFORMANCE REQUIREMENTS**	**ANNEX I** **GENERAL SAFETY AND PERFORMANCE REQUIREMENTS**	**ANNEX I** **GENERAL SAFETY AND PERFORMANCE REQUIREMENTS**	
18.	**I. GENERAL REQUIREMENTS**	**I. GENERAL REQUIREMENTS**	**I. GENERAL REQUIREMENTS**	**---**
19.	1. The devices shall achieve the performance intended by the manufacturer and be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose, taking into account the generally acknowledged state of the art.	1. The devices shall achieve the performance intended by the manufacturer and be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose, taking into account the generally acknowledged state of the art.	1. The devices shall achieve the performance intended by the manufacturer and be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose.	Removes the concept of the general state of the art from this point – to be included elsewhere in the document under a very different guise.

Row	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
20.	They shall not compromise, directly or indirectly, the clinical condition or the safety of the patients, or the safety or health of users or, where applicable, other persons, provided that any risks or limits to performance which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.	They shall not compromise, directly or indirectly, the clinical condition or the safety of the patients, or the safety or health of users or, where applicable, other persons, provided that any risks or limits to performance which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.	They shall be safe and effective and not compromise, directly or indirectly, the clinical condition or the safety of the patients, or the safety or health of users or, where applicable, other persons, provided that any risks or limits to performance which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety taking into account the generally acknowledged state of the art.	Includes the concept of IVDs being safe and "effective" – where effectiveness is not something well defined in the IVD field. State of the art included here (taken out of line 19) – so state of the art in safety and effectiveness but not in performance.
21.	This shall include:	This shall include:	**I. 2b.** In eliminating or reducing risks related to use error the manufacturer shall apply the following principles:	---
22.	- reducing as far as possible the risk of error due to ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and	- reducing as far as possible the risk of error due to ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and	- reducing risks as far as possible related to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient and user safety), and	Includes design for user safety as well as patient safety.
23.	- consideration of the technical knowledge, experience, education or training, and the medical and physical conditions of intended users (design for lay, professional, disabled or other users).	- consideration of the technical knowledge, experience, education or training, and the medical and physical conditions of intended users (design for lay, professional, disabled or other users).	- consideration of the technical knowledge, experience, education, training, use environment and, where applicable, the medical and physical conditions of intended users (design for lay, professional, disabled or other users).	Includes the need for consideration to "use environment" as well as the fact that the medical and physical conditions of users is relevant "where applicable"
24.			1aa. The requirements in this Annex to	Clarification from the Council

Row	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
			reduce risks as far as possible mean reduce risks as far as possible without adversely affecting the risk benefit ratio.	but it is unclear what it will mean in practice.
25.			1a. The manufacturer shall establish, implement, document and maintain a risk management process. Risk management is a continuous iterative process throughout the entire lifecycle of a device, requiring regular systematic update. It requires a manufacturer to:	
26.			(a) establish and document a risk management plan for each medical device;	This is not needed – each device needs to be covered by a risk management plan, but not every device needs an individual risk management plan. E.g: A 50 test kit and the 200 test kit of the exact same device would not need to have separate plans.
27.			(c) estimate and evaluate the associated risks occurring during the intended use and during reasonably foreseeable misuse;	Standard risk management practice…
28.			(d) eliminate or control these risks according to the requirements of clause 2;	Standard risk management practice…
29.			(e) evaluate the impact of information from the production phase and, in particular, from the post-market	Unclear why Council amalgamates production phase

Row	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
			surveillance system on hazards and their frequency of occurrence, estimates of their associated risks, as well as on the overall risk, benefit-risk ratio and risk acceptability;	and post-market surveillance phase information input into the risk management process. If each individual data point from production and post-market data is expected to trigger a review of the benefit-risk ratio and risk acceptability there is a problem.
30.			(f) based on the evaluation of the impact of information from the production phase or the post-market surveillance system if necessary amend control measures in line with the requirements of clause 2.	Standard risk management practice
31.	2. The solutions adopted by the manufacturer for the design and manufacture of the devices shall conform to safety principles, taking account of the generally acknowledged state of the art. To reduce risks, the manufacturer shall manage the risks so that the residual risk associated with each hazard as well as the overall residual risk is judged acceptable. The manufacturer shall apply the following principles in the priority order listed:	2. The solutions adopted by the manufacturer for the design and manufacture of the devices shall conform to safety principles, taking account of the generally acknowledged state of the art. To reduce risks, the manufacturer shall manage the risks so that the residual risk associated with each hazard as well as the overall residual risk is judged acceptable. The manufacturer shall apply the following principles in the priority order listed:	2. The risk control measures adopted by the manufacturer for the design and construction of the devices shall conform to safety principles, taking account of the generally acknowledged state of the art. To reduce risks, the manufacturer shall manage the risks so that the residual risk associated with each hazard as well as the overall residual risk is judged acceptable. In selecting the most appropriate solutions, the manufacturer shall apply the following principles in the priority order listed	Changed risk control measures rather than solutions and made it clear that the appropriate risk principles are the ones which would need to be applied.
32.	(a) identify known or foreseeable hazards and estimate the associated risks arising	(a) identify known or foreseeable hazards and estimate the associated risks arising	**1.a (b)** identify and analyse the known and foreseeable hazards associated	---

Row	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
	from the intended use and foreseeable misuse;	from the intended use and foreseeable misuse;	with each medical device;	
33.	(b) eliminate risks as far as possible through inherently safe design and manufacture;	(b) eliminate risks as far as possible through inherently safe design and manufacture;	(b) eliminate or reduce risks as far as possible and appropriate through safe design and construction;	---
34.	(c) reduce as far as possible the remaining risks by taking adequate protection measures, including alarms; and	(c) reduce as far as possible the remaining risks by taking adequate protection measures, including alarms; and	(c) where appropriate, take adequate protection measures, including alarms, if necessary, in relation to risks that cannot be eliminated; and	--- (change in wording but not in principles?)
35.	(d) provide training to users and/or inform users of any residual risks.	(d) provide training to users and/or inform users of any residual risks.	(d) provide information for safety (warnings/precautions/contraindications) and, where appropriate training to users. The manufacturer shall inform users of any residual risks.	Added redundant information – warning and precautions described in the label/IFU section. This actually undermines the principle of the Commission text.
36.	3. The characteristics and performances of the device shall not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions.	3. The characteristics and performances of the device shall not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions.	3. The characteristics and performances of the device shall not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the lifetime of the device, as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use and has been properly maintained in accordance with the manufacturer's instructions.	---
37.	When no lifetime is stated, the same applies for the lifetime reasonably to be	When no lifetime is stated, the same applies for the lifetime reasonably to be		Removed – unclear why. (No lifetime is stated for certain

Row	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
	expected of a device of that kind, having regard to the intended purpose and the anticipated use of the device.	expected of a device of that kind, having regard to the intended purpose and the anticipated use of the device.		instruments/equipment)
38.	4. The devices shall be designed, manufactured and packaged in such a way that their characteristics and performance during their intended use will not be adversely affected by transport and storage conditions (for example, fluctuations of temperature and humidity) taking account of the instructions and information provided by the manufacturer.	4. The devices shall be designed, manufactured and packaged in such a way that their characteristics and performance during their intended use will not be adversely affected by transport and storage conditions (for example, fluctuations of temperature and humidity) taking account of the instructions and information provided by the manufacturer.	4. Devices shall be designed, manufactured and packaged in such a way that their characteristics and performance during their intended use will not be adversely affected during transport and storage (for example, fluctuations of temperature and humidity) taking account of the instructions and information provided by the manufacturer.	---
39.	5. All known and foreseeable risks, and any undesirable effects, shall be minimised and be acceptable when weighed against the benefits to the patients of the intended performance of the device during normal conditions of use.	5. All known and foreseeable risks, and any undesirable effects, shall be minimised and be acceptable when weighed against the benefits to the patients of the intended performance of the device during normal conditions of use.	5. Any undesirable effects, shall be minimised and be acceptable when weighed against the evaluated potential benefits to the patients of the intended performance of the device during normal conditions of use.	Removes the concept of minimisation of risks – presumably captured in prior sections.
40.	**II. REQUIREMENTS REGARDING DESIGN AND CONSTRUCTION**	**II. REQUIREMENTS REGARDING DESIGN AND CONSTRUCTION**	**II. REQUIREMENTS REGARDING PERFORMANCE DESIGN AND MANUFACTURING**	**---**
41.	**6. Performance characteristics**	**6. Performance characteristics**	**6. Performance characteristics**	**---**
42.	6.1 The devices shall be designed and manufactured in such a way that the performance characteristics support the intended purpose, based on appropriate scientific and technical methods.	6.1 The devices shall be designed and manufactured in such a way that the performance characteristics support the intended purpose, based on appropriate scientific and technical methods.	6.1. The devices shall be designed and manufactured in such a way that they are suitable for the purposes referred to in Article 2(2), as specified by the manufacturer and suitable with the	Change, no impact, but emphasis again on state of the art.

Row	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
			regards to the performance taking account of the generally acknowledged state of the art.	
43.	They shall achieve the performances, as stated by the manufacturer and in particular, where appropriate:	They shall achieve the performances, as stated by the manufacturer and in particular, where appropriate:	They shall achieve the performances, as stated by the manufacturer and in particular, where applicable:	---
44.	(a) the analytical performance, such as accuracy (trueness and precision), bias, analytical sensitivity, analytical specificity, limits of detection and quantitation, measuring range, linearity, cut-off, repeatability, reproducibility, including determination of appropriate criteria for specimen collection and handling and control of known relevant endogenous and exogenous interference, cross-reactions; and	(a) the analytical performance, such as accuracy (trueness and precision), bias, analytical sensitivity, analytical specificity, limits of detection and quantitation, measuring range, linearity, cut-off, repeatability, reproducibility, including determination of appropriate criteria for specimen collection and handling and control of known relevant endogenous and exogenous interference, cross-reactions; and	(a) the analytical performance, such as, analytical sensitivity, analytical specificity, trueness (bias), precision (repeatability and reproducibility), accuracy (resulting from trueness and precision), limits of detection and quantitation, measuring range, linearity, cut-off, including determination of appropriate criteria for specimen collection and handling and control of known relevant endogenous and exogenous interference, cross-reactions; and	More precise wording – welcome.
45.	(b) the clinical performance, such as diagnostic sensitivity, diagnostic specificity, positive and negative predictive value, likelihood ratio, expected values in normal or affected populations.	(b) the clinical performance, including measures of clinical validity such as diagnostic sensitivity, diagnostic specificity, positive and negative predictive value, likelihood ratio, expected values in normal or affected populations;	(b) the clinical performance, such as diagnostic sensitivity, diagnostic specificity, positive predictive value, negative predictive value, likelihood ratio, expected values in normal and affected populations.	No significant change
46.		and, where appropriate, measures of clinical utility. In the case of companion diagnostics evidence of the clinical utility of the device for the intended purpose		

Row	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
		(selection of patients with a previously diagnosed condition or predisposition eligible for a targeted therapy) is required. For a companion diagnostic, the manufacturer should supply clinical evidence relating to the impact of a positive or negative test on (1) patient care; and (2) health outcomes when used as directed with the stated therapeutic intervention.		
47.	6.2 The performance characteristics of the device need to be maintained during the lifetime of the device as indicated by the manufacturer.	6.2 The performance characteristics of the device need to be maintained during the lifetime of the device as indicated by the manufacturer.	6.2. The performance characteristics of the device need to be maintained during the lifetime of the device as indicated by the manufacturer.	---
48.	6.3 Where the performance of devices depends on the use of calibrators and/or control materials, the metrological traceability of values assigned for a given analyte to such calibrators and/or control materials shall be assured through available and suitable reference measurement procedures and/or available and suitable reference materials of a higher metrological order.	6.3 Where the performance of devices depends on the use of calibrators and/or control materials, the metrological traceability of values assigned for a given analyte to such calibrators and/or control materials shall be assured through available and suitable reference measurement procedures and/or available and suitable reference materials of a higher metrological order.	6.3. Where the performance of devices depends on the use of calibrators and/or control materials, the metrological traceability of values assigned to calibrators and/or control materials shall be assured through suitable reference measurement procedures and/or suitable reference materials of a higher metrological order.	Unclear why reference to a given analyte has been removed. A single calibrator can indeed have different values assigned to different analytes.
49.	The device shall be designed and manufactured to enable the user to provide measurement results in patient specimens metrologically traceable to available and suitable higher order reference materials and/or reference measurement procedures following the instructions and information provided by	The device shall be designed and manufactured to enable the user to provide measurement results in patient specimens metrologically traceable to available and suitable higher order reference materials and/or reference measurement procedures following the instructions and information provided by	Where available, metrological traceability of values assigned to calibrators and control materials shall be assured to certified reference materials or reference measurement procedures.	Two important changes: - Principle of traceability from the patient results is lost. - Traceability to certified reference materials as opposed to higher order reference materials

Row	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
	the manufacturer.	the manufacturer.		(improvement)
50.			6.4. Characteristics and performances of the device must be checked when they may be affected in normal and intended use conditions, concerning: - for devices for self-testing, performances obtained by layperson; - for devices for near-patient testing, performances obtained in various medicalised environments (for example, patient home, emergency units, ambulances).	**New requirement –** Self test performance needs to be assessed in a lay use environment POCT performance needs to be assessed in a POCT environment.
51.	**7. Chemical, physical and biological properties**	**7. Chemical, physical and biological properties**	**7. Chemical, physical and biological properties**	**---**
52.	7.1 The devices shall be designed and manufactured in such a way as to ensure the characteristics and performance referred to in Chapter I 'General Requirements'. Particular attention shall be paid to the possibility of impairment of analytical performance due to incompatibility between the materials used and the specimens and/or analyte to be detected (such as biological tissues, cells, body fluids and microorganisms), taking account of the intended purpose of the device.	7.1 The devices shall be designed and manufactured in such a way as to ensure the characteristics and performance referred to in Chapter I 'General Requirements'. Particular attention shall be paid to the possibility of impairment of analytical performance due to incompatibility between the materials used and the specimens and/or analyte to be detected (such as biological tissues, cells, body fluids and microorganisms), taking account of the intended purpose of the device.	7.1. The devices shall be designed and manufactured in such a way as to ensure the characteristics and performance referred to in Chapter I 'General Requirements'. Particular attention shall be paid to the possibility of impairment of analytical performance due to physical and/or chemical incompatibility between the materials used and the specimens, analyte or marker to be detected (such as biological tissues, cells, body fluids and micro-organisms), taking account of the intended purpose of the device.	Restricts incompatibilities only to chemical and physical incompatibilities. This is actually a simplification of the requirement. Unclear why biological incompatibilities for instance have been excluded.
53.	7.2 The devices shall be designed, manufactured and packaged in such a	7.2 The devices shall be designed, manufactured and packaged in such a	7.2. The devices shall be designed, manufactured and packaged in such a	Simplification of the requirement, in line with the fact

Row	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
	way as to minimise the risk posed by contaminants and residues to patients, taking account of the intended purpose of the device, and to the persons involved in the transport, storage and use of the devices. Particular attention shall be paid to tissues exposed and to the duration and frequency of exposure.	way as to minimise the risk posed by contaminants and residues to patients, taking account of the intended purpose of the device, and to the persons involved in the transport, storage and use of the devices. Particular attention shall be paid to tissues exposed and to the duration and frequency of exposure.	way as to minimise the risk posed by contaminants and residues to patients, taking account of the intended purpose of the device, and to the persons involved in the transport, storage and use of the devices.	that IVDs do not generally include tissues.
54.	7.3. The devices shall be designed and manufactured in such a way as to reduce as far as possible the risks posed by substances that may leach or leak from the device.	7.3. The devices shall be designed and manufactured in such a way as to reduce as far as possible the risks posed by substances that may leach or leak from the device.	7.3. The devices shall be designed and manufactured in such a way as to reduce to a level as low as reasonably practicable the risks posed by substances or particles, including wear debris, degradation products, processing residues that may be released from the device.	Two key changes - Concept of substances which leach or leak has been removed - Added degradation products, processing residues and wear debris which may be released from the device. After assessment this seems to be a simpler approach as release is simpler to manage than leaching or leaking.
55.	Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC,	Special attention shall be given to substances which are carcinogenic, mutagenic or toxic to reproduction, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC,	Special attention shall be given to substances or particles which are carcinogenic, mutagenic or toxic to reproduction, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and	Minor change – added particles to substances – reference in practice to nanoparticles.

Row	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
	and amending Regulation (EC) No 1907/2006, and to substances having endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) .	and amending Regulation (EC) No 1907/2006, and to substances having endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) .	1999/45/EC, and amending Regulation (EC) No 1907/2006, and to substances having endocrine disrupting properties for which there is scientific evidence of probable serious effects to human health and which are identified in accordance with the procedure set out in Article 59 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH).	
56.	7.4. The devices shall be designed and manufactured in such a way as to reduce as far as possible the risks posed by the unintentional ingress or egress of substances into or from the device, taking into account the device and the nature of the environment in which it is intended to be used.	7.4. The devices shall be designed and manufactured in such a way as to reduce as far as possible the risks posed by the unintentional ingress or egress of substances into or from the device, taking into account the device and the nature of the environment in which it is intended to be used.	7.4. The devices shall be designed and manufactured in such a way as to reduce as far as possible the risks posed by the unintentional ingress of substances into the device, taking into account the device and the nature of the environment in which it is intended to be used.	Egress of substances removed.
57.	**8. Infection and microbial contamination**	**8. Infection and microbial contamination**	**8. Infection and microbial contamination**	**---**
58.	8.1. The devices and their manufacturing processes shall be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the user, professional or lay, or, where applicable, other persons. The design shall:	8.1. The devices and their manufacturing processes shall be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the user, professional or lay, or, where applicable, other persons. The design shall:	8.1. The devices and their manufacturing processes shall be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the user, professional or lay, or, where applicable, other persons. The design shall:	---
59.	(a) allow easy and safe handling; and,	(a) allow easy and safe handling; and,	(a) allow easy and safe handling;	---

Row	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
	where necessary	where necessary		
60.	(b) reduce as far as possible and appropriate any microbial leakage from the device and/or microbial exposure during use;	(b) reduce as far as possible and appropriate any microbial leakage from the device and/or microbial exposure during use;	(b) reduce as far as possible and appropriate any microbial leakage from the device and/or microbial exposure during use;	---
61.	(c) prevent microbial contamination of the device or specimen.	(c) prevent microbial contamination of the device or specimen.	(c) where necessary, the devices shall be designed in such a way as to prevent microbial contamination of the device during use and, in the case of specimen receptacles, the risk of contamination of the specimen.	No significant change
62.	8.2. The devices labelled either as sterile or as having a special microbiological state shall be designed, manufactured and packaged to ensure that they remain so when placed on the market, and remain so under the transport and storage conditions specified by the manufacturer, until the protective packaging is damaged or opened.	8.2. The devices labelled either as sterile or as having a special microbiological state shall be designed, manufactured and packaged to ensure that they remain so when placed on the market, and remain so under the transport and storage conditions specified by the manufacturer, until the protective packaging is damaged or opened.	8.2. Devices labelled either as sterile or as having a specific microbial state shall be designed, manufactured and packaged to ensure that they remain so when placed on the market, and remain so under the transport and storage conditions specified by the manufacturer, until the protective packaging is damaged or opened.	Minor change in terminology: Special microbiological state replaced with specific microbial state.
63.	8.3. The devices labelled either as sterile or as having a special microbiological state shall have been processed, manufactured and, if applicable, sterilised by appropriate validated methods.	8.3. The devices labelled either as sterile or as having a special microbiological state shall have been processed, manufactured and, if applicable, sterilised by appropriate validated methods.	8.3. Devices labelled as sterile shall have been processed, manufactured, packaged and sterilised by appropriate validated methods.	Smaller requirement – only applies to sterile devices.
64.	8.4. The devices intended to be sterilised shall be manufactured in appropriately controlled (e.g. environmental) conditions.	8.4. The devices intended to be sterilised shall be manufactured in appropriately controlled (e.g. environmental) conditions.	8.4. Devices intended to be sterilised shall be manufactured and packaged in appropriate and controlled conditions and facilities.	Calls out packaging as well as manufacturing to ensure sterile conditions.

Row	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
65.	8.5. Packaging systems for non-sterile devices shall maintain the integrity and cleanliness of the device indicated by the manufacturer and, if the devices are to be sterilised prior to use, minimise the risk of microbial contamination; the packaging system shall be suitable taking account of the method of sterilisation indicated by the manufacturer.	8.5. Packaging systems for non-sterile devices shall maintain the integrity and cleanliness of the device indicated by the manufacturer and, if the devices are to be sterilised prior to use, minimise the risk of microbial contamination; the packaging system shall be suitable taking account of the method of sterilisation indicated by the manufacturer.	8.5. Packaging systems for non-sterile devices shall maintain the integrity and cleanliness of the device indicated by the manufacturer and, if the devices are to be sterilised prior to use, minimise the risk of microbial contamination; the packaging system shall be suitable taking account of the method of sterilisation indicated by the manufacturer.	---
66.	8.6. The labelling of the devices shall distinguish between identical or similar products placed on the market in both sterile and non-sterile condition.	8.6. The labelling of the devices shall distinguish between identical or similar products placed on the market in both sterile and non-sterile condition.	8.6. The labelling of the devices shall distinguish between identical or similar products placed on the market in both sterile and non-sterile condition additional to the symbol used to indicate that a product is sterile.	**Concern -** Unclear what this means, but it seems to be undermining the concept of symbols as information in addition to symbols is requested.
67.	**9. Devices incorporating materials of biological origin**	**9. Devices incorporating materials of biological origin**	**9. Devices incorporating materials of biological origin**	---
68.	9.1. Where the devices include tissues, cells and substances originating from animals, the processing, preservation, testing and handling of tissues, cells and substances of such origin shall be carried out so as to provide optimal safety for user, professional or lay, or other person.	9.1. Where the devices include tissues, cells and substances originating from animals, the processing, preservation, testing and handling of tissues, cells and substances of such origin shall be carried out so as to provide optimal safety for user, professional or lay, or other person.	9.1. Where the devices include tissues, cells and substances originating from animals or human, the selection of sources, the processing, preservation, testing and handling of tissues, cells and substances of such origin and control procedures shall be carried out so as to provide safety for user, professional or lay, or other person.	Expanded to include human tissues and cells as well as explicitly calling out control procedures.
69.	In particular, safety with regard to viruses and other transmissible agents shall be addressed by implementation of validated methods of elimination or inactivation in	In particular, safety with regard to viruses and other transmissible agents shall be addressed by implementation of validated methods of elimination or inactivation in	In particular, safety with regard to microbial and other transmissible agents shall be addressed by implementation of validated methods of elimination or	---

Row	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
	the course of the manufacturing process. This may not apply to certain devices if the activity of the virus and other transmissible agent are integral to the intended purpose of the device or when such elimination or inactivation process would compromise the performance of the device.	the course of the manufacturing process. This may not apply to certain devices if the activity of the virus and other transmissible agent are integral to the intended purpose of the device or when such elimination or inactivation process would compromise the performance of the device.	inactivation in the course of the manufacturing process. This may not apply to certain devices if the activity of the microbial and other transmissible agent are integral to the intended purpose of the device or when such elimination or inactivation process would compromise the performance of the device.	
70.	9.2. Where the devices include human tissues, cells or substances, the selection of sources, donors and/or substances of human origin, the processing, preservation, testing and handling of tissues, cells and substances of such origin shall be carried out so as to provide optimal safety for user, professional or lay, or other person. In particular, safety with regard to viruses and other transmissible agents shall be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process. This may not apply to certain devices if the activity of the virus and other transmissible agent are integral to the intended purpose of the device or when such elimination or inactivation process would compromise the performance of the device.	9.2. Where the devices include human tissues, cells or substances, the selection of sources, donors and/or substances of human origin, the processing, preservation, testing and handling of tissues, cells and substances of such origin shall be carried out so as to provide optimal safety for user, professional or lay, or other person. In particular, safety with regard to viruses and other transmissible agents shall be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process. This may not apply to certain devices if the activity of the virus and other transmissible agent are integral to the intended purpose of the device or when such elimination or inactivation process would compromise the performance of the device.		Included in principle under line 67 – however it does not include the specific safety measures with regards to viruses or other transmissible agents.
71.	9.3. Where the devices include cells or substances of microbial origin, the processing, preservation, testing and	9.3. Where the devices include cells or substances of microbial origin, the processing, preservation, testing and		Completely removed – this may be a concern when dealing with control materials which contain

Row	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
	handling of cells and substances shall be carried out so as to provide optimal safety for user, professional or lay, or other person. In particular, safety with regard to viruses and other transmissible agents shall be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process. This may not apply to certain devices if the activity of the virus and other transmissible agent are integral to the intended purpose of the device or when such elimination or inactivation process would compromise the performance of the device.	handling of cells and substances shall be carried out so as to provide optimal safety for user, professional or lay, or other person. In particular, safety with regard to viruses and other transmissible agents shall be addressed by implementation of validated methods of elimination or inactivation in the course of the manufacturing process. This may not apply to certain devices if the activity of the virus and other transmissible agent are integral to the intended purpose of the device or when such elimination or inactivation process would compromise the performance of the device.		microbiological materials.
72.	**10. Interaction of devices with their environment**	**10. Interaction of devices with their environment**	**10. Construction and environmental properties**	**---**
73.	10.1. If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system, shall be safe and shall not impair the specified performances of the devices.	10.1. If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system, shall be safe and shall not impair the specified performances of the devices.	10.1. If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system, shall be safe and shall not impair the specified performances of the devices.	---
74.	Any restrictions on use applying to such combinations shall be indicated on the label and/or in the instructions for use. Connections which the user has to handle shall be designed and constructed in such a way as to minimise all possible risks from incorrect connection.	Any restrictions on use applying to such combinations shall be indicated on the label and/or in the instructions for use. Connections which the user has to handle shall be designed and constructed in such a way as to minimise all possible risks from incorrect connection.	Any restrictions on use applying to such combinations shall be indicated on the label and/or in the instructions for use.	Removed requirement on connections handled by the user.

Row	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
75.	10.2. The devices shall be designed and manufactured in such a way as to remove or reduce as far as possible and appropriate:	10.2. The devices shall be designed and manufactured in such a way as to remove or reduce as far as possible and appropriate:	10.2. Devices shall be designed and manufactured in such a way as to remove or reduce as far as possible and appropriate:	---
76.	(a) the risks of injury to user, professional or lay, or other person in connection with their physical and ergonomic features;	(a) the risks of injury to user, professional or lay, or other person in connection with their physical and ergonomic features;	(a) the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features;	For some reason calls out volume/pressure ratio and dimensions. (PIP issue here – volume/pressure ratio is one of the factors in rupture of breast implants)
77.	(b) the risks of use error due to the ergonomic features, human factors and the environment in which the device is intended to be used;	(b) the risks of use error due to the ergonomic features, human factors and the environment in which the device is intended to be used;		Removed
78.	(c) the risks connected with any foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, pressure, humidity, temperature variations or radio signal interferences;	(c) the risks connected with any foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, pressure, humidity, temperature variations or radio signal interferences;	(c) risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, temperature, variations in pressure and acceleration or radio signal interferences;	Adds risks associated to radiation. Risk of radiation of therapeutic procedures is clearly not needed for IVDs.
79.	(d) the risks associated with the use of the device when it comes into contact with materials, liquids, and substances, including gases, to which it is exposed during normal conditions of use;	(d) the risks associated with the use of the device when it comes into contact with materials, liquids, and substances, including gases, to which it is exposed during normal conditions of use;	(d) the risks associated with the use of the device when it comes into contact with materials, liquids, and substances, including gases, to which it is exposed during normal conditions of use;	---

Row	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
80.	(e) the risks associated with the possible negative interaction between software and the environment within which it operates and interacts;	(e) the risks associated with the possible negative interaction between software and the environment within which it operates and interacts;	(e) the risks associated with the possible negative interaction between software and the IT environment within which it operates and interacts;	(minor change – IT environment not just environment)
81.	(f) the risks of accidental ingress of substances into the device;	(f) the risks of accidental ingress of substances into the device;	(f) the risks of accidental ingress of substances into the device;	---
82.	(g) the risk of incorrect identification of specimens;	(g) the risk of incorrect identification of specimens;	(g) the risk of incorrect identification of specimens, the risk of erroneous results due to confusing colour and/or numeric and/or character codings on specimen receptacles, removable parts and/or accessories used with IVDs in order to perform the test or assay as intended;	Specific requirement for colour and other codes on specimen receptacles.
83.	(h) the risks of any foreseeable interference with other devices.	(h) the risks of any foreseeable interference with other devices.	(h) the risks of any foreseeable interference with other devices.	---
84.	10.3. The devices shall be designed and manufactured in such a way as to minimise the risks of fire or explosion during normal use and in single fault condition.	10.3. The devices shall be designed and manufactured in such a way as to minimise the risks of fire or explosion during normal use and in single fault condition.	10.3. Devices shall be designed and manufactured in such a way as to minimise the risks of fire or explosion during normal use and in single fault condition.	---
85.	Particular attention shall be paid to devices whose intended purpose includes exposure to or use in association with flammable substances or substances which could cause combustion.	Particular attention shall be paid to devices whose intended purpose includes exposure to or use in association with flammable substances or substances which could cause combustion.	Particular attention shall be paid to devices whose intended use includes exposure to or use in association with flammable or explosive substances or substances which could cause combustion.	---
86.	10.4. The devices shall be designed and manufactured in such a way that	10.4. The devices shall be designed and manufactured in such a way that	10.4. Devices shall be designed and manufactured in such a way that	No significant change

Row	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
	adjustment, calibration, and maintenance, where such is necessary to achieve the performances intended, can be done safely.	adjustment, calibration, and maintenance, where such is necessary to achieve the performances intended, can be done safely.	adjustment, calibration, and maintenance, can be done safely and effectively.	
87.	10.5. The devices that are intended to be operated together with other devices or products shall be designed and manufactured in such a way that the interoperability is reliable and safe.	10.5. The devices that are intended to be operated together with other devices or products shall be designed and manufactured in such a way that the interoperability is reliable and safe.	10.5. Devices that are intended to be operated together with other devices or products shall be designed and manufactured in such a way that the interoperability and compatibility are reliable and safe.	Added compatibility to the requirement
88.	10.6. The devices shall be designed and manufactured in such a way as to facilitate the safe disposal of the device and/or of any waste substances by the user, professional or lay, or other person.	10.6. The devices shall be designed and manufactured in such a way as to facilitate the safe disposal of the device and/or of any waste substances by the user, professional or lay, or other person.	10.6. Devices shall be designed and manufactured in such a way as to facilitate the safe disposal of the device and/or related waste substances by the user, professional or lay, or other person.	---
89.			To that end, manufacturers shall investigate and test procedures and measures by which their devices can be safely disposed after use. These procedures shall be described in the instruction for use.	New requirement – testing and documenting of disposal procedures.
90.	10.7. The measuring, monitoring or display scale (including colour change and other visual indicators) shall be designed and manufactured in line with ergonomic principles, taking account of the intended purpose of the device.	10.7. The measuring, monitoring or display scale (including colour change and other visual indicators) shall be designed and manufactured in line with ergonomic principles, taking account of the intended purpose of the device.	10.7. The measuring, monitoring or display scale (including colour change and other visual indicators) shall be designed and manufactured in line with ergonomic principles, taking account of the intended users and the environmental condition in which the devices are intended to be used.	Removes requirement based on the intended purpose of the device. Instead based on the intended user and the environment in which it is used.

Row	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
91.	**11. Devices with a measuring function**	**11. Devices with a measuring function**	**11. Devices with a measuring function**	Incoherent with the articles.
92.	11.1. The devices having a primary analytical measuring function shall be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability of measurement within appropriate accuracy limits, taking into account the intended purpose of the device and of available and appropriate reference measurement procedures and materials. The accuracy limits shall be specified by the manufacturer.	11.1. The devices having a primary analytical measuring function shall be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability of measurement within appropriate accuracy limits, taking into account the intended purpose of the device and of available and appropriate reference measurement procedures and materials. The accuracy limits shall be specified by the manufacturer.	11.1. Devices having a primary analytical measuring function shall be designed and manufactured in such a way as to provide appropriate analytical performance (Annex I, II 6.1 first indent), taking into account the intended purpose of the device.	Incoherent with the articles.
93.	11.2. The measurements made by devices with a measuring function and expressed in legal units shall conform to the provisions of Council Directive 80/181/EEC.	11.2. The measurements made by devices with a measuring function and expressed in legal units shall conform to the provisions of Council Directive 80/181/EEC.	11.2. The measurements made by devices with a measuring function and expressed in legal units shall conform to the provisions of Council Directive 80/181/EEC.	Incoherent with the articles.
94.	**12. Protection against radiation**	**12. Protection against radiation**	**12. Protection against radiation**	**---**
95.	12.1. The devices shall be designed, manufactured and packaged in such a way that exposure of user, professional or lay, or other persons to the emitted radiation (intended, unintended, stray or scattered) is reduced as far as possible.	12.1. The devices shall be designed, manufactured and packaged in such a way that exposure of user, professional or lay, or other persons to the emitted radiation (intended, unintended, stray or scattered) is reduced as far as possible.	12.1. Devices shall be designed, manufactured and packaged in such a way that exposure of users, or other persons to radiation (intended, unintended, stray or scattered) is reduced as far as possible and appropriate, compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for diagnostic purposes.	Added the clause that it should not restrict the application of appropriate specified levels of radiation for diagnostic purposes. Seems to be a requirement for imaging not IVDs?

Row	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
96.	12.2. When the devices are intended to emit potentially hazardous, visible and/or invisible radiation, they shall as far as possible be:	12.2. When the devices are intended to emit potentially hazardous, visible and/or invisible radiation, they shall as far as possible be:	12.2. When the devices are intended to emit hazardous, ionizing and/or not ionizing radiation, they shall as far as possible be:	---
97.	(a) designed and manufactured in such a way as to ensure that the characteristics and the quantity of radiation emitted can be controlled and/or adjusted; and	(a) designed and manufactured in such a way as to ensure that the characteristics and the quantity of radiation emitted can be controlled and/or adjusted; and	(a) designed and manufactured in such a way as to ensure that the characteristics and the quantity of radiation emitted can be controlled and/or adjusted; and	---
98.	(b) fitted with visual displays and/or audible warnings of such emissions.	(b) fitted with visual displays and/or audible warnings of such emissions.	(b) fitted with visual displays and/or audible warnings of such emissions.	---
99.	12.3. The operating instructions for devices emitting radiation shall give detailed information as to the nature of the emitted radiation, means of protecting the user, and on ways of avoiding misuse and of eliminating the risks inherent in installation.	12.3. The operating instructions for devices emitting radiation shall give detailed information as to the nature of the emitted radiation, means of protecting the user, and on ways of avoiding misuse and of eliminating the risks inherent in installation.	12.3. The operating instructions for devices emitting radiation shall give detailed information as to the nature of the emitted radiation, means of protecting the user, and on ways of avoiding misuse and of reducing the risks inherent in to installation as far as possible and appropriate. Information regarding the acceptance testing, the performance testing and the acceptance criteria shall also be specified, as well as the maintenance procedure.	Additional information regarding acceptance testing and criteria for emitted radiation.
100.	**13. Software incorporated in devices and standalone software**	**13. Software incorporated in devices and standalone software**	**13. Electronic programmable systems and devices that incorporate electronic programmable systems**	Change in title.
101.	13.1. The devices that incorporate electronic programmable systems, including software, or standalone software that are devices in themselves,	13.1. The devices that incorporate electronic programmable systems, including software, or standalone software that are devices in themselves,	13.1. The devices that incorporate an electronic programmable system shall be designed to ensure repeatability, reliability and performance according to	No significant change

Row	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
	shall be designed to ensure repeatability, reliability and performance according to the intended purpose.	shall be designed to ensure repeatability, reliability and performance according to the intended purpose.	their intended use.	
102.	In the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible and appropriate consequent risks.	In the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible and appropriate consequent risks.	In the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible consequent risks or impairment of performance.	Adds impairment of performance to risk.
103.	13.2. For the devices that incorporate software or for standalone software that are devices in themselves, the software shall be developed and manufactured according to the state of the art taking into account the principles of development life cycle, risk management, verification and validation.	13.2. For the devices that incorporate software or for standalone software that are devices in themselves, the software shall be developed and manufactured according to the state of the art taking into account the principles of development life cycle, risk management, verification and validation.	13.2. For the devices that incorporate software or for software that are devices in themselves, the software shall be developed and manufactured according to the state of the art taking into account the principles of development life cycle, risk management, including information security, verification and validation.	Adds information security
104.	13.3. Software referred to in this Section that are intended to be used in combination with mobile computing platforms shall be designed and manufactured taking into account the specific features of the mobile platform (e.g. size and contrast ratio of the screen) and the external factors related to their use (varying environment as regards to level of light or noise).	13.3. Software referred to in this Section that are intended to be used in combination with mobile computing platforms shall be designed and manufactured taking into account the specific features of the mobile platform (e.g. size and contrast ratio of the screen) and the external factors related to their use (varying environment as regards to level of light or noise).		Deleted requirement on mobile platforms
105.			13.3. The manufacturer shall describe minimum requirements on hardware, IT networks characteristics and IT security measures, including protection against unauthorized access, necessary to run	New requirement – describing minimum system requirements and security measures.

Row	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
			the software as intended.	
106.	**14. Devices connected to or equipped with an energy source**	**14. Devices connected to or equipped with an energy source**	**14. Devices connected to or equipped with an energy source**	**---**
107.	14.1. For the devices connected to or equipped with an energy source, in the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible and appropriate consequent risks.	14.1. For the devices connected to or equipped with an energy source, in the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible and appropriate consequent risks.	14.1 For the devices connected to or equipped with an energy source, in the event of a single fault condition, appropriate means shall be adopted to eliminate or reduce as far as possible and appropriate consequent risks.	---
108.	14.2. The devices where the safety of the patient depends on an internal power supply in the device shall be equipped with a means of determining the state of the power supply.	14.2. The devices where the safety of the patient depends on an internal power supply in the device shall be equipped with a means of determining the state of the power supply.	14.2. Devices where the safety of the patient depends on an internal power supply shall be equipped with a means of determining the state of the power supply and an appropriate warning or indication if or if necessary before the capacity of the power supply becomes critical.	Adds requirement of warning of low power supply.
109.	14.3. The devices shall be designed and manufactured in such a way as to reduce as far as possible the risks of creating electromagnetic interference which could impair the operation of this or other devices or equipment in the intended environment.	14.3. The devices shall be designed and manufactured in such a way as to reduce as far as possible the risks of creating electromagnetic interference which could impair the operation of this or other devices or equipment in the intended environment.	14.3. Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks of creating electromagnetic interference which could impair the operation of this or other devices or equipment in the intended environment.	---
110.	14.4. The devices shall be designed and manufactured in such a way as to provide an adequate level of intrinsic immunity to electromagnetic disturbance to enable them to operate as intended.	14.4. The devices shall be designed and manufactured in such a way as to provide an adequate level of intrinsic immunity to electromagnetic disturbance to enable them to operate as intended.	14.4. Devices shall be designed and manufactured in such a way as to provide an adequate level of intrinsic immunity to electromagnetic disturbance to enable them to operate as intended.	---

Row	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
111.	14.5. The devices shall be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks to the user, professional or lay, or other person both during normal use of the device and in the event of a single fault condition in the device, provided the device is installed and maintained as indicated by the manufacturer.	14.5. The devices shall be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks to the user, professional or lay, or other person both during normal use of the device and in the event of a single fault condition in the device, provided the device is installed and maintained as indicated by the manufacturer.		Deleted, unclear why.
112.	**15. Protection against mechanical and thermal risks**	**15. Protection against mechanical and thermal risks**	**15. Protection against mechanical and thermal risks**	**---**
113.	15.1. The devices shall be designed and manufactured in such a way as to protect the user, professional or lay, or other person against mechanical risks.	15.1. The devices shall be designed and manufactured in such a way as to protect the user, professional or lay, or other person against mechanical risks.	15.1. Devices shall be designed and manufactured in such a way as to protect the user, professional or lay, or other person against mechanical risks.	---
114.	15.2. The devices shall be sufficiently stable under the foreseen operating conditions. They shall be suitable to withstand stresses inherent in the foreseen working environment, and to retain this resistance during the expected lifetime of the devices, subject to any inspection and maintenance requirements as indicated by the manufacturer.	15.2. The devices shall be sufficiently stable under the foreseen operating conditions. They shall be suitable to withstand stresses inherent in the foreseen working environment, and to retain this resistance during the expected lifetime of the devices, subject to any inspection and maintenance requirements as indicated by the manufacturer.	15.2. Devices shall be sufficiently stable under the foreseen operating conditions. They shall be suitable to withstand stresses inherent in the foreseen working environment, and to retain this resistance during the expected lifetime of the devices, subject to any inspection and maintenance requirements as indicated by the manufacturer.	---
115.	15.3. Where there are risks due to the presence of moving parts, risks due to break-up or detachment, or leakage of substances, then appropriate protection	15.3. Where there are risks due to the presence of moving parts, risks due to break-up or detachment, or leakage of substances, then appropriate protection	15.3 Where there are risks due to the presence of moving parts, risks due to break-up or detachment, or leakage of substances, then appropriate protection	---

Row	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
	means shall be incorporated.	means shall be incorporated.	means shall be incorporated.	
116.	Any guards or other means included with the device to provide protection, in particular against moving parts, shall be secure and shall not interfere with access for the normal operation of the device, or restrict routine maintenance of the device as intended by the manufacturer.	Any guards or other means included with the device to provide protection, in particular against moving parts, shall be secure and shall not interfere with access for the normal operation of the device, or restrict routine maintenance of the device as intended by the manufacturer.	Any guards or other means included with the device to provide protection, in particular against moving parts, shall be secure and shall not interfere with access for the normal operation of the device, or restrict routine maintenance of the device as intended by the manufacturer.	---
117.	15.4. The devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.	15.4. The devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.	15.4 The devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from vibration generated by the devices, taking account of technical progress and of the means available for limiting vibrations, particularly at source, unless the vibrations are part of the specified performance.	---
118.	15.5. The devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.	15.5. The devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.	15.5 The devices shall be designed and manufactured in such a way as to reduce to the lowest possible level the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.	---
119.	15.6. Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user, professional or lay, or other person has to handle shall be designed and	15.6. Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user, professional or lay, or other person has to handle shall be designed and	15.6. Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user, professional or lay, or other person has to handle shall be designed and	---

Row	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
	constructed in such a way as to minimise all possible risks.	constructed in such a way as to minimise all possible risks.	constructed in such a way as to minimise all possible risks.	
120.	15.7. Errors likely to be made when fitting or refitting, or connecting or reconnecting, certain parts before or during use which could be a source of risk must be made impossible by the design and construction of such parts or, failing this, by information given on the parts themselves and/or their housings. The same information must be given on moving parts and/or their housings where the direction of movement needs to be known in order to avoid a risk.	15.7. Errors likely to be made when fitting or refitting, or connecting or reconnecting, certain parts before or during use which could be a source of risk must be made impossible by the design and construction of such parts or, failing this, by information given on the parts themselves and/or their housings. The same information must be given on moving parts and/or their housings where the direction of movement needs to be known in order to avoid a risk.	15.7. Errors likely to be made when fitting or refitting, or connecting or reconnecting, certain parts before or during use which could be a source of risk must be made impossible by the design and construction of such parts or, failing this, by information given on the parts themselves and/or their housings. The same information must be given on moving parts and/or their housings where the direction of movement needs to be known in order to avoid a risk.	---
121.	15.8. Accessible parts of the devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings shall not attain potentially dangerous temperatures under normal conditions of use.	15.8. Accessible parts of the devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings shall not attain potentially dangerous temperatures under normal conditions of use.	15.8. Accessible parts of the devices (excluding the parts or areas intended to supply heat or reach given temperatures) and their surroundings shall not attain potentially dangerous temperatures under normal conditions of use.	---
122.	**16. Protection against the risks posed by devices intended by the manufacturer for self-testing or near-patient testing**	**16. Protection against the risks posed by devices intended by the manufacturer for self-testing**	**16. Protection against the risks posed by devices intended for self-testing or near-patient testing**	**---**
123.	16.1. The devices intended for self-testing or near-patient testing shall be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means	16.1. The devices intended for self-testing shall be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to the intended user	16.1. The devices intended for self-testing or near-patient testing shall be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means	---

Row	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
	available to the intended user and the influence resulting from variation that can be reasonably anticipated in the intended user's technique and environment.	and the influence resulting from variation that can be reasonably anticipated in the intended user's technique and environment.	available to the intended user and the influence resulting from variation that can be reasonably anticipated in the intended user's technique and environment.	
124.	The information and instructions provided by the manufacturer shall be easy for the intended user to understand and apply.	The information and instructions provided by the manufacturer shall be easy for the intended user to understand and apply.	The information and instructions provided by the manufacturer shall be easy for the intended user to understand and apply in order to correctly interpret the result provided by the device and to avoid misleading information.	Minor change
125.			In the case of near-patient testing the information and the instructions provided by the manufacturer shall make clear the level of training, qualifications and/or experience required by the user.	New requirement
126.	16.2. The devices intended for self-testing or near-patient testing shall be designed and manufactured in such a way as to	16.2. The devices intended for self-testing shall be designed and manufactured in such a way as to	16.2. The devices intended for self-testing or near-patient testing shall be designed and manufactured in such a way as to	---
127.	- ensure that the device is easy to use by the intended user at all stages of the procedure; and	- ensure that the device is easy to use by the intended user at all stages of the procedure; and	- ensure that the device is, if necessary after appropriate training and information, safely and accurately to use by the intended user at all stages of the procedure; and	No significant change
128.	- reduce as far as possible the risk of error by the intended user in the handling of the device and, if applicable, the specimen, and also in the interpretation of the results.	- reduce as far as possible the risk of error by the intended user in the handling of the device and, if applicable, the specimen, and also in the interpretation of the results.	- reduce as far as possible the risk of error by the intended user in the handling of the device and, if applicable, the specimen, and also in the interpretation of the results.	---

Row	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
129.	16.3. The devices intended for self-testing and near-patient testing shall, where reasonably possible, include a procedure by which the intended user can: - verify that, at the time of use, the device will perform as intended by the manufacturer; and - be warned if the device has failed to provide a valid result.	16.3. The devices intended for self-testing shall, where reasonably possible, include a procedure by which the intended user can: - verify that, at the time of use, the device will perform as intended by the manufacturer; and - be warned if the device has failed to provide a valid result.	16.3. The devices intended for self-testing and near-patient testing shall, where feasible, include a procedure by which the intended user can: - verify that, at the time of use, the device will perform as intended by the manufacturer; and - be warned if the device has failed to provide a valid result.	---
130.	**III. REQUIREMENTS REGARDING INFORMATION SUPPLIED WITH THE DEVICE**	**III. REQUIREMENTS REGARDING INFORMATION SUPPLIED WITH THE DEVICE**	**III. REQUIREMENTS REGARDING INFORMATION SUPPLIED WITH THE DEVICE**	**---**
131.	**17. Label and instructions for use**	**17. Label and instructions for use**	**17. Label and instructions for use**	**---**
132.	**17.1. General requirements regarding the information supplied by the manufacturer**	**17.1. General requirements regarding the information supplied by the manufacturer**	**17.1. General requirements regarding the information supplied by the manufacturer**	**---**
133.	Each device shall be accompanied by the information needed to identify the device and its manufacturer, and communicate safety and performance related information to the user, professional or lay, or other person, as appropriate.	Each device shall be accompanied by the information needed to identify the device and its manufacturer, and communicate safety and performance related information to the user, professional or lay, or other person, as appropriate.	Each device shall be accompanied by the information needed to identify the device and its manufacturer, and communicate safety and performance related information to the user, or other person, as appropriate.	Distinction between professional or lay user is removed.
134.	Such information may appear on the device itself, on the packaging or in the instructions for use, taking into account the following:	Such information may appear on the device itself, on the packaging or in the instructions for use, and must be made available on the manufacturer's website	Such information may appear on the device itself, on the packaging or in the instructions for use, taking into account the following:	**---**

Row	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
		taking into account the following:		
135.	(i) The medium, format, content, legibility, and location of the label and instructions for use shall be appropriate to the particular device, its intended purpose and the technical knowledge, experience, education or training of the intended user(s). In particular, instructions for use shall be written in terms readily understood by the intended user and, where appropriate, supplemented with drawings and diagrams. Some devices may include separate information for the professional user and the lay person.	(i) The medium, format, content, legibility, and location of the label and instructions for use shall be appropriate to the particular device, its intended purpose and the technical knowledge, experience, education or training of the intended user(s). In particular, instructions for use shall be written in terms readily understood by the intended user and, where appropriate, supplemented with drawings and diagrams. Some devices may include separate information for the professional user and the lay person.	(i) The format, content, legibility, and location of the label and instructions for use shall be appropriate to the particular device, its intended purpose and the technical knowledge, experience, education or training of the intended user(s). In particular, instructions for use shall be written in terms readily understood by the intended user and, where appropriate, supplemented with drawings and diagrams.	'Medium' is removed: intention is unclear. Format = medium? Distinction between professional or lay user is removed.
136.	(ii) The information required on the label, shall be provided on the device itself.	(ii) The information required on the label, shall be provided on the device itself.	(ii) The information required on the label, shall be provided on the device itself.	**---**
137.	If this is not practicable or appropriate, some or all of the information may appear on the packaging for each unit, and/or on the packaging of multiple devices.	If this is not practicable or appropriate, some or all of the information may appear on the packaging for each unit, and/or on the packaging of multiple devices.	If this is not practicable or appropriate, some or all of the information may appear on the packaging for each unit.—If individual full labelling of each unit is not practicable, the information must be set out on the packaging of multiple devices.	The concept "If individual full labelling of each unit is not practicable" has been taken over from IVDD
138.	Where multiple devices are supplied to a single user and/or location, a single copy of the instructions for use may be provided if so agreed by the purchaser who in any case may request further copies to be provided.	Where multiple devices are supplied to a single user and/or location, a single copy of the instructions for use may be provided if so agreed by the purchaser who in any case may request further copies to be provided.	Where multiple devices, with the exception of devices intended for self-testing or near-patient testing, are supplied to a single user and/or location, a single copy of the instructions for use may be provided if so agreed by the	"with the exception of devices intended for self-testing or near-patient testing" – can be an issue for self-tests but more for near-patient tests: an IFU need to be provided for every single

Row	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
			purchaser who in any case may request further copies to be provided.	device even for rapid tests/strips packaged 50 in a sales box.
139.	(iii) In duly justified and exceptional cases instructions for use may not be needed or may be abbreviated if the device can be used safely and as intended by the manufacturer without any such instructions for use.	(iii) In duly justified and exceptional cases instructions for use may not be needed or may be abbreviated if the device can be used safely and as intended by the manufacturer without any such instructions for use.	(iii) In duly justified and exceptional cases instructions for use may not be needed or may be abbreviated if the device can be used safely and as intended by the manufacturer without any such instructions for use.	---
140.	(iv) Labels shall be provided in a human-readable format but may be supplemented by machine-readable forms, such as radio-frequency identification (RFID) or bar codes.	(iv) Labels shall be provided in a human-readable format but may be supplemented by machine-readable forms, such as radio-frequency identification (RFID) or bar codes.	(iv) Labels shall be provided in a human-readable format and may be supplemented by machine-readable information, such as radio-frequency identification (RFID) or bar codes.	Adjustment in wording.
141.	(v) When the device is intended for professional use only , instructions for use may be provided to the user in non-paper format (e.g. electronic), except when the device is intended for near-patient testing.	(v) When the device is intended for professional use only , instructions for use may be provided to the user in non-paper format (e.g. electronic), except when the device is intended for near-patient testing.	(v) When the device is intended for professional use only, instructions for use may be provided to the user in non-paper format (e.g. electronic), except when the device is intended for near-patient testing.	---
142.	(vi) Residual risks which are required to be communicated to the user and/or other person shall be included as limitations, contraindications, precautions or warnings in the information supplied by the manufacturer.	(vi) Residual risks which are required to be communicated to the user and/or other person shall be included as limitations, precautions or warnings in the information supplied by the manufacturer.	(vi) Residual risks which are required to be communicated to the user and/or other person shall be included as limitations, contraindications, precautions or warnings in the information supplied by the manufacturer.	---
143.	(vii) Where appropriate, this information should take the form of internationally recognised symbols. Any symbol or	(vii) Where appropriate, this information should take the form of internationally recognised symbols. Any symbol or	(vii) Where appropriate, the information supplied by the manufacturer should take the form of internationally recognised	**"**information ***supplied by the manufacturer*****"** – clarification in wording, no concern.

Row	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
	identification colour used shall conform to the harmonised standards or CTS. In areas for which no standards or CTS exist, the symbols and colours shall be described in the documentation supplied with the device.	identification colour used shall conform to the harmonised standards or CTS. In areas for which no standards or CTS exist, the symbols and colours shall be described in the documentation supplied with the device.	symbols, taking into account the intended users. Any symbol or identification colour used shall conform to the harmonised standards or CS. In areas for which no standards or CS exist, the symbols and colours shall be described in the documentation supplied with the device.	**"*taking into account the intended users*"** – no concern. Same wording as in the current IVDD.
144.	(viii) In the case of devices containing a substance or a mixture which may be considered as being dangerous, taking account of the nature and quantity of its constituents and the form under which they are present, relevant hazard pictograms and labelling requirements of Regulation (EC) 1272/2008 shall apply.	(viii) In the case of devices containing a substance or a mixture which may be considered as being dangerous, taking account of the nature and quantity of its constituents and the form under which they are present, relevant hazard pictograms and labelling requirements of Regulation (EC) 1272/2008 shall apply.	(viii) In the case of devices containing a substance or a mixture which may be considered as being dangerous, taking account of the nature and quantity of its constituents and the form under which they are present, relevant hazard pictograms and labelling requirements of Regulation (EC) 1272/2008 shall apply.	---
145.	Where there is insufficient space to put all the information on the device itself or on its label, the relevant hazard pictograms shall be put on the label and the other information required by that Regulation shall be given in the instructions for use.	Where there is insufficient space to put all the information on the device itself or on its label, the relevant hazard pictograms shall be put on the label and the other information required by that Regulation shall be given in the instructions for use.	Where there is insufficient space to put all the information on the device itself or on its label, the relevant hazard pictograms shall be put on the label and the other information required by that Regulation shall be given in the instructions for use.	---
146.	(ix) The provisions of Regulation (EC) 1907/2006 on the safety data sheet shall apply, unless all relevant information as appropriate is already made available by the instructions for use.	(ix) The provisions of Regulation (EC) 1907/2006 on the safety data sheet shall apply, unless all relevant information as appropriate is already made available by the instructions for use.	(ix) The provisions of Regulation (EC) 1907/2006 on the safety data sheet shall apply, unless all relevant information as appropriate is already made available by the instructions for use.	---
147.	**17.2. Information on the label**	**17.2. Information on the label**	**17.2. Labelling**	Confusing change to a more general wording. COM proposal is more appropriate to differentiate between label and

Row	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
				IFU: 17.2. Information on the label 17.3. Information in the instructions for use
148.	The label shall bear the following particulars:	The label shall bear the following particulars:	The following particulars shall appear on the device or, where not practicable or appropriate on the packaging:	More detailed text.
149.	(i) The name or trade name of the device;	(i) The name or trade name of the device;	(i) The name or trade name of the device;	---
150.	(ii) The details strictly necessary for the user to identify the device and, where it is not obvious for the user, the intended purpose of the device;	(ii) The details strictly necessary for the user to identify the device and, where it is not obvious for the user, the intended purpose of the device;	(ii) The details strictly necessary for the user to identify the device and, where it is not obvious for the user, the intended purpose of the device;	---
151.	(iii) The name, registered trade name or registered trade mark of the manufacturer and the address of his registered place of business at which he can be contacted and his location be established;	(iii) The name, registered trade name or registered trade mark of the manufacturer and the address of his registered place of business at which he can be contacted and his location be established;	(iii) The name, registered trade name or registered trade mark of the manufacturer and the address of his registered place of business;	**"**at which he can be contacted and his location be established" has been taken out – unclear intention.
152.			(iiia) The Single Registration Number of the manufacturer in accordance with Article 23a;	Single Registration Number to be added on the label required. Redundant since the device has its own UDI carrier.
153.	(iv) For imported devices, the name, registered trade name or registered trade mark of the authorised representative established within the Union and the address of his registered place of business at which he can be contacted	(iv) For imported devices, the name, registered trade name or registered trade mark of the authorised representative established within the Union and the address of his registered place of business at which he can be contacted	(iv) If the manufacturer has his registered place of business not within the Union, the name and address of the authorised representative and its Single Registration Number in accordance with Article 23a	According to the IVD Directive the AR name and address can either be on the label or the IFU. IVDR requires the AR name and address on the label with no alternative.

Row	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
	and his location be established;	and his location be established;		IVD Directive: *"Annex I 8.4 (a) the name or trade name and address of the manufacturer. For devices imported into the Community with a view to their distribution in the Community, the label, the outer packaging, or the instructions for use shall contain in addition the name and address of the authorised representative of the manufacturer;"* LAB opinion: remove it from here and move to 17.3.1 (xxvi) as a requirement for IFU Justification? "Registered trade name or registered trade mark" has been removed for AR, but kept for manufacturer – no concern. AR's Single Registration Number: see above.
154.	(v) An indication that the device is for in vitro diagnostic use;	(v) An indication that the device is for in vitro diagnostic use;	(v) An indication that the device is an in vitro diagnostic medical device, or if the device is a 'device for performance evaluation', an indication of that fact;	No changes, only the requirement for 'device for performance evaluation' moved here from (xvii)
155.	(vi) The batch code/lot number or the serial number of the device preceded by the word LOT or SERIAL NUMBER or an equivalent symbol, as appropriate;	(vi) The batch code/lot number or the serial number of the device preceded by the word LOT or SERIAL NUMBER or an equivalent symbol, as appropriate;	(vi) The batch code/lot number or the serial number of the device preceded by the word LOT or SERIAL NUMBER or an equivalent symbol, as appropriate;	---

Row	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
156.	(vii) Where applicable, the unique device identification (UDI);	(vii) Where applicable, the unique device identification (UDI);	(vii) the unique device identification (UDI) carrier according to Article 24 and Annex V Part C;	"where applicable" removed, adding UDI is a must.
157.	(viii) An unambiguous indication of the date until when the device may be used safely, without degradation of performance, expressed at least as the year, the month and, where relevant, the day, in that order;	(viii) An unambiguous indication of the date until when the device may be used safely, without degradation of performance, expressed at least as the year, the month and, where relevant, the day, in that order;	(viii) An unambiguous indication of the date until when the device may be used safely, without degradation of performance, expressed at least as the year, the month and, where relevant, the day, in that order;	---
158.	(ix) Where there is no indication of the date until when it may be used safely, the year of manufacture. This year of manufacture may be included as part of the batch or serial number, provided the date is clearly identifiable;	(ix) Where there is no indication of the date until when it may be used safely, the year of manufacture. This year of manufacture may be included as part of the batch or serial number, provided the date is clearly identifiable;	(ix) Where there is no indication of the date until when it may be used safely, the data of manufacture. This data of manufacture may be included as part of the batch or serial number, provided the date is clearly identifiable;	the ~~year~~ ***data*** (typo: it should have been date) Date of manufacture: applicable to instruments and consumables (not applicable to reagents since they have expiry date). Year of manufacture gives appropriate info, more details are meaningless (i.e. year + month + day) although year+month is still doable.
159.	(x) Where relevant, an indication of the net quantity of contents, expressed in terms of weight or volume, numerical count, or any combination of these, or other terms which accurately reflect the contents of the package;	(x) Where relevant, an indication of the net quantity of contents, expressed in terms of weight or volume, numerical count, or any combination of these, or other terms which accurately reflect the contents of the package;	(x) Where relevant, an indication of the net quantity of contents, expressed in terms of weight or volume, numerical count, or any combination of these, or other terms which accurately reflect the contents of the package;	---
160.	(xi) An indication of any special storage and/or handling condition that applies;	(xi) An indication of any special storage and/or handling condition that applies;	(xi) An indication of any special storage and/or handling condition that applies;	---

Row	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
161.	(xii) Where appropriate, an indication of the sterile state of the device and the sterilisation method, or a statement indicating any special microbiological state or state of cleanliness;	(xii) Where appropriate, an indication of the sterile state of the device and the sterilisation method, or a statement indicating any special microbiological state or state of cleanliness;	(xii) Where appropriate, an indication of the sterile state of the device and the sterilisation method, or a statement indicating any special microbiological state or state of cleanliness;	---
162.	(xiii)Warnings or precautions to be taken that need to be brought to the immediate attention of the user, professional or lay, or other person. This information may be kept to a minimum in which case more detailed information shall appear in the instructions for use;	(xiii)Warnings or precautions to be taken that need to be brought to the immediate attention of the user, professional or lay, or other person. This information may be kept to a minimum in which case more detailed information shall appear in the instructions for use;	(xiii) Warnings or precautions to be taken that need to be brought to the immediate attention of the user, or other person. This information may be kept to a minimum in which case more detailed information shall appear in the instructions for use, taking into account the intended users;	"~~professional or lay~~" removed. "taking into account the intended users" – no concern.
163.			(xiiia) If the device instructions for use are not provided in paper form as indicated in point 17.1(v), a mention referring to their accessibility (or availability), and where applicable the website address where they can be consulted;	e-labelling, same as currently required: use of symbol is appropriate – no concern.
164.	(xiv) Where applicable, any particular operating instructions;	(xiv) Where applicable, any particular operating instructions;	(xiv) Where applicable, any particular operating instructions;	---
165.	(xv) If the device is intended for single use, an indication of that fact. A manufacturer's indication of single use shall be consistent across the Union;		(xv) If the device is intended for single use, an indication of that fact. A manufacturer's indication of single use shall be consistent across the Union;	---
166.	(xvi) If the device is intended for self-testing or near-patient testing, an indication of that fact;	(xvi) If the device is intended for self-testing or near-patient testing, an indication of that fact;	(xvi) If the device is intended for self-testing or near-patient testing, an indication of that fact;	---

Row	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
167.			(xvia) Where rapid assays are not intended for self-testing or near-patient testing, the explicit exclusion hereof;	The only negative information, exclusion in the lab requirements. As a risk mitigation measure does not seem to be appropriate. More important to use the same space on the label to ensure that the test is used safely and properly. Changes the nature of the label. Translation into different languages is an issue. No definition exists for rapid assays in IVDR.
168.	(xvii) If the device is for performance evaluation only, an indication of that fact;	(xvii) If the device is for performance evaluation only, an indication of that fact;		Moved up to (iii)
169.	(xviii) Where device kits include individual reagents and articles that may be made available as separate devices, each of these devices shall comply with the labelling requirements contained in this Section;	(xviii) Where device kits include individual reagents and articles that may be made available as separate devices, each of these devices shall comply with the labelling requirements contained in this Section;	(xviii) Where device kits include individual reagents and articles that are made available as separate devices, each of these devices shall comply with the labelling requirements contained in this Section and with the requirements of this Regulation;	articles that ***are*** ~~may be~~ made available as separate devices ***and with the requirements of this Regulation*** – no concern.
170.	(xix) Wherever reasonable and practicable, the devices and separate components shall be identified, where appropriate in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components.	(xix) Wherever reasonable and practicable, the devices and separate components shall be identified, where appropriate in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components.	(xix) The devices and separate components shall be identified, where applicable in terms of batches, to allow all appropriate action to detect any potential risk posed by the devices and detachable components.	**---**

Row	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
171.			As far as practicable and appropriate, the information must be set out on the device itself and/or, where appropriate, on the sales packaging. In addition, the label for devices intended for self-testing shall bear the following particulars: (i) The type of specimen(s) required to perform the test (e.g. blood, urine or saliva); (ii) Information on disease effects and prevalence; (iii) The need for additional materials for the test to function properly; (iv) Contact details for further advice and assistance. The name of devices for self-testing shall not reflect an intended purpose other than that specified by the manufacturer.	"Wherever reasonable and practicable" removed" Significant change for self-test labelling. Required information is already in the IFU, what is the additional benefit? (ii) There is no disease effect defined for each test (e.g. pregnancy). (ii) Prevalence is variable from country to country. (iii) This info is expected when purchasing a consumer product. From sales packaging point of view it makes sense, but the same info is in the IFU. (iv) contact details for further assistance (e.g. HCP): not a realistic requirement, it falls out of the responsibility of the manufacturer Specific exclusionary case.
172.	**17.3. Information in the instructions for use**	**17.3. Information in the instructions for use**	**17.3. Information in the instructions for use**	---
173.	17.3.1. The instructions for use shall contain the following particulars:	17.3.1. The instructions for use shall contain the following particulars:	17.3.1. The instructions for use shall contain the following particulars:	---
174.	(i) The name or trade name of the device;	(i) The name or trade name of the device;	(i) The name or trade name of the device;	---

Row	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
175.			(ia) The details strictly necessary for the user to uniquely identify the device;	Product name, GTIN, catalogue number: whatever identification the manufacturer uses.
176.	(ii) The device's intended purpose:	(ii) The device's intended purpose which may include:	(ii) The device's intended purpose:	---
177.	- what is detected and/or measured;	- what is detected and/or measured;	- what is detected and/or measured;	---
178.	- its function (e.g. screening, monitoring, diagnosis or aid to diagnosis);	- its function (e.g. screening, monitoring, diagnosis or aid to diagnosis, prognosis, companion diagnosis);		Deleted.
179.	- the specific disorder, condition or risk factor of interest that it is intended to detect, define or differentiate;	- the specific disorder, condition or risk factor of interest that it is intended to detect, define or differentiate;	- the specific information that is intended to be provided in the context of: = a physiological or pathological state; = a congenital abnormality; = the predisposition to a medical condition or a disease; = the determination of the safety and compatibility with potential recipients; = the prediction of treatment response or reactions; = the definition or monitoring of therapeutic measure; = where the device may be used for reasonably foreseeable purposes other than those intended by the manufacturer, the exclusion of such unintended purpose, if a higher classification for that unintended purpose is applicable, or for rapid assays not intended for self-testing or near-patient testing, the explicit	The risk management would highlight some of the listed requirements, but is not part of the IFU: included in the technical documentation. Last bullet: if the manufacturer is aware that users do something that they should not: this can be a long list

Row	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
			exclusion hereof;	
180.	- whether it is automated or not;	- whether it is automated or not;	- whether it is automated or not;	---
181.	- whether it is qualitative, semi-quantitative or quantitative;	- whether it is qualitative, semi-quantitative or quantitative;	- whether it is qualitative, semi-quantitative or quantitative;	---
182.	- the type of specimen(s) required; and	- the type of specimen(s) required; and	- the type of specimen(s) required; and	---
183.	- where applicable, the testing population.	- where applicable, the testing population.	- where applicable, the testing population.	---
184.		- for companion diagnostics, the relevant target population and directions for use with associated therapeutic(s).		
185.			- for companion diagnostics, the INN (International Nonproprietary Name) of the associated drug for which it is a companion test.	The opinion of the CompDx task force: companies are comfortable with the proposal because it strengthens the differentiation between the CDx from other assays with the same biomarker. It is also consistent with the FDA requirements.
186.	(iii) An indication that the device is for in vitro diagnostic use;	(iii) An indication that the device is for in vitro diagnostic use;	(iii) An indication that the device is an in vitro diagnostic medical device, or if the device is a 'device for performance evaluation' an indication of that fact;	The requirement to indicate 'device for performance evaluation'

Row	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
187.	(iv) The intended user, as appropriate (e.g. healthcare professionals, lay person).	(iv) The intended user, as appropriate (e.g. healthcare professionals, lay person).	(iv) The intended user, as appropriate (e.g. self-testing, near patient and laboratory professional use, healthcare professionals);	"Self-testing, near patient and laboratory professional use" are not intended users.
188.	(v) The test principle;	(v) The test principle;	(v) The test principle;	---
189.	(vi) A description of the reagents, calibrators and controls and any limitation upon their use (e.g. suitable for a dedicated instrument only);	(vi) A description of the reagents, calibrators and controls and any limitation upon their use (e.g. suitable for a dedicated instrument only);	(vi) A description of the reagents, calibrators and controls and any limitation upon their use (e.g. suitable for a dedicated instrument only);	---
190.			(via) Composition of the reagent product by nature and amount or concentration of the active ingredient(s) of the reagent(s) or kit as well as a statement, where appropriate, that the device contains other ingredients which might influence the measurement;	Concept comes from pharma, not appropriate/does not work for IVDs.
191.	(vii) A list of materials provided and a list of special materials required but not provided;	(vii) A list of materials provided and a list of special materials required but not provided;	(vii) A list of materials provided and a list of special materials required but not provided;	---
192.	(viii) For devices intended for use together with other devices and/or general purpose equipment:	(viii) For devices intended for use together with other devices and/or general purpose equipment:	(viii) For devices intended for use in combination with or installed with or connected to other devices and/or general purpose equipment:	Align wording with the ER to which it is linked and which does not include as many details. Annex I. 10.1. If the device is intended for use in combination with other devices or equipment, the whole combination, including the

Row	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
				connection system, shall be safe and shall not impair the specified performances of the devices. Any restrictions on use applying to such combinations shall be indicated on the label and/or in the instructions for use. Current requirements are similar in concept: of the IVDD: "8.7 (m) if the device must be used in combination with or installed with or connected to other medical devices or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct devices or equipment to use in order to obtain a safe and proper combination"
193.	- information to identify such devices or equipment, in order to obtain a safe combination, and/or	- information to identify such devices or equipment, in order to obtain a safe combination, and/or	- information to identify such devices or equipment, in order to obtain a validated and safe combination, including key performance characteristics, and/or	See above Validation and key performance characteristics introduced.
194.	- information on any known restrictions to combinations of devices and equipment.	- information on any known restrictions to combinations of devices and equipment.	- information on any known restrictions to combinations of devices and equipment.	See above
195.	(ix) An indication of any special storage (e.g. temperature, light, humidity, etc.)	(ix) An indication of any special storage (e.g. temperature, light, humidity, etc.)	(ix) An indication of any special storage (e.g. temperature, light, humidity, etc.)	---

Row	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
	and/or handling conditions which apply;	and/or handling conditions which apply;	and/or handling conditions which apply;	
196.	(x) In-use stability which may include the storage conditions, and shelf life following the first opening of the primary container, together with the storage conditions and stability of working solutions, where this is relevant;	(x) In-use stability which may include the storage conditions, and shelf life following the first opening of the primary container, together with the storage conditions and stability of working solutions, where this is relevant;	(x) In-use stability which may include the storage conditions, and shelf life following the first opening of the primary container, together with the storage conditions and stability of working solutions, where this is relevant;	---
197.	(xi) If the device is supplied as sterile, an indication of its sterile state, the sterilisation method and instructions in the event of the sterile packaging being damaged before use;	(xi) If the device is supplied as sterile, an indication of its sterile state, the sterilisation method and instructions in the event of the sterile packaging being damaged before use;	(xi) If the device is supplied as sterile, an indication of its sterile state, the sterilisation method and instructions in the event of the sterile packaging being damaged before use;	---
198.	(xii) Information that allows the user to be informed of any warnings, precautions, measures to be taken and limitations of use regarding the device. This information shall cover, where appropriate:	(xii) Information that allows the user to be informed of any warnings, precautions, measures to be taken and limitations of use regarding the device. This information shall cover, where appropriate:	(xii) Information that allows the user to be informed of any warnings, precautions, measures to be taken and limitations of use regarding the device. This information shall cover, where appropriate:	---
199.	- warnings, precautions and/or measures to be taken in the event of malfunction of the device or its degradation as suggested by changes in its appearance that may affect performance;	- warnings, precautions and/or measures to be taken in the event of malfunction of the device or its degradation as suggested by changes in its appearance that may affect performance;	- warnings, precautions and/or measures to be taken in the event of malfunction of the device or its degradation as suggested by changes in its appearance that may affect performance;	---
200.	- warnings, precautions and/or measures to be taken in regards to the exposure to reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects,	- warnings, precautions and/or measures to be taken in regards to the exposure to reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects,	- warnings, precautions and/or measures to be taken in regards to the exposure to reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects,	---

Row	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
	electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or temperature;	electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or temperature;	electrostatic discharge, radiation associated with diagnostic or therapeutic procedures, pressure, humidity, or temperature;	
201.	- warnings, precautions and/or measures to be taken in regards to the risks of interference posed by the reasonably foreseeable presence of the device during specific diagnostic investigations, evaluations, therapeutic treatment or other procedures (e.g. electromagnetic interference emitted by the device affecting other equipment);	- warnings, precautions and/or measures to be taken in regards to the risks of interference posed by the reasonably foreseeable presence of the device during specific diagnostic investigations, evaluations, therapeutic treatment or other procedures (e.g. electromagnetic interference emitted by the device affecting other equipment);	- warnings, precautions and/or measures to be taken in regards to the risks of interference posed by the reasonably foreseeable presence of the device during specific diagnostic investigations, evaluations, therapeutic treatment or other procedures (e.g. electromagnetic interference emitted by the device affecting other equipment);	---
202.	- precautions related to materials incorporated into the device that are carcinogenic, mutagenic or toxic, or that have endocrine disrupting properties or that could result in sensitisation or allergic reaction of the patient or user;	- precautions related to materials incorporated into the device that are carcinogenic, mutagenic or toxic, or that have endocrine disrupting properties or that could result in sensitisation or allergic reaction of the patient or user;	- precautions related to materials incorporated into the device that are carcinogenic, mutagenic or toxic, or that have endocrine disrupting properties or that could result in sensitisation or allergic reaction of the patient or user;	---
203.	- if the device is intended for single use, an indication of that fact. A manufacturer's indication of single use shall be consistent across the Union;	- if the device is intended for single use, an indication of that fact. A manufacturer's indication of single use shall be consistent across the Union;	- if the device is intended for single use, an indication of that fact. A manufacturer's indication of single use shall be consistent across the Union;	---
204.	- if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, decontamination, packaging and, where appropriate, the validated method of re-sterilization. Information shall be provided to identify when the device should no longer be reused, e.g. signs of material	- if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, decontamination, packaging and, where appropriate, the validated method of re-sterilization. Information shall be provided to identify when the device should no longer be reused, e.g. signs of material	- if the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, decontamination, packaging and, where appropriate, the validated method of re-sterilization. Information shall be provided to identify when the device should no longer be reused, e.g. signs of material	---

Row	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
	degradation or the maximum number of allowable reuses.	degradation or the maximum number of allowable reuses.	degradation or the maximum number of allowable reuses.	
205.	(xiii) Any warnings and/or precautions related to potentially infectious material that is included in the device;	(xiii) Any warnings and/or precautions related to potentially infectious material that is included in the device;	(xiii) Any warnings and/or precautions related to potentially infectious material that is included in the device;	---
206.	(xiv) Where relevant, requirements for special facilities (e.g. clean room environment) or special training (e.g. radiation safety), or particular qualifications of the device intended user;	(xiv) Where relevant, requirements for special facilities (e.g. clean room environment) or special training (e.g. radiation safety), or particular qualifications of the device intended user;	(xiv) Where relevant, requirements for special facilities (e.g. clean room environment) or special training (e.g. radiation safety), or particular qualifications of the device intended user;	---
207.	(xv) Conditions for collection, handling, and preparation of the specimen;	(xv) Conditions for collection, handling, and preparation of the specimen;	(xv) Conditions for collection, handling, and preparation of the specimen;	---
208.	(xvi) Details of any preparatory treatment or handling of the device before it is ready for use (e.g. sterilisation, final assembly, calibration, etc.);	(xvi) Details of any preparatory treatment or handling of the device before it is ready for use (e.g. sterilisation, final assembly, calibration, etc.);	(xvi) Details of any preparatory treatment or handling of the device before it is ready for use (e.g. sterilisation, final assembly, calibration, etc.) for the device to be used as intended by the manufacturer;	"***device to be used as intended by the manufacturer***" added. No issue.
209.	(xvii) The information needed to verify whether the device is properly installed and is ready to perform safely and as intended by the manufacturer, together with, where relevant:	(xvii) The information needed to verify whether the device is properly installed and is ready to perform safely and as intended by the manufacturer, together with, where relevant:	(xvii) The information needed to verify whether the device is properly installed and is ready to perform safely and as intended by the manufacturer, together with, where relevant:	---
210.	- details of the nature, and frequency, of preventative and regular maintenance, including cleaning and disinfection;	- details of the nature, and frequency, of preventative and regular maintenance, including cleaning and disinfection;	- details of the nature, and frequency, of preventative and regular maintenance, including cleaning and disinfection;	---

Row	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
211.	- identification of any consumable components and how to replace them;	- identification of any consumable components and how to replace them;	- identification of any consumable components and how to replace them;	---
212.	- information on any necessary calibration to ensure that the device operates properly and safely during its intended lifetime;	- information on any necessary calibration to ensure that the device operates properly and safely during its intended lifetime;	- information on any necessary calibration to ensure that the device operates properly and safely during its intended lifetime;	---
213.	- methods of mitigating the risks encountered by persons involved in installing, calibrating or servicing devices.	- methods of mitigating the risks encountered by persons involved in installing, calibrating or servicing devices.	- methods of mitigating the risks encountered by persons involved in installing, calibrating or servicing devices.	---
214.	(xviii) Where relevant, recommendations for quality control procedures;	(xviii) Where relevant, recommendations for quality control procedures;	(xviii) Where applicable, recommendations for quality control procedures;	***applicable*** ~~relevant~~ – no concern
215.	(xix) The metrological traceability of values assigned to calibrators and trueness-control materials, including identification of applicable reference materials and/or reference measurement procedures of higher order;	(xix) The metrological traceability of values assigned to calibrators and trueness-control materials, including identification of applicable reference materials and/or reference measurement procedures of higher order;	(xix) The metrological traceability of values assigned to calibrators and control materials, including identification of applicable applied reference materials and/or reference measurement procedures of higher order, information regarding batch to batch variation provided with relevant figures and units of measure ;	EFLM amendment (NL supported): ***"information regarding batch to batch variation provided with relevant figures and units of measure"*** IFU is not a batch specific doc. Living data should not be included in a static doc. who would be liable if a user started modifying a reagent/instrument by using correction factors? More arguments needed!
216.	(xx) Assay procedure including calculations and interpretation of results	(xx) Assay procedure including calculations and interpretation of results	(xx) Assay procedure including calculations and interpretation of results	EFLM amendments: **"information regarding batch**

Row	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
	and where relevant if any confirmatory testing shall be considered;	and where relevant if any confirmatory testing shall be considered;	and where relevant if any confirmatory testing shall be considered, information regarding batch to batch variation provided with relevant figures and units of measure ;	**to batch variation provided with relevant figures and units of measure"** – see above
217.	(xxi) Analytical performance characteristics, such as sensitivity, specificity, and accuracy, repeatability, reproducibility, limits of detection and measurement range, including information needed for the control of known relevant interferences, limitations of the method and information about the use of available reference measurement procedures and materials by the user;	(xxi) Analytical performance characteristics, such as sensitivity, specificity, and accuracy, repeatability, reproducibility, limits of detection and measurement range, including information needed for the control of known relevant interferences, limitations of the method and information about the use of available reference measurement procedures and materials by the user;	(xxi) Analytical performance characteristics, such as sensitivity, specificity, trueness (bias), precision (repeatability and reproducibility), accuracy (resulting from trueness and precision), limits of detection and measurement range, (information needed for the control of known relevant interferences, cross-reactions, and limitations of the method), measuring range, linearity and information about the use of available reference measurement procedures and materials by the user;	Clarification in terminology introduced (according to VIM): "such as sensitivity, specificity~~,~~ ~~and accuracy, repeatability, reproducibility~~, ***trueness (bias), precision (repeatability and reproducibility), accuracy (resulting from trueness and precision),*** limits of detection and measurement range, ~~including~~ ***(***information needed for the control of known relevant interferences, ***cross-reactions, and*** limitations of the method***), measuring range, linearity***"
218.			(xxia) Clinical performance characteristics as defined in Chapter II Section 6.1. of this Annex;	Clinical performance is a problematic area which needs to be further discussed.
219.			(xxib) The mathematical approach upon which the calculation of the analytical result is made;	No concern.

Row	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
220.	(xxii) Where relevant, clinical performance characteristics, such as diagnostic sensitivity and diagnostic specificity;	(xxii) Where relevant, clinical performance characteristics, such as diagnostic sensitivity and diagnostic specificity;	(xxii) Where relevant, clinical performance characteristics, such as threshold value, diagnostic sensitivity and diagnostic specificity, positive and negative predictive value;	"**threshold value, positive and negative predictive value**" are added. No concern.
221.	(xxiii) Where relevant, reference intervals;	(xxiii) Where relevant, reference intervals;	(xxiii) Where relevant, reference intervals in normal and affected populations;	*"**in normal and affected populations**"* added. Since the requirement gives an option, it is not an issue.
222.	(xxiv) Information on interfering substances or limitations (e.g. visual evidence of hyperlipidaemia or haemolysis, age of specimen) that may affect the performance of the device;	(xxiv) Information on interfering substances or limitations (e.g. visual evidence of hyperlipidaemia or haemolysis, age of specimen) that may affect the performance of the device;	(xxiv) Information on interfering substances or limitations (e.g. visual evidence of hyperlipidaemia or haemolysis, age of specimen) that may affect the performance of the device;	---
223.	(xxv) Warnings or precautions to be taken in order to facilitate the safe disposal of the device, its accessories, and the consumables used with it, if any. This information shall cover, where appropriate:	(xxv) Warnings or precautions to be taken in order to facilitate the safe disposal of the device, its accessories, and the consumables used with it, if any. This information shall cover, where appropriate:	(xxv) Warnings or precautions to be taken in order to facilitate the safe disposal of the device, its accessories, and the consumables used with it, if any. This information shall cover, where appropriate:	---
224.	- infection or microbial hazards (e.g. consumables contaminated with potentially infectious substances of human origin); - environmental hazards (e.g. batteries or materials that emit potentially hazardous levels of radiation); - physical hazards (e.g. explosion).	- infection or microbial hazards (e.g. consumables contaminated with potentially infectious substances of human origin); - environmental hazards (e.g. batteries or materials that emit potentially hazardous levels of radiation); - physical hazards (e.g. explosion).	- infection or microbial hazards (e.g. consumables contaminated with potentially infectious substances of human origin); - environmental hazards (e.g. batteries or materials that emit potentially hazardous levels of radiation); - physical hazards (e.g. explosion).	---

Row	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
225.	(xxvi) The name, registered trade name or registered trade mark of the manufacturer and the address of his registered place of business at which he can be contacted and his location be established, together with a telephone number and/or fax number and/or website address to obtain technical assistance;	(xxvi) The name, registered trade name or registered trade mark of the manufacturer and the address of his registered place of business at which he can be contacted and his location be established, together with a telephone number and/or fax number and/or website address to obtain technical assistance;	(xxvi) The name, registered trade name or registered trade mark of the manufacturer and the address of his registered place of business at which he can be contacted and his location be established, together with a telephone number and/or fax number and/or website address to obtain technical assistance;	---
226.	(xxvii) Date of issue of the instructions for use or, if they have been revised, date of issue and identifier of the latest revision of the instructions for use;	(xxvii) Date of issue of the instructions for use or, if they have been revised, date of issue and identifier of the latest revision of the instructions for use;	(xxvii) Date of issue of the instructions for use or, if they have been revised, date of issue and identifier of the latest revision of the instructions for use, with a clear indication of the introduced modifications;	"with a clear indication of the introduced modifications" added. No concern.
227.	(xxviii) A notice to the user, professional or lay, that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is established;	(xxviii) A notice to the user, professional or lay, that any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State where the user and/or patient is established;		Deleted.
228.	(xxix) Where device kits include individual reagents and articles that may be made available as separate devices, each of these devices shall comply with the instructions for use requirements contained in this Section.	(xxix) Where device kits include individual reagents and articles that may be made available as separate devices, each of these devices shall comply with the instructions for use requirements contained in this Section.	(xxix) Where device kits include individual reagents and articles that may be made available as separate devices, each of these devices shall comply with the instructions for use requirements contained in this Section and with the requirements of this Regulation.	"**and with the requirements of this Regulation**" added. No concern, although it is not the appropriate place for such clarification.

Row	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
229.			In the case of following devices, other than devices for performance evaluation, the clinical evidence as presented in the clinical evidence report, referred to in Section 3 of Part A of Annex XII: (i) companion diagnostic intended to be used to assess the patient eligibility to a treatment with a specific medicinal product; (ii) devices intended to be used in screening for or in the diagnosis of cancer; (iii) devices intended for human genetic testing.	New paragraph driven by transparency. (ii) and (iii) are not linked to pathology. Suggestion: summary of clinical evidence is sufficient for this purpose.
230.	17.3.2. In addition, the instructions for use for devices intended for self-testing or near-patient testing shall comply with the following principles	17.3.2. In addition, the instructions for use for devices intended for self-testing or near-patient testing shall comply with the following principles	17.3.2. In addition, the instructions for use for devices intended for self-testing shall comply with the following principles.	Near-patient testing is deleted.
231.	(i) Details of the test procedure shall be given, including any reagent preparation, specimen collection and/or preparation and information on how to run the test and read the results;	(i) Details of the test procedure shall be given, including any reagent preparation, specimen collection and/or preparation and information on how to run the test and read the results;	(i) Details of the test procedure shall be given, including any reagent preparation, specimen collection and/or preparation and information on how to run the test and read the results;	---
232.			(ia) Specific particulars may be omitted provided that the other information supplied by the manufacturer is sufficient to enable the user to use the device and to understand the result(s) produced by the device;	Newly introduced. Intention is unclear, clarification is needed. Does it refer to the requirements introduced in 17.2 (xix) for self-testing devices? Not a real concern.

Row	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
233.		The instructions for use shall be comprehensible to the layman and reviewed by the representatives of relevant stakeholders, including patients, healthcare professionals' organisations and manufacturers' associations.		
234.			(ib) The device's intended purpose shall provide sufficient information to enable the user to understand the medical context and to allow the intended user to make a correct interpretation of the results, taking into account the state of the art in medicines;	Newly introduced. The state of the art in medicines is different from country to country, therefore this concept should be taken out.
235.	(ii) The results need to be expressed and presented in a way that is readily understood by the intended user;	(ii) The results need to be expressed and presented in a way that is readily understood by the intended user;	(ii) The results need to be expressed and presented in a way that is readily understood by the intended user;	---
236.	(iii) Information needs to be provided with advice to the user on action to be taken (in case of positive, negative or indeterminate result), on the test limitations and on the possibility of false positive or false negative result. Information shall also be provided as to any factors that can affect the test result (e.g. age, gender, menstruation, infection, exercise, fasting, diet or medication);	(iii) Information needs to be provided with advice to the user on action to be taken (in case of positive, negative or indeterminate result), on the test limitations and on the possibility of false positive or false negative result. Information shall also be provided as to any factors that can affect the test result (e.g. age, gender, menstruation, infection, exercise, fasting, diet or medication);	(iii) Information needs to be provided with advice to the user on action to be taken (in case of positive, negative or indeterminate result), on the test limitations and on the possibility of false positive or false negative result. Information shall also be provided as to any factors that can affect the test result (e.g. age, gender, menstruation, infection, exercise, fasting, diet or medication);	---
237.	(iv) for devices intended for self-testing, the information provided shall include a statement clearly directing that the user	(iv) for devices intended for self-testing, the information provided shall include a statement clearly directing that the user	(iv) for devices intended for self-testing, the information provided shall include a statement clearly directing that the user	"**where available, information specific to the Member State(s) where the device is**

Row	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
	should not take any decision of medical relevance without first consulting the appropriate healthcare professional;	should not take any decision of medical relevance without first consulting the appropriate healthcare professional;	should not take any decision of medical relevance without first consulting the appropriate healthcare professional and, where available, information specific to the Member State(s) where the device is placed on the market on where a user can obtain further advice (e.g. national helplines, websites, etc.);	**placed on the market on where a user can obtain further advice (e.g. national helplines, websites, etc.)**" Not a realistic requirement, it falls out of the control of the manufacturer who does not have such expertise, neither access to such information in each country (due to lack of personnel based in each country). This requirement contradicts with the one just above (advice to the user on action to be taken) which is to consult a HCP. Fulfilling this requirement would result in country specific IFUs.
238.	(v) for devices intended for self-testing used for the monitoring of an existing disease, the information shall specify that the patient should only adapt the treatment if he has received the appropriate training to do so.	(v) for devices intended for self-testing used for the monitoring of an existing disease, the information shall specify that the patient should only adapt the treatment if he has received the appropriate training to do so.	(v) for devices intended for self-testing used for the monitoring of previously diagnosed existing disease or condition, the information shall specify that the patient shall only adapt the treatment if he has received the appropriate training to do so.	"a~~n~~ ***previously diagnosed*** existing disease ***or condition***" – change in wording does not change the meaning, no concern.
239.	**ANNEX II** **TECHNICAL DOCUMENTATION**	**ANNEX II** **TECHNICAL DOCUMENTATION**	**ANNEX II** **TECHNICAL DOCUMENTATION**	
240.	The technical documentation and, if applicable, the summary technical documentation (STED) to be drawn up by	The technical documentation and, if applicable, the summary technical documentation (STED) to be drawn up by	The technical documentation and, if applicable, the summary technical documentation (STED) to be drawn up by	More detailed text.

Row	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
	the manufacturer shall include in particular the following elements:	the manufacturer shall include in particular the following elements:	the manufacturer shall be presented in a clear, organized, readily searchable and unequivocal way and shall include in particular the elements described in this Annex. The STED shall summarize the elements of the technical documentation.	
241.	**1. DEVICE DESCRIPTION AND SPECIFICATION, INCLUDING VARIANTS AND ACCESSORIES**	**1. DEVICE DESCRIPTION AND SPECIFICATION, INCLUDING VARIANTS AND ACCESSORIES**	**1. DEVICE DESCRIPTION AND SPECIFICATION, INCLUDING VARIANTS AND ACCESSORIES**	**---**
242.	**1.1. Device description and specification**	**1.1. Device description and specification**	**1.1. Device description and specification**	**---**
243.	(a) product or trade name and a general description of the device, including its intended purpose;	(a) product or trade name and a general description of the device, including its intended purpose;	(a) product or trade name and a general description of the device, including its intended purpose, and intended user;	Adds intended user
244.	(b) the UDI device identifier as referred to in item (i) of point (a) of Article 22(1) attributed by the manufacturer to the device in question, as soon as identification of this device shall be based on a UDI system, or otherwise clear identification by means of product code, catalogue number or other unambiguous reference allowing traceability;	(b) the UDI device identifier as referred to in item (i) of point (a) of Article 22(1) attributed by the manufacturer to the device in question, as soon as identification of this device shall be based on a UDI system, or otherwise clear identification by means of product code, catalogue number or other unambiguous reference allowing traceability;	(b) the UDI device identifier and the Basic UDI devices identifier as referred to in item (i) of point (a) of Article 22(1) attributed by the manufacturer to the device in question, as soon as identification of this device shall be based on a UDI system, or otherwise clear identification by means of product code, catalogue number or other unambiguous reference allowing traceability;	**---**
245.	(c) the intended purpose of the device which may include: (i) what is detected and/or measured; (ii) its function (e.g. screening,	(c) the intended purpose of the device which may include: (i) what is detected and/or measured; (ii) its function (e.g. screening,	(c) the intended purpose of the device which may include: (i) what is detected and/or measured; (ii) its function (e.g. screening,	---

Row	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
	monitoring, diagnosis or aid to diagnosis); (iii) the specific disorder, condition or risk factor of interest that it is intended to detect, define or differentiate; (iv) whether it is automated or not; (v) whether it is qualitative, semi-quantitative or quantitative; (vi) the type of specimen(s) required; (vii) where applicable, the testing population; (viii) the intended user.	monitoring, diagnosis or aid to diagnosis, prognosis, companion diagnosis); (iii) the specific disorder, condition or risk factor of interest that it is intended to detect, define or differentiate; (iv) whether it is automated or not; (v) whether it is qualitative, semi-quantitative or quantitative; (vi) the type of specimen(s) required; (vii) where applicable, the testing population; (viii) the intended user; (viia) for companion diagnostics, the relevant target population and directions for use with the associated therapeutic(s).	monitoring, diagnosis or aid to diagnosis); (iii) the specific disorder, condition or risk factor of interest that it is intended to detect, define or differentiate; (iv) whether it is automated or not; (v) whether it is qualitative, semi-quantitative or quantitative; (vi) the type of specimen(s) required; (vii) where applicable, the testing population; (viii) the intended user.	
246.	(d) the description of the principle of the assay method or instrument principles of operation;	(d) the description of the principle of the assay method or instrument principles of operation;	(d) the description of the principle of the assay method or the principles of operation of an instrument;	**---**
247.			(da) the determination of the regulatory status of the device, including the rationale for qualification as a device;	Rationale for the qualification as an IVD is needed as opposed to not an IVD.
248.	(e) the risk class of the device and the applicable classification rule according to Annex VII;	(e) the risk class of the device and the applicable classification rule according to Annex VII;	(e) the risk class of the device and the justification of the classification rule(s) applied according to Annex VII;	Justification of classification is required.
249.	(f) the description of the components and where appropriate, the description of the reactive ingredients of relevant components (such as antibodies,	(f) the description of the components and where appropriate, the description of the reactive ingredients of relevant components (such as antibodies,	(f) the description of the components and where appropriate, the description of the reactive ingredients of relevant components (such as antibodies,	---

Row	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
	antigens, nucleic acid primers); and where applicable: (g) the description of the specimen collection and transport materials provided with the device or descriptions of specifications recommended for use; (h) for instruments of automated assays: the description of the appropriate assay characteristics or dedicated assays; (i) for automated assays: a description of the appropriate instrumentation characteristics or dedicated instrumentation; (j) a description of any software to be used with the device; (k) a description or complete list of the various configurations/variants of the device that will be made available; (l) a description of the accessories, other in vitro diagnostic medical devices and other products, which are intended to be used in combination with the device.	antigens, nucleic acid primers); and where applicable: (g) the description of the specimen collection and transport materials provided with the device or descriptions of specifications recommended for use; (h) for instruments of automated assays: the description of the appropriate assay characteristics or dedicated assays; (i) for automated assays: a description of the appropriate instrumentation characteristics or dedicated instrumentation; (j) a description of any software to be used with the device; (k) a description or complete list of the various configurations/variants of the device that will be made available; (l) a description of the accessories, other in vitro diagnostic medical devices and other products, which are intended to be used in combination with the device.	antigens, nucleic acid primers); and where applicable: (g) the description of the specimen collection and transport materials provided with the device or descriptions of specifications recommended for use; (h) for instruments of automated assays: the description of the appropriate assay characteristics or dedicated assays; (i) for automated assays: a description of the appropriate instrumentation characteristics or dedicated instrumentation; (j) a description of any software to be used with the device; (k) a description or complete list of the various configurations/variants of the device that will be made available; (l) a description of the accessories, other *in vitro* diagnostic medical devices and other products, which are intended to be used in combination with the device.	
250.	**1.2. Reference to previous and similar generations of the device** (a) an overview of the manufacturer's previous generation(s) of the device, if such exist;	**1.2. Reference to previous and similar generations of the device** (a) an overview of the manufacturer's previous generation(s) of the device, if such exist;	**1.2. Reference to previous and similar generations of the device** (a) an overview of the manufacturer's previous generation(s) of the device, if such exist;	**---**
251.	(b) an overview of the manufacturer's similar devices available on the EU or international markets, if such exist.	(b) an overview of the manufacturer's similar devices available on the EU or international markets, if such exist.	(b) an overview of identified similar devices available on the EU or international markets, if such exist.	Similar devices from other manufacturers also would need to be included.

Row	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
252.	**2. INFORMATION SUPPLIED BY THE MANUFACTURER**	**2. INFORMATION SUPPLIED BY THE MANUFACTURER**	**2. INFORMATION SUPPLIED BY THE MANUFACTURER**	---
253.	(a) a complete set of	(a) a complete set of	(a) a complete set of	---
254.	- the label(s) on the device and on its packaging;	- the label(s) on the device and on its packaging;	- the label(s) on the device and on its packaging (single unit packaging, sales packaging, transport packaging in case of specific management conditions), in the languages accepted in the Member States where the device is envisaged to be sold;	Label must include all relevant languages
255.	- the instructions for use;	- the instructions for use;	- the instructions for use in the languages accepted in the Member States where the device is envisaged to be sold;	IFU must include all relevant languages
256.	(b) a list of the language variants for the Member States where the device is envisaged to be marketed.	(b) a list of the language variants for the Member States where the device is envisaged to be marketed.		List of languages no longer required.
257.	**3. DESIGN AND MANUFACTURING INFORMATION**	**3. DESIGN AND MANUFACTURING INFORMATION**	**3. DESIGN AND MANUFACTURING INFORMATION**	---
258.	**3.1. Design information** Information to allow a general understanding of the design stages applied to the device. This shall include:	**3.1. Design information** Information to allow a general understanding of the design stages applied to the device. This shall include:	**3.1. Design information** Information to allow the understanding of the design stages applied to the device. This shall include:	---
259.	(a) the description of the critical ingredients of the device such as antibodies, antigens, enzymes and	(a) the description of the critical ingredients of the device such as antibodies, antigens, enzymes and	(a) the description of the critical ingredients of the device such as antibodies, antigens, enzymes and	---

Row	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
	nucleic acid primers provided or recommended for use with the device;	nucleic acid primers provided or recommended for use with the device;	nucleic acid primers provided or recommended for use with the device;	
260.	(b) for instruments, the description of major subsystems, analytical technology (e.g. operating principles, control mechanisms), dedicated computer hardware and software;	(b) for instruments, the description of major subsystems, analytical technology (e.g. operating principles, control mechanisms), dedicated computer hardware and software;	(b) for instruments, the description of major subsystems, analytical technology (e.g. operating principles, control mechanisms), dedicated computer hardware and software;	---
261.	(c) for instruments and software, the overview of the entire system;	(c) for instruments and software, the overview of the entire system;	(c) for instruments and software, the overview of the entire system;	---
262.	(d) for standalone software, the description of the data interpretation methodology (i.e. algorithm);	(d) for standalone software, the description of the data interpretation methodology (i.e. algorithm);	(d) for software, the description of the data interpretation methodology (i.e. algorithm);	**---**
263.	(e) for devices intended for self-testing or near-patient testing devices the description of the design aspects that make them suitable for self-testing or near-patient testing.	(e) for devices intended for self-testing or near-patient testing devices the description of the design aspects that make them suitable for self-testing or near-patient testing.	(e) for devices intended for self-testing or near-patient testing devices the description of the design aspects that make them suitable for self-testing or near-patient testing.	---
264.	**3.2. Manufacturing information**	**3.2. Manufacturing information**	**3.2. Manufacturing information**	**---**
265.	(a) Information to allow a general understanding of the manufacturing processes such as production, assembly, final product testing, and packaging of the finished device. More detailed information needs to be provided for the audit of the quality management system or other applicable conformity assessment procedures;	(a) Information to allow a general understanding of the manufacturing processes such as production, assembly, final product testing, and packaging of the finished device. More detailed information needs to be provided for the audit of the quality management system or other applicable conformity assessment procedures;	(a) Information to allow the understanding of the manufacturing processes such as production, assembly, final product testing, and packaging of the finished device. More detailed information needs to be provided for the audit of the quality management system or other applicable conformity assessment procedures;	**---**

Row	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
266.	(b) identification of all sites, including suppliers and sub-contractors, where manufacturing activities are performed.	(b) identification of all sites, including suppliers and sub-contractors, where critical manufacturing activities are performed.	(b) identification of all sites, including suppliers and sub-contractors, where manufacturing activities are performed.	**---**
267.	**4. GENERAL SAFETY AND PERFORMANCE REQUIREMENTS**	**4. GENERAL SAFETY AND PERFORMANCE REQUIREMENTS**	**4. GENERAL SAFETY AND PERFORMANCE REQUIREMENTS**	**---**
268.	The documentation shall contain information regarding the solutions adopted to meet the general safety and performance requirements laid down in Annex I. This information may take the form of a checklist identifying:	The documentation shall contain information regarding the solutions adopted to meet the general safety and performance requirements laid down in Annex I. This information may take the form of a checklist identifying:	The documentation shall contain demonstration of conformity with the general safety and performance requirements laid down in Annex I, applicable to the device and taking into account its intended purpose, including the justification, validation and verification of the solutions adopted to meet those requirements. This demonstration shall include:	No significant change
269.	(a) the general safety and performance requirements that apply to the device and why others do not apply;	(a) the general safety and performance requirements that apply to the device and why others do not apply;	(a) the general safety and performance requirements that apply to the device and why others do not apply;	---
270.	(b) the method(s) used to demonstrate conformity with each applicable general safety and performance requirement;	(b) the method(s) used to demonstrate conformity with each applicable general safety and performance requirement;	(b) the method(s) used to demonstrate conformity with each applicable general safety and performance requirement;	---
271.	(c) the harmonised standards or CTS applied or other method(s) employed;	(c) the harmonised standards or CTS applied or other method(s) employed;	(c) the harmonised standards or CS applied and to which extent or other method(s) employed and to which extent;	No significant change
272.	(d) the precise identity of the controlled documents offering evidence of conformity with each harmonised	(d) the precise identity of the controlled documents offering evidence of conformity with each harmonised	(d) the precise identity of the controlled documents offering evidence of conformity with each harmonised	---

Row	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
	standard, CTS or other method employed to demonstrate conformity with the general safety and performance requirements. This information shall incorporate a cross-reference to the location of such evidence within the full technical documentation and, if applicable, the summary technical documentation.	standard, CTS or other method employed to demonstrate conformity with the general safety and performance requirements. This information shall incorporate a cross-reference to the location of such evidence within the full technical documentation and, if applicable, the summary technical documentation.	standard, CS or other method employed to demonstrate conformity with the general safety and performance requirements. This information shall incorporate a cross-reference to the location of such evidence within the full technical documentation and, if applicable, the summary technical documentation.	
273.	**5. RISK/BENEFIT ANALYSIS AND RISK MANAGEMENT**	**5. RISK/BENEFIT ANALYSIS AND RISK MANAGEMENT**	**5. RISK/BENEFIT ANALYSIS AND RISK MANAGEMENT**	**---**
274.	The documentation shall contain a summary of (a) the risk/benefit analysis referred to in Section 1 and 5 of Annex I; and (b) the solutions adopted and the results of the risk management referred to in Section 2 of Annex I.	The documentation shall contain a summary of (a) the risk/benefit analysis referred to in Section 1 and 5 of Annex I; and (b) the solutions adopted and the results of the risk management referred to in Section 2 of Annex I.	The documentation shall contain (a) the risk/benefit analysis referred to in Section 1 and 5 of Annex I; and (b) the solutions adopted and the results of the risk management referred to in Section 2 of Annex I.	---
275.	**6. PRODUCT VERIFICATION AND VALIDATION**	**6. PRODUCT VERIFICATION AND VALIDATION**	**6. PRODUCT VERIFICATION AND VALIDATION**	**---**
276.	The documentation shall contain the results of verification and validation testing and/or studies undertaken to demonstrate conformity of the device with the requirements of this Regulation and in particular the applicable general safety and performance requirements. This includes:	The documentation shall contain the results of verification and validation testing and/or studies undertaken to demonstrate conformity of the device with the requirements of this Regulation and in particular the applicable general safety and performance requirements. This includes:	The documentation shall contain the results of all the verification and validation testing and/or studies undertaken and their critical analysis to demonstrate conformity of the device with the requirements of this Regulation and in particular the applicable general safety and performance requirements. This includes:	No significant change

Row	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
277.	**6.1 Information on analytical performance**	**6.1 Information on analytical performance**	**6.1. Information on analytical performance**	**---**
278.	6.1.1 Specimen type This section shall describe the different specimen types that can be used, including their stability (e.g. storage and where applicable transport conditions) and storage conditions (e.g. duration, temperature limits and freeze/thaw cycles).	6.1.1 Specimen type This section shall describe the different specimen types that can be used, including their stability (e.g. storage and where applicable transport conditions) and storage conditions (e.g. duration, temperature limits and freeze/thaw cycles).	6.1.1. Specimen type This section shall describe the different specimen types that can be used, including their stability (e.g. storage, where applicable transport conditions and, with a view to time-critical analysis methods, information on the timeframe between taking the specimen and its analysis) and storage conditions (e.g. duration, temperature limits and freeze/thaw cycles).	No significant change (more detail)
279.	6.1.2 Analytical performance characteristics	6.1.2 Analytical performance characteristics	6.1.2. Analytical performance characteristics	---
280.	6.1.2.1 Accuracy of measurement (a) Trueness of measurement This section shall provide information on the trueness of the measurement procedure and summarise the data in sufficient detail to allow assessment of the adequacy of the means selected to establish the trueness. Trueness measures apply to both quantitative and qualitative assays only when a reference standard or method is available. (b) Precision of measurement This section shall describe repeatability and reproducibility studies.	6.1.2.2 Accuracy of measurement (a) Trueness of measurement This section shall provide information on the trueness of the measurement procedure and summarise the data in sufficient detail to allow assessment of the adequacy of the means selected to establish the trueness. Trueness measures apply to both quantitative and qualitative assays only when a reference standard or method is available. (b) Precision of measurement This section shall describe repeatability and reproducibility studies.	6.1.2.1. Accuracy of measurement (a) Trueness of measurement This section shall provide information on the trueness of the measurement procedure and summarise the data in sufficient detail to allow assessment of the adequacy of the means selected to establish the trueness. Trueness measures apply to both quantitative and qualitative assays only when a reference standard or method is available. (b) Precision of measurement This section shall describe repeatability and reproducibility studies.	---

Row	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
281.	6.1.2.2 Analytical sensitivity This section shall include information about the study design and results. It shall provide a description of specimen type and preparation including matrix, analyte levels, and how levels were established. The number of replicates tested at each concentration shall also be provided as well as a description of the calculation used to determine assay sensitivity.	6.1.2.2 Analytical sensitivity This section shall include information about the study design and results. It shall provide a description of specimen type and preparation including matrix, analyte levels, and how levels were established. The number of replicates tested at each concentration shall also be provided as well as a description of the calculation used to determine assay sensitivity.	6.1.2.2. Analytical sensitivity This section shall include information about the study design and results. It shall provide a description of specimen type and preparation including matrix, analyte levels, and how levels were established. The number of replicates tested at each concentration shall also be provided as well as a description of the calculation used to determine assay sensitivity.	---
282.	6.1.2.3 Analytical specificity	6.1.2.3 Analytical specificity	6.1.2.3. Analytical specificity	---
283.	This section shall describe interference and cross reactivity studies to determine the analytical specificity in the presence of other substances/agents in the specimen.	This section shall describe interference and cross reactivity studies to determine the analytical specificity in the presence of other substances/agents in the specimen.	This section shall describe interference and cross reactivity studies to determine the analytical specificity in the presence of other substances/agents in the specimen.	---
284.	Information shall be provided on the evaluation of potentially interfering and cross reacting substances/agents on the assay, on the substance/agent type and concentration tested, specimen type, analyte test concentration, and results. Interferents and cross reacting substances/agents, which vary greatly depending on the assay type and design, could derive from exogenous or endogenous sources such as:	Information shall be provided on the evaluation of potentially interfering and cross reacting substances/agents on the assay, on the substance/agent type and concentration tested, specimen type, analyte test concentration, and results. Interferents and cross reacting substances/agents, which vary greatly depending on the assay type and design, could derive from exogenous or endogenous sources such as:	Information shall be provided on the evaluation of potentially interfering and cross reacting substances/agents on the assay, on the substance/agent type and concentration tested, specimen type, analyte test concentration, and results. Interferents and cross reacting substances/agents, which vary greatly depending on the assay type and design, could derive from exogenous or endogenous sources such as:	---
285.	(a) substances used for patient treatment (e.g. medicinal products);	(a) substances used for patient treatment (e.g. medicinal products);	(a) substances used for patient treatment (e.g. medicinal products);	---

Row	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
286.	(b) substances ingested by the patient (e.g. alcohol, foods);	(b) substances ingested by the patient (e.g. alcohol, foods);	(b) substances ingested by the patient (e.g. alcohol, foods);	---
287.	(c) substances added during specimen preparation (e.g. preservatives, stabilisers);	(c) substances added during specimen preparation (e.g. preservatives, stabilisers);	(c) substances added during specimen preparation (e.g. preservatives, stabilisers);	---
288.	(d) substances encountered in specific specimens types (e.g. haemoglobin, lipids, bilirubin, proteins);	(d) substances encountered in specific specimens types (e.g. haemoglobin, lipids, bilirubin, proteins);	(d) substances encountered in specific specimens types (e.g. haemoglobin, lipids, bilirubin, proteins);	---
289.	(e) analytes of similar structure (e.g. precursors, metabolites) or medical conditions unrelated to the test condition including specimens negative for the assay but positive for a condition that may mimic the test condition.	(e) analytes of similar structure (e.g. precursors, metabolites) or medical conditions unrelated to the test condition including specimens negative for the assay but positive for a condition that may mimic the test condition.	(e) analytes of similar structure (e.g. precursors, metabolites) or medical conditions unrelated to the test condition including specimens negative for the assay but positive for a condition that may mimic the test condition.	---
290.	6.1.2.4 Metrological traceability of calibrator and control material values	6.1.2.4 Metrological traceability of calibrator and control material values	6.1.2.4. Metrological traceability of calibrator and control material values	---
291.	6.1.2.5 Measuring range of the assay This section shall include information on the measuring range (linear and non-linear measuring systems) including the limit of detection and describe information on how these were established. This information shall include a description of specimen type, number of specimen, number of replicates, and preparation including information on matrix, analyte levels and how levels were established. If applicable, a description of high dose hook effect and	6.1.2.5 Measuring range of the assay This section shall include information on the measuring range (linear and non-linear measuring systems) including the limit of detection and describe information on how these were established. This information shall include a description of specimen type, number of specimen, number of replicates, and preparation including information on matrix, analyte levels and how levels were established. If applicable, a description of high dose hook effect and	6.1.2.5. Measuring range of the assay This section shall include information on the measuring range (linear and non-linear measuring systems) including the limit of detection and describe information on how these were established. This information shall include a description of specimen type, number of specimen, number of replicates, and preparation including information on matrix, analyte levels and how levels were established. If applicable, a description of high dose hook effect and	---

Row	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
	the data supporting the mitigation (e.g. dilution) steps shall be added.	the data supporting the mitigation (e.g. dilution) steps shall be added.	the data supporting the mitigation (e.g. dilution) steps shall be added.	
292.	6.1.2.6 Definition of assay cut-off This section shall provide a summary of analytical data with a description of the study design including methods for determining the assay cut-off, including: (a) the population(s) studied (demographics / selection / inclusion and exclusion criteria / number of individuals included); (b) method or mode of characterisation of specimens; and (c) statistical methods e.g. Receiver Operator Characteristic (ROC) to generate results and if applicable, define grey-zone/equivocal zone.	6.1.2.6 Definition of assay cut-off This section shall provide a summary of analytical data with a description of the study design including methods for determining the assay cut-off, including: (a) the population(s) studied (demographics / selection / inclusion and exclusion criteria / number of individuals included); (b) method or mode of characterisation of specimens; and (c) statistical methods e.g. Receiver Operator Characteristic (ROC) to generate results and if applicable, define grey-zone/equivocal zone.	6.1.2.6. Definition of assay cut-off This section shall provide a summary of analytical data with a description of the study design including methods for determining the assay cut-off, including: (a) the population(s) studied (demographics / selection / inclusion and exclusion criteria / number of individuals included); (b) method or mode of characterisation of specimens; and (c) statistical methods e.g. Receiver Operator Characteristic (ROC) to generate results and if applicable, define grey-zone/equivocal zone.	---
293.			6.1.3. The Analytical Performance Report according to Annex XII.	Specific analytical performance report
294.	**6.2 Information on clinical performance**	**6.2 Information on clinical performance**	**6.2. Information on clinical performance and clinical evidence. Performance Evaluation Report**	Clinical performance vs clinical evidence
295.	Where applicable, the documentation shall contain data on the clinical performance of the device.	Where applicable, the documentation shall contain data on the clinical performance of the device.	The documentation shall contain the performance evaluation report, which includes the reports on the scientific validity, the analytical and on the clinical performance, according to Annex XII, together with an assessment of these reports.	Three reports and an assessment – unclear as the performance evaluation is the assessment – confusing terminology.

Row	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
296.	The clinical evidence report referred to in Section 3 of Annex XII shall be included and/or fully referenced in the technical documentation.	The clinical evidence report referred to in Section 3 of Annex XII shall be included and fully referenced in the technical documentation.	The clinical performance study documents referred to in Part A, Section 2 of Annex XII shall be included and/or fully referenced in the technical documentation.	Clinical evidence vs Clinical performance
297.	**6.3 Stability (excluding specimen stability)** This section shall describe claimed shelf life, in use stability and shipping stability studies.	**6.3 Stability (excluding specimen stability)** This section shall describe claimed shelf life, in use stability and shipping stability studies.	**6.3. Stability (excluding specimen stability)** This section shall describe claimed shelf life, in use stability and shipping stability studies.	**---**
298.	6.3.1 Claimed shelf life This section shall provide information on stability testing studies to support the claimed shelf life. Testing shall be performed on at least three different lots manufactured under conditions that are essentially equivalent to routine production conditions (these lots do not need to be consecutive lots). Accelerated studies or extrapolated data from real time data are acceptable for initial shelf life claim but need to be followed up with real time stability studies. Such detailed information shall describe: (a) the study report (including the protocol, number of lots, acceptance criteria and testing intervals); (b) when accelerated studies have been performed in anticipation of the real time studies, the method used for accelerated studies;	6.3.1 Claimed shelf life This section shall provide information on stability testing studies to support the claimed shelf life. Testing shall be performed on at least three different lots manufactured under conditions that are essentially equivalent to routine production conditions (these lots do not need to be consecutive lots). Accelerated studies or extrapolated data from real time data are acceptable for initial shelf life claim but need to be followed up with real time stability studies. Such detailed information shall describe: (a) the study report (including the protocol, number of lots, acceptance criteria and testing intervals); (b) when accelerated studies have been performed in anticipation of the real time studies, the method used for accelerated studies;	6.3.1. Claimed shelf-life This section shall provide information on stability testing studies to support the claimed shelf life. Testing shall be performed on at least three different lots manufactured under conditions that are essentially equivalent to routine production conditions (these lots do not need to be consecutive lots). Accelerated studies or extrapolated data from real time data are acceptable for initial shelf life claim but need to be followed up with real time stability studies. Such detailed information shall describe: (a) the study report (including the protocol, number of lots, acceptance criteria and testing intervals); (b) when accelerated studies have been performed in anticipation of the real time studies, the method used for accelerated studies;	---

Row	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
	(c) the conclusions and claimed shelf life.	(c) the conclusions and claimed shelf life.	(c) the conclusions and claimed shelf life.	
299.	6.3.2 In-use stability This section shall provide information on in-use stability studies for one lot reflecting actual routine use of the device (real or simulated). This may include open vial stability and/or, for automated instruments, on board stability. In the case of automated instrumentation if calibration stability is claimed, supporting data shall be included. Such detailed information shall describe: (a) the study report (including the protocol, acceptance criteria and testing intervals); (b) the conclusions and claimed in-use stability.	6.3.2 In-use stability This section shall provide information on in-use stability studies for one lot reflecting actual routine use of the device (real or simulated). This may include open vial stability and/or, for automated instruments, on board stability. In the case of automated instrumentation if calibration stability is claimed, supporting data shall be included. Such detailed information shall describe: (a) the study report (including the protocol, acceptance criteria and testing intervals); (b) the conclusions and claimed in-use stability.	6.3.2. In-use stability This section shall provide information on in-use stability studies for one lot reflecting actual routine use of the device (real or simulated). This may include open vial stability and/or, for automated instruments, on board stability. In the case of automated instrumentation if calibration stability is claimed, supporting data shall be included. Such detailed information shall describe: (a) the study report (including the protocol, acceptance criteria and testing intervals); (b) the conclusions and claimed in-use stability.	---
300.	6.3.3 Shipping stability This section shall provide information on shipping stability studies for one lot to evaluate the tolerance of products to the anticipated shipping conditions. Shipping studies can be done under real and/or simulated conditions and shall include variable shipping conditions such as extreme heat and/or cold. Such information shall describe:	6.3.3 Shipping stability This section shall provide information on shipping stability studies for one lot to evaluate the tolerance of products to the anticipated shipping conditions. Shipping studies can be done under real and/or simulated conditions and shall include variable shipping conditions such as extreme heat and/or cold. Such information shall describe:	6.3.3. Shipping stability This section shall provide information on shipping stability studies for one lot to evaluate the tolerance of products to the anticipated shipping conditions. Shipping studies can be done under real and/or simulated conditions and shall include variable shipping conditions such as extreme heat and/or cold. Such information shall describe:	---

Row	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
	(a) the study report (including the protocol, acceptance criteria); (b) the method used for simulated conditions; (c) the conclusion and recommended shipping conditions	(a) the study report (including the protocol, acceptance criteria); (b) the method used for simulated conditions; (c) the conclusion and recommended shipping conditions	(a) the study report (including the protocol, acceptance criteria); (b) the method used for simulated conditions; (c) the conclusion and recommended shipping conditions.	
301.	**6.4 Software verification and validation** The documentation shall contain evidence of the validation of the software, as used in the finished device. This information shall typically include the summary results of all verification, validation and testing performed in-house and as applicable in an actual user environment prior to final release. It shall also address all of the different hardware configurations and, where applicable, operating systems identified in the labelling.	**6.4 Software verification and validation** The documentation shall contain evidence of the validation of the software, as used in the finished device. This information shall typically include the summary results of all verification, validation and testing performed in-house and as applicable in an actual user environment prior to final release. It shall also address all of the different hardware configurations and, where applicable, operating systems identified in the labelling.	**6.4. Software verification and validation** The documentation shall contain evidence of the validation of the software, as used in the finished device. This information shall typically include the summary results of all verification, validation and testing performed in-house and as applicable in an actual user environment prior to final release. It shall also address all of the different hardware configurations and, where applicable, operating systems identified in the labelling.	---
302.	**6.5 Additional information in specific cases** (a) In the case of devices placed on the market in a sterile or defined microbiological condition, a description of the environmental conditions for the relevant manufacturing steps. In the case of devices placed on the market in a sterile condition, a description of the methods used, including the validation reports, with respect to packaging, sterilisation and maintenance of sterility. The validation report shall address	**6.5 Additional information in specific cases** (a) In the case of devices placed on the market in a sterile or defined microbiological condition, a description of the environmental conditions for the relevant manufacturing steps. In the case of devices placed on the market in a sterile condition, a description of the methods used, including the validation reports, with respect to packaging, sterilisation and maintenance of sterility. The validation report shall address	**6.5. Additional information in specific cases** (a) In the case of devices placed on the market in a sterile or defined microbiological condition, a description of the environmental conditions for the relevant manufacturing steps. In the case of devices placed on the market in a sterile condition, a description of the methods used, including the validation reports, with respect to packaging, sterilisation and maintenance of sterility. The validation report shall address	---

Row	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
	bioburden testing, pyrogen testing and, if applicable, testing for sterilant residues. (b) In the case of devices containing tissues, cells and substances of animal, human or microbial origin, information on the origin of such material and on the conditions in which it was collected. (c) In the case of devices placed on the market with a measuring function, a description of the methods used in order to ensure the accuracy as given in the specifications. (d) If the device is to be connected to other equipment in order to operate as intended, a description of this combination including proof that it conforms to the general safety and performance requirements when connected to any such equipment having regard to the characteristics specified by the manufacturer.	bioburden testing, pyrogen testing and, if applicable, testing for sterilant residues. (b) In the case of devices containing tissues, cells and substances of animal, human or microbial origin, information on the origin of such material and on the conditions in which it was collected. (c) In the case of devices placed on the market with a measuring function, a description of the methods used in order to ensure the accuracy as given in the specifications. (d) If the device is to be connected to other equipment in order to operate as intended, a description of this combination including proof that it conforms to the general safety and performance requirements when connected to any such equipment having regard to the characteristics specified by the manufacturer.	bioburden testing, pyrogen testing and, if applicable, testing for sterilant residues. (b) In the case of devices containing tissues, cells and substances of animal, human or microbial origin, information on the origin of such material and on the conditions in which it was collected. (c) In the case of devices placed on the market with a measuring function, a description of the methods used in order to ensure the accuracy as given in the specifications. (d) If the device is to be connected to other equipment in order to operate as intended, a description of this combination including proof that it conforms to the general safety and performance requirements when connected to any such equipment having regard to the characteristics specified by the manufacturer.	
303.			**ANNEX IIa** **TECHNICAL DOCUMENTATION ON POST-MARKET SURVEILLANCE**	**New section – however how can it be fulfilled prior to placing a device on the market?**
304.			The technical documentation on post-market surveillance to be drawn up by the manufacturer in accordance with the Section 0 of Chapter VII shall be presented in a clear, organized, readily searchable and unequivocal way and shall include in particular:	Information shall be clear.

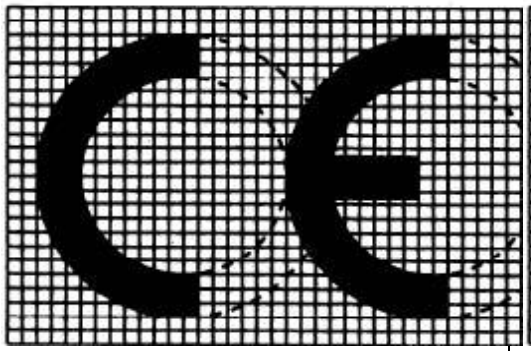
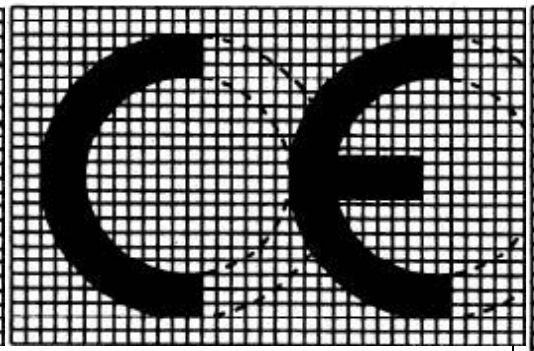
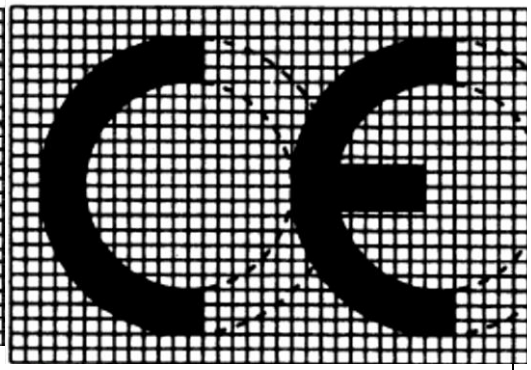
Row	European Commission proposal for IVD Regulation Dated 26 September 2012	European Parliament Integrated Text Dated 22 October 2013	Latvian Presidency Consolidated Text Dated 02 June 2015	Comments
305.			**1.1. Post-market surveillance plan in accordance with Article 58b.**	Post market surveillance plan
306.			The manufacturer shall prove in a post-market surveillance plan that it complies with the obligation referred to in Article 58a.	No comment
307.			(a) The post-market surveillance plan shall see to the collection and utilization of available information, in particular:	No comment
308.			- information concerning serious incidents, including periodic safety update report, and field safety corrective actions,	Not relevant pre-market
309.			- records referred to not serious incident and data on any undesirable side effects,	Not relevant pre-market
310.			- and information on trend reporting,	Only if applicable
311.			- relevant specialist or technical literature, databases and/or registers,	Only if applicable
312.			- information, including feedbacks and complaints, provided by users, distributors, importers,	Not relevant pre-market

Row	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
313.			- publicly available information about similar medical devices.	Question on how to compile and ensure completeness
314.			(b) The post-market surveillance plan shall include at least:	No comment
315.			- a proactive and systematic process to collect any information referred to in paragraph (a) the process shall allow a correct characterization of the performance of the devices also comparing the device with the similar products available on the market;	Comparison question – based on what information – can this become a problem if public?
316.			- effective and appropriate methods and processes to assess the collected data;	No comment
317.			- suitable indicators and threshold values that shall be used in the continuous reassessment of the risk benefit analysis and of the risk management as referred to in Sections I of Annex I;	No comment
318.			- effective and appropriate methods and tools to investigate complaints or market experiences collected in the field;	No comment
319.			- methods and protocols to manage the events subject to trend report as	No comment

Row	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
			provided in Article 59a, including those to be used to establish any statistically significant increase in the frequency or severity of incidents as well as the observation period;	
320.			- methods and protocols to communicate effectively with competent authorities, notified bodies, economic operators~~,~~ and users;	No comment
321.			- reference to procedures to fulfil the manufacturers obligations laid down in Article 58a, 58b and 58c;	No comment
322.			- systematic procedures to identify and initiate appropriate measures including corrective actions;	No comment
323.			- effective tools to trace and identify devices for which corrective actions might be necessary;	No comment
324.			- a post-market performance follow-up plan according to Part B of Annex XII, or any justification why a post-market performance follow-up is not deemed necessary or appropriate.	No comment
325.			**1.2. Post-market performance follow-up evaluation report in accordance with Part B of Annex XII.**	See Annex XII

Row	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
326.			**1.3. Periodic safety update report referred to in Article 58c.**	No comment
327.	**ANNEX III** **EU DECLARATION OF CONFORMITY**	**ANNEX III** **EU DECLARATION OF CONFORMITY**	**ANNEX III** **EU DECLARATION OF CONFORMITY**	**---**
328.	1. Name, registered trade name or registered trade mark of the manufacturer and, if applicable, his authorised representative, and the address of their registered place of business where they can be contacted and their location be established;	1. Name, registered trade name or registered trade mark of the manufacturer and, if applicable, his authorised representative, and the address of their registered place of business where they can be contacted and their location be established;	1. Name, registered trade name or registered trade mark, single registration number referred to in Article 25a of the manufacturer and, if applicable, his authorised representative, and the address of their registered place of business where they can be contacted and their location be established;	**Concern –** Single registration number to be included in the DoC is a problem.
329.	2. A statement that the declaration of conformity is issued under the sole responsibility of the manufacturer;	2. A statement that the declaration of conformity is issued under the sole responsibility of the manufacturer;	2. A statement that the declaration of conformity is issued under the sole responsibility of the manufacturer;	---
330.	3. The UDI device identifier as referred to in item (i) of point (a) of Article 22(1) as soon as identification of the device that is covered by the declaration shall be based on a UDI system;	3. The UDI device identifier as referred to in item (i) of point (a) of Article 22(1) as soon as identification of the device that is covered by the declaration shall be based on a UDI system;	3. The UDI device identifier as referred to in item (i) of point (a) of Article 22(1) as soon as identification of the device that is covered by the declaration shall be based on a UDI system;	---
331.	4. Product or trade name, product code, catalogue number or other unambiguous reference allowing identification and traceability of the device that is covered by the declaration (it may include a photograph, where appropriate). Except for the product or trade name, the information allowing identification and traceability may be provided by the	4. Product or trade name, product code, catalogue number or other unambiguous reference allowing identification and traceability of the device that is covered by the declaration (it may include a photograph, where appropriate). Except for the product or trade name, the information allowing identification and traceability may be provided by the	4. Product and trade name, product code, catalogue number or other unambiguous reference allowing identification and traceability of the device that is covered by the declaration (it may include a photograph, where appropriate), including its intended purpose. Except for the product or trade name, the information allowing identification and	

Row	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
	device identifier referred to in point 3;	device identifier referred to in point 3;	traceability may be provided by the device identifier referred to in point 3;	
332.	5. Risk class of the device in accordance with the rules set out in Annex VII;	5. Risk class of the device in accordance with the rules set out in Annex VII;	5. Risk class of the device in accordance with the rules set out in Annex VII;	--
333.	6. A statement that the device that is covered by the present declaration is in conformity with this Regulation and, if applicable, with other relevant Union legislation that make provision for the issuing of a declaration of conformity;	6. A statement that the device that is covered by the present declaration is in conformity with this Regulation and, if applicable, with other relevant Union legislation that make provision for the issuing of a declaration of conformity;	6. A statement that the device that is covered by the present declaration is in conformity with this Regulation and, if applicable, with other relevant Union legislation that make provision for the issuing of a declaration of conformity;	---
334.	7. References to the relevant harmonised standards or CTS used in relation to which conformity is declared;		7. References to the relevant harmonised standards or CS used in relation to which conformity is declared;	--
335.	8. Where applicable, name and identification number of the notified body, description of the conformity assessment procedure performed and identification of the certificate(s) issued;	7. Where applicable, name and identification number of the notified body, description of the conformity assessment procedure performed and identification of the certificate(s) issued;	8. Where applicable, name and identification number of the notified body, description of the conformity assessment procedure performed and identification of the certificate(s) issued;	---
336.	9. Where applicable, additional information;	8. Where applicable, additional information;	9. Where applicable, additional information;	---
337.	10. Place and date of issue, name and function of the person who signs as well as indication for and on behalf of whom he/she signs, signature.	9. Place and date of issue, name and function of the person who signs as well as indication for and on behalf of whom he/she signs, signature.	10. Place and date of issue, name and function of the person who signs as well as indication for and on behalf of whom he/she signs, signature.	---
338.	**ANNEX IV** **CE MARKING OF CONFORMITY**	**ANNEX IV** **CE MARKING OF CONFORMITY**	**ANNEX IV** **CE MARKING OF CONFORMITY**	**---**

Row	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
339.	1. The CE marking shall consist of the initials 'CE' taking the following form: 	1. The CE marking shall consist of the initials 'CE' taking the following form: 	1. The CE marking shall consist of the initials 'CE' taking the following form: 	---
340.	2. If the CE marking is reduced or enlarged, the proportions given in the above graduated drawing shall be respected.	2. If the CE marking is reduced or enlarged, the proportions given in the above graduated drawing shall be respected.	2. If the CE marking is reduced or enlarged the proportions given in the above graduated drawing shall be respected.	---
341.	3. The various components of the CE marking shall have substantially the same vertical dimension, which may not be less than 5 mm. This minimum dimension may be waived for small-scale devices.	3. The various components of the CE marking shall have substantially the same vertical dimension, which may not be less than 5 mm. This minimum dimension may be waived for small-scale devices.	3. The various components of the CE marking shall have substantially the same vertical dimension, which may not be less than 5 mm. This minimum dimension may be waived for small-scale devices.	---
342.	**ANNEX V** **INFORMATION TO BE SUBMITTED WITH THE REGISTRATION OF DEVICES AND ECONOMIC OPERATORS IN ACCORDANCE WITH ARTICLE 23** **AND**	**ANNEX V** **INFORMATION TO BE SUBMITTED WITH THE REGISTRATION OF DEVICES AND ECONOMIC OPERATORS IN ACCORDANCE WITH ARTICLE 23** **AND**	**ANNEX V** **INFORMATION TO BE SUBMITTED WITH THE REGISTRATION OF DEVICES AND ECONOMIC OPERATORS IN ACCORDANCE WITH ARTICLE 23a** **AND**	Core UDI Data elements

Row	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
	DATA ELEMENTS OF THE UDI DEVICE IDENTIFIER IN ACCORDANCE WITH ARTICLE 22	**DATA ELEMENTS OF THE UDI DEVICE IDENTIFIER IN ACCORDANCE WITH ARTICLE 22**	**CORE DATA ELEMENTS TO BE PROVIDED TO OF THE UDI DATA BASE TOGETHER WITH THE DEVICE IDENTIFIER IN ACCORDANCE WITH ARTICLE 22a** **AND** **THE EUROPEAN UNIQUE DEVICE IDENTIFCATION SYSTEM**	
343.	**Part A** **Information to be submitted with the registration of devices in accordance with Article 23**	**Part A** **Information to be submitted with the registration of devices in accordance with Article 23**	**Part A** **Information to be submitted with the registration of devices in accordance with Article 23a**	It seems that certain requirements laid down in Annex V Part A should be applicable to device registration and therefore should be removed from this section to avoid unnecessary confusion. This part should either be divided into two parts, one for registration of devices and one for registration economic operators, or points that are relevant for economic operators and ones that are relevant for devices need to be clearly outlined to avoid unnecessary confusion. Points relevant for registration of the economic operators include: 1, 2, 3 and 4a (not 4). The rest falls under device registration and therefore this

Row	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
				needs to be clearly outlined.
344.	Manufacturers or, when applicable, authorised representatives, and, when applicable, importers shall submit the following information:	Manufacturers or, when applicable, authorised representatives, and, when applicable, importers shall submit the following information:	Manufacturers or, when applicable, authorised representatives, and, when applicable, importers shall submit the information referred to in points 1 to 4a and ensure that the information referred to in other points is complete, correct and updated by relevant party:	Points that are relevant for importers need to be also clarified – points that are applicable to importers ae the following: 1 and 2. Points relevant to registration of the Manufacturer/AR include: 1, 2, 3 and 4a (not 4).
345.	1. economic operator's role (manufacturer, authorised representative, or importer),	1. economic operator's role (manufacturer, authorised representative, or importer),	1. economic operator's role (manufacturer, authorised representative, or importer),	---
346.	2. name, address and contact details of the economic operator,	2. name, address and contact details of the economic operator,	2. name, address and contact details of the economic operator,	---
347.	3. where submission of information is completed by another person on behalf of any of the economic operators mentioned under point 1, the name, address and contact details of this person,	3. where submission of information is completed by another person on behalf of any of the economic operators mentioned under point 1, the name, address and contact details of this person,	3. where submission of information is completed by another person on behalf of any of the economic operators mentioned under point 1, the name, address and contact details of this person,	---
348.	4. UDI device identifier, or where identification of the device is not yet based on a UDI system, the data elements laid down in points 5 to 18 of Part B of this Annex,	4. UDI device identifier, or where identification of the device is not yet based on a UDI system, the data elements laid down in points 5 to 18 of Part B of this Annex,	4. UDI device identifier, or where identification of the device is not yet based on a UDI system, the data elements laid down in points 5 to 18 of Part B of this Annex,	---
349.			4a. name address and contact details of the person responsible for regulatory compliance	There may be more than one qualified person per manufacturer.

Row	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
			(qualified person) according to Article 13,	
350.	5. type, number and expiry date of certificate and name or identification number of the notified body that has issued the certificate (and link to the information on the certificate entered by the notified body in the electronic system on certificates),	5. type, number and expiry date of certificate and name or identification number of the notified body that has issued the certificate (and link to the information on the certificate entered by the notified body in the electronic system on certificates),	5. type, number and expiry date of certificate and name or identification number of the notified body that has issued the certificate (and link to the information on the certificate entered by the notified body in the electronic system on certificates),	---
351.	6. Member State where the device shall or has been placed on the market in the Union,	6. Member State where the device shall or has been placed on the market in the Union,	6. Member State where the device shall or has been placed on the market in the Union,	---
352.	7. in case of devices classified as classes B, C or D: Member States where the device is or shall be made available,	7. in case of devices classified as classes B, C or D: Member States where the device is or shall be made available,	7. in case of devices classified as classes B, C or D: Member States where the device is or shall be made available,	---
353.	8. in case of imported device: country of origin,	8. in case of imported device: country of origin,		Removed for no good reason.
354.	9. presence of tissues, cells or substances of human origin (y/n),	9. presence of tissues, cells or substances of human origin (y/n),	9. presence of tissues, cells or substances of human origin (y/n),	---
355.	10. presence of tissues, cells or substances of animal origin (y/n),	10. presence of tissues, cells or substances of animal origin (y/n),	10. presence of tissues, cells or substances of animal origin (y/n),	---
356.	11. presence of cells or substances of microbial origin (y/n),	11. presence of cells or substances of microbial origin (y/n),	11. presence of cells or substances of microbial origin (y/n),	---
357.	12. risk class of the device according to the rules set out in Annex VII,	12. risk class of the device according to the rules set out in Annex VII,	12. risk class of the device according to the rules set out in Annex VII,	---

Row	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
358.	13. where applicable, single identification number of the interventional clinical performance study and other clinical performance study involving risks for the subjects of the study conducted in relation to the device (or link to the clinical performance study registration in the electronic system regarding clinical performance studies),	13. where applicable, single identification number of the interventional clinical performance study and other clinical performance study involving risks for the subjects of the study conducted in relation to the device (or link to the clinical performance study registration in the electronic system regarding clinical performance studies),	13. where applicable, single identification number of the interventional clinical performance study and other clinical performance study involving risks for the subjects of the study conducted in relation to the device (or link to the clinical performance study registration in the electronic system regarding clinical performance studies),	---
359.	14. in case of devices designed and manufactured by another legal or natural person as referred in Article 8(10), the name, address and contact details of that legal or natural person,	14. in case of devices designed and manufactured by another legal or natural person as referred in Article 8(10), the name, address and contact details of that legal or natural person,	14. in case of devices designed and manufactured by another legal or natural person as referred in Article 8(10), the name, address and contact details of that legal or natural person,	---
360.	15. in case of devices classified as class C or D, the summary of safety and performance,	15. in case of devices classified as class C or D, the summary of safety and performance, and the full dataset collected during the clinical study and the post-market clinical follow-up	15. in case of devices classified as class C or D, the summary of safety and performance,	--- (note that this is a problem as class D and C devices are not equivalent to class III and implants)
361.	16. status of the device (on the market, no longer manufactured, withdrawn from the market, recalled),	16. status of the device (on the market, no longer manufactured, withdrawn from the market, recalled),	16. status of the device (on the market, no longer manufactured, withdrawn from the market, recalled),	---
362.	17. indication when the device is a 'new' device. A device shall be considered as 'new' if: (a) there has been no such device continuously available on the Union market during the previous three years for the relevant analyte or other parameter;	17. indication when the device is a 'new' device. A device shall be considered as 'new' if: (a) there has been no such device continuously available on the Union market during the previous three years for the relevant analyte or other parameter;	17. indication when the device is a 'new' device. A device shall be considered as 'new' if: (a) there has been no such device continuously available on the Union market during the previous three years for the relevant analyte or other parameter;	--- (oddly, this is not a requirement under the MD)

Row	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
	(b) the procedure involves analytical technology not continuously used in connection with a given analyte or other parameter on the Union market during the previous three years.	(b) the procedure involves analytical technology not continuously used in connection with a given analyte or other parameter on the Union market during the previous three years.	(b) the procedure involves analytical technology not continuously used in connection with a given analyte or other parameter on the Union market during the previous three years.	
363.	18. Indication if the device is intended for self-testing or near-patient testing.	18. Indication if the device is intended for self-testing or near-patient testing.	18. Indication if the device is intended for self-testing or near-patient testing.	---
364.		(18a) Full technical documentation and the clinical performance report.		
365.	**Part B** **Data elements of the UDI device identifier in accordance with Article 22**	**Part B** **Data elements of the UDI device identifier in accordance with Article 22**	**Part B** **Data elements of the UDI device identifier in accordance with Article 22a**	---
366.	The UDI device identifier shall provide access to the following information related to the manufacturer and the device model:	The UDI device identifier shall provide access to the following information related to the manufacturer and the device model:	The manufacturer shall provide to the UDI data base the UDI device identifier (UDI-DI) and to the following information related to the manufacturer and the device:	Different concept – it is key that the UDI provides access to the different database elements.
367.	1. quantity per package configuration,	1. quantity per package configuration,	1. quantity per package configuration,	---
368.	2. if applicable, alternative or additional identifier(s),	2. if applicable, alternative or additional identifier(s),	2. if applicable, the Basic UDI-DI according to article 24(4b) and additional identifier(s),	Unit of use concept and definition preferred.
369.	3. the way how the device production is controlled (expiration date or manufacturing date, lot or batch number, serialisation number),	3. the way how the device production is controlled (expiration date or manufacturing date, lot or batch number, serialisation number),	3. the way how the device production is controlled (expiration date or manufacturing date, lot or batch number, serialisation number),	---

Row	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
370.	4. if applicable, the 'unit of use' device identifier (when a UDI is not assigned to the device at the level of its 'unit of use', a 'unit of use' device identifier shall be assigned to associate the use of a device with a patient),	4. if applicable, the 'unit of use' device identifier (when a UDI is not assigned to the device at the level of its 'unit of use', a 'unit of use' device identifier shall be assigned to associate the use of a device with a patient),	4. if applicable, the 'unit of use' device identifier (when a UDI is not assigned to the device at the level of its 'unit of use', a 'unit of use' device identifier shall be assigned to associate the use of a device with a patient),	---
371.	5. name and address of the manufacturer (as indicated on the label),	5. name and address of the manufacturer (as indicated on the label),	5. name and address of the manufacturer (as indicated on the label),	---
372.			5a. the single registration number according to Article 23a(2),	This should be assigned directly by the database not entered again.
373.	6. if applicable, name and address of the authorised representative (as indicated on the label),	6. if applicable, name and address of the authorised representative (as indicated on the label),	6. if applicable, name and address of the authorised representative (as indicated on the label),	---
374.	7. Global Medical Device Nomenclature (GMDN) code or internationally recognised nomenclature code,	7. Global Medical Device Nomenclature (GMDN) code or internationally recognised nomenclature code,	7. Medical Device Nomenclature code according to Article 23a,	Wider nomenclature questions.
375.			7a. risk class of the device,	Redundant with 354 actually
376.	8. if applicable, trade/brand name,	8. if applicable, trade/brand name,	8. if applicable, trade/brand name,	---
377.	9. if applicable, device model, reference, or catalogue number,	9. if applicable, device model, reference, or catalogue number,	9. if applicable, device model, reference, or catalogue number,	---
378.	10. additional product description (optional),	10. additional product description (optional),	10. additional product description (optional),	---

Row	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
379.	11. if applicable, storage and/or handling conditions (as indicated on the label or in the instructions for use),	11. if applicable, storage and/or handling conditions (as indicated on the label or in the instructions for use),	11. if applicable, storage and/or handling conditions (as indicated on the label or in the instructions for use),	---
380.	12. if applicable, additional trade names of the device,	12. if applicable, additional trade names of the device,	12. if applicable, additional trade names of the device,	---
381.	13. labelled as single use device (y/n),	13. labelled as single use device (y/n),	13. labelled as single use device (y/n),	---
382.	14. if applicable, restricted number of reuses,	14. if applicable, restricted number of reuses,	14. if applicable, restricted number of reuses,	---
383.	15. device packaged sterile (y/n),	15. device packaged sterile (y/n),	15. device packaged sterile (y/n),	---
384.	16. need for sterilisation before use (y/n),	16. need for sterilisation before use (y/n),	16. need for sterilisation before use (y/n),	---
385.	17. URL for additional information, e.g. electronic instructions for use (optional),	17. URL for additional information, e.g. electronic instructions for use (optional),	17. URL for additional information, e.g. electronic instructions for use (optional),	---
386.	18. if applicable, critical warnings or contraindications.	18. if applicable, critical warnings or contraindications.	18. if applicable, critical warnings or contraindications.	--- (Note – this is not free text but a selection from a drop down menu or equivalent)
387.			19. status of the device on the market (choice box, stop of placing on the market, recalled, FSA initiated).	**Concern –** recall and FSA often apply to certain batches or serial numbers, not to a whole device. This section refers to the information associated to the UDI-DI not to the UDI-PI. This should be in the section on vigilance of Eudamed.

Row	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
388.			**PART C** **The European Unique Device Identification System**	No Comment
389.			**1.Definitions**	No Comment
390.			***Automatic Identification and Data Capture (hereinafter AIDC)*** AIDC is a technology used to automatically capture data. AIDC technologies include bar codes, smart cards, biometrics and RFID.	No Comment
391.			***Basic UDI-DI*** The Basic UDI-DI is the primary identifier of a device model. It is the DI assigned at the level of the device unit of use. It is the main key for records in the UDI database and shall be referenced in relevant certificates and declarations of conformity. In instances when a UDI is not labelled at the level of the device unit of use (e.g. several units contained in a plastic bag) it is also the purpose of the Basic UDI DI to associate the use of a device to/on a patient to data related to that patient.	Definition of UDI – DI and Unit of Use needs to be restored. On FDA side it is allowed to use the same UoU-DI for multiple Primary-DI's. And that is necessary for many Sutures. The Primary-Di has to be unique, the UoU-DI not ! The current EU wording regarding 'Basic UDI-DI / primary identifier' would not allow such a way to allocate GTINs !
392.			***Configurable device*** A configurable device is a device that consists of several components which can be assembled by the manufacturer in multiple configurations. Those individual	**---**

Row	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
			components may be devices in themselves.	
393.			***Configuration*** Configuration is a combination of items of equipment, as specified by the manufacturer, that operate together to provide an intended use or purpose as a device. The combination of items may be modified, adjusted or customized to meet a customer need.	**---**
394.			***Device Identifier (hereinafter UDI-DI)*** The UDI-DI is a unique numeric or alphanumeric code specific to a model of device and that is also used as the "access key" to information stored in a UDI database.	**---**
395.			***Human Readable Interpretation (hereinafter HRI)*** Human Readable Interpretation is a legible interpretation of the data characters encoded in the UDI Carrier.	**---**
396.			***Packaging levels*** Packaging levels means the various levels of device packages that contain a fixed quantity of devices, e.g. each, carton, or case.	**---**
397.			***Production Identifier (hereinafter UDI-PI)***	**---**

Row	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
			The Production Identifier is a numeric or alphanumeric code that identifies the unit of device production. The different types of Production Identifier(s) include serial number, lot/batch number, Software identification and/or manufacturing and/or expiration date.	
398.			***Radio Frequency Identification (hereinafter RFID)*** RFID is a technology that uses communication through the use of radio waves to exchange data between a reader and an electronic tag attached to an object, for the purpose of identification.	**---**
399.			***Shipping containers*** Shipping container is a container where the traceability is controlled by a process specific to logistics systems.	The proposed definition describes a process and is not a description of a shipping container, this should be addressed and amended accordingly.
400.			***Unique Device Identification*** The UDI is a series of numeric or alphanumeric characters that is created through a globally accepted device identification and coding standard. It allows the unambiguous identification of a specific device on the market. The UDI is comprised of the UDI-DI and the UDI-PI. Note: The word "Unique" does not imply	**---**

Row	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
			serialization of individual production units.	
401.			***UDI Carrier*** The UDI Carrier is the means to convey the UDI by using AIDC and, if applicable, its HRI. Note: Carriers include, inter alia, ID/linear bar code, 2D/Matrix bar code, RFID.	**---**
402.			***UDI database*** The UDI database contains identifying information and other elements associated with the specific device.	**---**
403.			**2. UDI system - General requirements**	Where are the exemptions mentioned? I.e. custom made devices, investigational devices for medical devices or devices for performance evaluation for IVDs ?
404.			2.1. The marking of the UDI is an additional requirement – it does not replace any other marking or labelling requirements described in Annex I of this regulation.	**---**
405.			2.2. The manufacturer shall create and maintain unique UDIs on his devices.	**---**
406.			2.3. Only the manufacturer may establish the UDI on the device or its packaging.	**---**

Row	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
407.			2.4. Only coding standards offered by assigning entities designated by the European Commission according to article 22(2) may be used by the manufacturers.	**---**
408.			**3. The UDI**	**---**
409.			3.1. A UDI shall be assigned to the device itself or its package. Higher levels of packaging shall have their own UDI.	Need consistency with articles – articles state that the device will always have a UDI assigned to it. Here it seems that the UDI is assigned to the packaging. (Note – this is probably confusion over UDI assignment vs UDI placement)
410.			3.2. Shipping containers shall be exempted. As an example, UDI is not required on a logistics unit; when a healthcare provider orders multiple devices using the UDI or model number of individual devices and the manufacturer places these devices in a container for shipping or to protect the individually packaged devices, the container (logistics unit) is not subject to UDI requirements.	**---**
411.			3.3. The UDI shall contains two parts: an UDI-DI and an UDI-PI.	**---**
412.			3.4. The UDI-DI shall be unique at all levels of device packaging.	**---**

Row	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
413.			3.5. If a lot number, serial number, software identification or expiration date appears on the label, they shall be part of the UDI-PI. If there is also a manufacturing date on the label, it does NOT need to be included in the UDI-PI. If there is only a manufacturing date on the label, this shall be used as the UDI-PI.	---
414.			3.7. Each component that is considered an device and is commercially available on its own shall be assigned a separate UDI unless the components are part of a configurable device that is marked with its own UDI.	---
415.			3.8. Kits shall be assigned and bear their own UDI.	---
416.			3.9. The manufacturer shall assign the UDI to a device following the relevant coding standard.	---
417.			3.10. A new UDI-DI shall be required whenever there is a change that could lead to misidentification of the device and/or ambiguity in its traceability, in particular any change of one of the following UDI database data elements require a new UDI-DI: (a) Brand Name or Trade name, (b) Device version or model, (d) Labelled as single use, (e) Packaged sterile,	Would change to configuration of the device trigger the need for new UDI-DI? Language issue and new UDI-DI: GS1 allocation rules require to change the GTIN of a product if it is destined to be supplied to a certain market in a certain language in the package, label and IFU different to the

Row	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
			(f) Need for sterilization before use, (g) Quantity of devices provided in a package, (h) Critical warnings or contraindications	language with which another identical device is supplied. Normally the reason behind is because both devices coexist in the market but are destined to be supplied to two different markets with different language requirements or language acceptance. GS1 allocation rules do not require change the GTIN when adding an additional language to the packaging of a product that is sold in several markets.
418.			3.12. Manufacturers who repackages or relabels devices with their own label shall retain record of the Original Equipment Manufacturer's (OEM) UDI.	**---**
419.			**4. UDI Carrier**	**---**
420.			4.1. The UDI Carrier (AIDC and HRI representation of the UDI) shall be placed on the label and on all higher levels of device packaging. Higher levels do not include shipping containers.	**---**
421.			4.2. In case of significant space constraints on the unit of use package the UDI carrier may be placed on the next higher package level.	--- (unit of use package – strange phrase)
422.			4.3. For single use devices of class A and	**---**

Row	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
			B packaged and labelled individually the UDI Carrier shall not be required to appear on its the package but it shall appear on a higher level of packaging e.g. a carton containing several packages. However when the healthcare provider is not expected to have access (home healthcare settings) to the higher level of device packaging, the UDI shall be placed on the package.	
423.			4.4. For devices exclusively intended for retail Point of Sale (POS) the Production Identifiers in AIDC shall not be required to appear on the point of sale package.	---
424.			4.5. When AIDC carriers other than the UDI Carrier are part of the product labelling, the UDI Carrier shall be readily identifiable.	---
425.			4.6. If linear bar codes are used, the UDI-DI and UDI-PI may be concatenated or non-concatenated in two or more bar codes. All parts and elements of the linear bar code shall be distinguishable and identifiable.	---
426.			4.7. If there are significant constraints limiting the use of both AIDC and HRI on the label, only the AIDC format shall be required to appear on the label. For devices indented to be used outside of healthcare facilities such as devices for home care, the HRI shall however appear	---

Row	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
			on the label even if this means that there is no space for the AIDC.	
427.			4.8. The HRI format shall follow the rules of the UDI code issuing organization.	Regarding 4.8: Suggest following FDA approach as it is more flexible and would require less continuous updating.
428.			4.9. If the manufacturer is using RFID technology, a linear or 2D bar code according to the standard by the assigning entities shall also be provided on the label.	**---**
429.			4.10. devices that are reusable shall bear a UDI Carrier on the device itself. The UDI Carrier of reusable devices that require disinfection, sterilisation or refurbishing between patient uses shall be permanent and readable after each process performed to make the device ready for the next use for the intended lifetime of the device.	**---**
430.			4.11. The UDI Carrier shall be readable during normal use and throughout the intended life of the device.	**---**
431.			4.12. If the UDI Carrier is readily readable or scanable through the device's package, then the placing of the UDI Carrier on the package shall not be required.	**---**

Row	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
432.			4.13. A single finished device made up of multiple parts that must be assembled before first use may bear the UDI Carrier on only one part.	---
433.			4.14. The UDI Carrier shall be placed so that the AIDC can be accessed during normal operation or storage.	---
434.			4.15. The bar code carrier(s) that include(s) UDI data identifiers "UDI-DI" and "UDI-PI" may also include essential data for the device to operate or other data.	---
435.			**5. The UDI database - General principles of the UDI database**	---
436.			5.1. The UDI database shall support the use of all core UDI database data elements.	---
437.			5.3. The manufacturer is shall be responsible for the initial submission and updates to of the identifying information and other device data elements in the UDI database.	---
438.			5.4. Appropriate methods/procedures for validation of the provided data shall be implemented.	---
439.			5.5. The manufacturers shall periodically	It seems strange to list an

Row	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
			reconfirm all the data relevant to devices he has placed on the market, except for devices that are no more available on the market.	obligation of manufacturers in a section that otherwise seems to simply 'describe' the database
440.			5.7. The presence of the device UDI-DI in the UDI database does not mean that the device is in conformity with this Regulation.	---
441.			5.8. The database shall allow for the linking of all the packaging levels of the device.	---
442.			5.9. The data for new UDI-DI shall be available at the time the device is placed on the market.	---
443.			5.10. Manufacturers shall update the relevant UDI database record within 30 days when a change is made to an element that does NOT require a new UDI-DI.	It seems strange to list an obligation of manufacturers in a section that otherwise seems to simply 'describe' the database
444.			5.11. The UDI database shall use internationally accepted standards for data submission and updates. Additional submission means may, however, also be accommodated.	---
445.			5.12. The core elements are the minimum elements needed to identify a device throughout its distribution and use.	---

Row	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
446.			5.13. The design of the UDI database shall support the languages required in the Member States where the device is placed on the market. The use of free-text fields shall, however, be minimized in order to reduce translations.	**---**
447.			5.14. Data relating to devices that are no more available on the market shall be retained in the UDI database.	**---**
448.			**6. Rules for specific device types**	**---**
449.			6.2. Reusable medical devices that are part of kits and that require cleaning, disinfection, sterilisation or refurbishing between uses	**---**
450.			6.2.1. The UDI of such devices shall be placed on the device and be readable after each procedure to make the device ready for the next use;	**---**
451.			6.2.2. The PI characteristics (e.g. lot or serial number) shall be defined by the manufacturer.	**---**
452.			6.5. In vitro diagnostic Medical Device Software	**---**
453.			6.5.1. UDI Assignment Criteria The UDI shall be assigned at the system level of the Software. Only software	For consistency purposes, it should read: ***available on the market*** for reasons of

Row	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
			which are commercially available on their own and software which are medical devices in themselves, shall be subject to this requirement. The Software identification is shall be considered the manufacturing control mechanism and shall be displayed in the UDI-PI.	consistency with the rest of the Regulation and Blue Guide terminology in general
454.			6.5.1a. A new UDI-DI shall be required whenever there is a modification that changes: (a) the original performance and effectiveness, (b) the safety or the intended use of the Software. (c) interpretation of data. These changes may include new or modified algorithms, database structures, operating platform, architecture or new user interfaces or new channels for interoperability.	---
455.			6.5.1b. The following changes of a Software shall require only a new UDI-PI (not a new UDI-DI): Minor Software revisions shall be identified with a new UDI-PI; Minor Software revisions are generally associated with bug fixes, usability enhancements (not for safety purpose), security patches or operating efficiency. Minor revisions shall be identified by	**---**

Row	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
			manufacturer-specific identification.	
456.			6.5.2. UDI Placement Criteria for Software (a) When the Software is delivered on a physical medium, e.g. CD or DVD, each package level shall bear the human readable and AIDC representation of the complete UDI. The UDI that is applied to the physical medium containing the Software and its packaging must be identical to the UDI assigned to the system level Software. (b) The UDI shall be provided on a readily accessible screen by for the user in an easily-readable plain-text format (e.g. an "about" file or included on the start-up screen). (c) Software lacking a user interface (e.g. middleware for image conversion) shall be capable of transmitting the UDI through an Application Programming Interface (API). (d) Only the human readable portion of the UDI is shall be required in electronic displays of the Software. The UDI AIDC marking shall not be required in the electronic displays, e.g. about menu, splash screen, etc. (e) The human readable format of the UDI for the Software shall include the Application Identifiers (AI) of the used standard of the assigning entities, to assist the user in identifying the UDI and determining which standard is being used	---

Row	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
			to create the UDI.	
457.	**ANNEX VI** **MINIMUM REQUIREMENTS TO BE MET BY NOTIFIED BODIES**	**ANNEX VI** **MINIMUM REQUIREMENTS TO BE MET BY NOTIFIED BODIES**	**ANNEX VI** **REQUIREMENTS TO BE MET BY NOTIFIED BODIES**	**Under Assessment**
458.	**1. ORGANISATIONAL AND GENERAL REQUIREMENTS**	**1. ORGANISATIONAL AND GENERAL REQUIREMENTS**	**1. ORGANISATIONAL AND GENERAL REQUIREMENTS**	Under assessment
459.	**1.1. Legal status and organisational structure**	**1.1. Legal status and organisational structure**	**1.1. Legal status and organisational structure**	
460.	1.1.1. A notified body shall be established under the national law of a Member State, or under the law of a third country with which the Union has concluded an agreement in this respect, and shall have full documentation of its legal personality and status. This shall include information about ownership and the legal or natural persons exercising control over the notified body.	1.1.1. A notified body shall be established under the national law of a Member State, or under the law of a third country with which the Union has concluded an agreement in this respect, and shall have full documentation of its legal personality and status. This shall include information about ownership and the legal or natural persons exercising control over the notified body.	1.1.1. A notified body shall be established under the national law of a Member State, or under the law of a third country with which the Union has concluded an agreement in this respect, and shall have full documentation of its legal personality and status. This shall include information about ownership and the legal or natural persons exercising control over the notified body.	No change
461.	1.1.2. If the notified body is a legal entity that is part of a larger organisation, the activities of this organisation as well as its organisational structure and governance, and the relationship with the notified body shall be clearly documented.	1.1.2. If the notified body is a legal entity that is part of a larger organisation, the activities of this organisation as well as its organisational structure and governance, and the relationship with the notified body shall be clearly documented.	1.1.2. If the notified body is a legal entity that is part of a larger organisation, the activities of this organisation as well as its organisational structure and governance, and the relationship with the notified body shall be clearly documented.	
462.			In this instance, the requirements of section 1.2 of this Annex are applicable to both the notified body and the organisation to which it belongs.	

Row	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
463.	1.1.3. If the notified body wholly or partly owns legal entities established in a Member State or in a third country, the activities and responsibilities of those entities, as well as their legal and operational relationships with the notified body, shall be clearly defined and documented.	1.1.3. If the notified body wholly or partly owns legal entities established in a Member State or in a third country, the activities and responsibilities of those entities, as well as their legal and operational relationships with the notified body, shall be clearly defined and documented.	1.1.3. If the notified body wholly or partly owns legal entities established in a Member State or in a third country or is owned by another legal entity, the activities and responsibilities of those entities, as well as their legal and operational relationships with the notified body, shall be clearly defined and documented.	
464.			Personnel of those entities performing conformity assessment activities according to this Regulation are subject to the applicable requirements of this Regulation.	
465.	1.1.4. The organisational structure, distribution of responsibilities and operation of the notified body shall be such that it assures confidence in the performance and results of the conformity assessment activities conducted.	1.1.4. The organisational structure, distribution of responsibilities and operation of the notified body shall be such that it assures confidence in the performance and results of the conformity assessment activities conducted.	1.1.4. The organisational structure, allocation of responsibilities, reporting lines and operation of the notified body shall be such that it assures confidence in the performance and results of the conformity assessment activities conducted.	
466.	The organisational structure and the functions, responsibilities and authority of its top-level management and of other personnel with influence upon the performance and results of the conformity assessment activities shall be clearly documented.	The organisational structure and the functions, responsibilities and authority of its top-level management and of other personnel with influence upon the performance and results of the conformity assessment activities shall be clearly documented. This information shall be made publicly available.	1.1.5. The notified body shall clearly document its organisational structure and the functions, responsibilities and authority of its top-level management and of other personnel who may have an influence upon the performance and results of the conformity assessment activities.	
467.			1.1.6. The notified body shall identify the	

Row	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
			top-level management that have overall authority and responsibility for each of the following: - the provision of adequate resources for conformity assessment activities; - the development of procedures and policies for the operation of the notified body; - the supervision of implementation of the procedures, policies and quality management systems; - the supervision of the notified body's finances; - the activities and decisions taken by the notified body, including contractual agreements; - the delegation of authority to personnel and/or committees, where necessary, for the performance of defined activities ; and - the interaction with the national authority responsible for notified bodies and the obligations regarding communications with other competent authorities, the Commission and other notified bodies.	
468.	**1.2. Independence and impartiality**	**1.2. Independence and impartiality**	**1.2. Independence and impartiality**	
469.	1.2.1. The notified body shall be a third-party body that is independent of the manufacturer of the product in relation to which it performs conformity assessment activities.	1.2.1. The notified body shall be a third-party body that is independent of the manufacturer of the product in relation to which it performs conformity assessment activities.	1.2.1. The notified body shall be a third-party body that is independent of the manufacturer of the product in relation to which it performs conformity assessment activities.	

Row	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
	The notified body shall also be independent of any other economic operator having an interest in the product as well as of any competitor of the manufacturer.	The notified body shall also be independent of any other economic operator having an interest in the product as well as of any competitor of the manufacturer.	The notified body shall also be independent of any other economic operator having an interest in the product as well as of any competitors of the manufacturer.	
470.		This does not preclude the notified body to perform conformity assessment activities for different economic operators producing different or similar products.	This does not preclude conformity assessment activities for competing manufacturers.	
471.	1.2.2. The notified body shall be organised and operated so as to safeguard the independence, objectivity and impartiality of its activities.	1.2.2. The notified body shall be organised and operated so as to safeguard the independence, objectivity and impartiality of its activities.	1.2.2. The notified body shall be organised and operated so as to safeguard the independence, objectivity and impartiality of its activities.	
472.	The notified body shall have procedures in place that effectively ensure identification, investigation and resolution of any case in which a conflict of interests may arise, including involvement in consultancy services in the field of in vitro diagnostic medical devices prior to taking up employment with the notified body.	The notified body shall have procedures in place that effectively ensure identification, investigation and resolution of any case in which a conflict of interests may arise, including involvement in consultancy services in the field of in vitro diagnostic medical devices prior to taking up employment with the notified body.	The notified body shall document and implement a structure and procedures for safeguarding impartiality and for promoting and applying the principles of impartiality throughout its organisation, personnel and assessment activities. These procedures shall allow for the identification, investigation and resolution of any case in which a conflict of interests may arise including involvement in consultancy services in the field of in vitro diagnostic medical devices prior to taking up employment with the notified body. The investigation, outcome and its resolution shall be documented.	
473.	1.2.3. The notified body, its top-level management and the personnel	1.2.3. The notified body, its top-level management and the personnel	1.2.3. The notified body, its top-level management and the personnel	

Row	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
	responsible for carrying out the conformity assessment tasks shall not	responsible for carrying out the conformity assessment tasks shall not	responsible for carrying out the conformity assessment tasks shall not	
474.	- be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the products, nor the authorised representative of any of those parties. This shall not preclude the purchase and use of assessed products that are necessary for the operations of the notified body (e.g. measuring equipment), the conduct of the conformity assessment or the use of such products for personal purposes;	- be the designer, manufacturer, supplier, installer, purchaser, owner, user or maintainer of the products, nor the authorised representative of any of those parties. This shall not preclude the purchase and use of assessed products that are necessary for the operations of the notified body (e.g. measuring equipment), the conduct of the conformity assessment or the use of such products for personal purposes;	- be the designer, manufacturer, supplier, installer, purchaser, owner or maintainer of the products which they assess, nor the authorised representative of any of those parties. This shall not preclude the purchase and use of assessed products that are necessary for the operations of the notified body, the conduct of the conformity assessment or the use of such products for personal purposes;	
475.	- be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of the products which they assess, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified;	- be directly involved in the design, manufacture or construction, the marketing, installation, use or maintenance of the products which they assess, or represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified;	- be involved in the design, manufacture or construction, the marketing, installation and use or maintenance of those products which they are designated, nor represent the parties engaged in those activities. They shall not engage in any activity that may conflict with their independence of judgement or integrity in relation to conformity assessment activities for which they are notified;	
476.	- offer or provide any service which may jeopardise the confidence in their independence, impartiality or objectivity. In particular, they shall not offer or provide consultancy services to the manufacturer, his authorised representative, a supplier or a commercial competitor as regards the design, construction, marketing or	- offer or provide any service which may jeopardise the confidence in their independence, impartiality or objectivity. In particular, they shall not offer or provide consultancy services to the manufacturer, his authorised representative, a supplier or a commercial competitor as regards the design, construction, marketing or	- offer or provide any service which may jeopardise the confidence in their independence, impartiality or objectivity. In particular, they shall not offer or provide consultancy services to the manufacturer, his authorised representative, a supplier or a commercial competitor as regards the design, construction, marketing or	

Row	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
	maintenance of the products or processes under assessment.	maintenance of the products or processes under assessment.	maintenance of the products or processes under assessment.	
477.	This does not preclude general training activities relating to medical device regulations or related standards that are not client specific.	This does not preclude general training activities relating to medical device regulations or related standards that are not client specific.	- be linked to any organisation which itself provides consultancy services as referred to in the previous indent. This does not preclude general training activities relating to medical device regulations or related standards that are not client specific.	
478.		The notified body shall make publicly available the declarations of interest of its top-level management and the personnel responsible for carrying out the conformity assessment tasks. The national authority shall verify the compliance of the notified body with the provisions under this point and shall report to the Commission twice a year in full transparency.		
479.			1.2.3a. Involvement in consultancy services in the field of in vitro diagnostic medical devices prior to taking up employment with a notified body shall be fully documented at the time of employment and potential conflicts of interests shall be monitored and resolved according to criteria set out in this Annex. Personnel who were former employees or provided consultancy services in the field of in vitro diagnostic medical devices for a specific client, prior to taking up employment with a notified body shall not	

Row	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
			be assigned for conformity assessment activities for that specific client or companies belonging to the same group for a period of 3 years.	
480.	1.2.4. The impartiality of the notified bodies, of their top level management and of the assessment personnel shall be guaranteed. The remuneration of the top level management and assessment personnel of a notified body shall not depend on the results of the assessments.	1.2.4. The impartiality of the notified bodies, of their top level management and of the assessment personnel and subcontractors shall be guaranteed. The remuneration of the top level management and assessment personnel and subcontractors of a notified body shall not depend on the results of the assessments.	1.2.4. The impartiality of the notified bodies, of their top level management and of the assessment personnel shall be guaranteed. The remuneration of the top level management and assessment personnel of a notified body shall not depend on the results of the assessments.	No change
481.	1.2.5. If a notified body is owned by a public entity or institution, independence and absence of any conflict of interests shall be ensured and documented between, on the one hand, the national authority responsible for notified bodies and/or competent authority and, on the other hand, the notified body.	1.2.5. If a notified body is owned by a public entity or institution, independence and absence of any conflict of interests shall be ensured and documented between, on the one hand, the national authority responsible for notified bodies and/or competent authority and, on the other hand, the notified body.	1.2.5. If a notified body is owned by a public entity or institution, independence and absence of any conflict of interests shall must be ensured and documented between, on the one hand, the national authority responsible for notified bodies and/or competent authority and, on the other hand, the notified body.	
482.	1.2.6. The notified body shall ensure and document that the activities of its subsidiaries or subcontractors, or of any associated body, do not affect its independence, impartiality or objectivity of its conformity assessment activities.	1.2.6. The notified body shall ensure and document that the activities of its subsidiaries or subcontractors, or of any associated body, do not affect its independence, impartiality or objectivity of its conformity assessment activities.	1.2.6. The notified body shall ensure and document that the activities of its subsidiaries or subcontractors**,** or of any associated body, including the activities of its owners do not affect its independence, impartiality or objectivity of its conformity assessment activities.	
483.		The notified body shall provide evidence to the national authority of compliance		

Row	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
		with this point.		
484.	1.2.7. The notified body shall operate in accordance with a set of consistent, fair and reasonable terms and conditions, taking into account the interests of small and medium-sized enterprises as defined by Commission Recommendation 2003/361/EC.	1.2.7. The notified body shall operate in accordance with a set of consistent, fair and reasonable terms and conditions, taking into account the interests of small and medium-sized enterprises as defined by Commission Recommendation 2003/361/EC.	1.2.7. The notified body shall operate in accordance with a set of consistent, fair and reasonable terms and conditions, taking into account the interests of small and medium-sized enterprises as defined by Commission Recommendation 2003/361/EC in relation to fees.	
485.	1.2.8. The requirements of this section in no way preclude exchanges of technical information and regulatory guidance between a notified body and a manufacturer seeking their conformity assessment.	1.2.8. The requirements of this section in no way preclude exchanges of technical information and regulatory guidance between a notified body and a manufacturer seeking their conformity assessment.	1.2.8. The requirements of this section in no way preclude exchanges of technical information and regulatory guidance between a notified body and a manufacturer seeking their conformity assessment.	No change
486.	**1.3. Confidentiality**	**1.3. Confidentiality**	**1.3. Confidentiality**	
487.			1.3.1. The notified body shall have documented procedures in place ensuring that confidentiality of the information which comes into its possession during the performance of the conformity assessment activities is observed by its personnel, committees, subsidiaries, subcontractors, any associated body or personnel of external bodies, except when disclosure is required by law.	
488.	The personnel of a notified body shall observe professional secrecy with regard to all information obtained in carrying out	The personnel of a notified body shall observe professional secrecy with regard to all information obtained in carrying out	1.3.2. The personnel of a notified body shall observe professional secrecy with regard to all information obtained in	

Row	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
	their tasks under this Regulation, except in relation to the national authorities responsible for notified bodies, competent authorities or the Commission.	their tasks under this Regulation, only in justified cases and except in relation to the national authorities responsible for notified bodies, competent authorities or the Commission.	carrying out their tasks under this Regulation or any provision of national law giving effect to it, except in relation to the national authorities responsible for notified bodies, competent authorities for in vitro diagnostic medical devices in the Member States or the Commission.	
489.	Proprietary rights shall be protected. To this end, the notified body shall have documented procedures in place.	Proprietary rights shall be protected. To this end, the notified body shall have documented procedures in place.	Proprietary rights shall be protected. To this end, the notified body shall have documented procedures in place.	
490.		Where information and data are requested from the notified body by the public or healthcare professionals and where such request is declined, the notified body shall justify the reasons for non-disclosure and shall make publicly available its justification.		
491.	**1.4. Liability**	**1.4. Liability**	**1.4. Liability**	
492.	The notified body shall take out appropriate liability insurance that corresponds to the conformity assessment activities for which it is notified,	The notified body shall take out appropriate liability insurance that corresponds to the conformity assessment activities for which it is notified,	1.4.1. The notified body shall take out appropriate liability insurance, unless liability is assumed by the State in accordance with national law, or the Member State itself is directly responsible for the conformity assessment.	
493.	including the possible suspension, restriction or withdrawal of certificates, and the geographic scope of its activities, unless liability is assumed by the State in accordance with national law, or the	including the possible suspension, restriction or withdrawal of certificates, and the geographic scope of its activities, unless liability is assumed by the State in accordance with national law, or the	1.4.2. The scope and overall financial value of liability insurance shall correspond to the level and geographic scope of activities of the notified body and be commensurate with the risk	

Row	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
	Member State itself is directly responsible for the conformity assessment.	Member State itself is directly responsible for the conformity assessment.	profile of the devices certified by the notified body. The liability insurance shall cover cases where the notified body may be obliged to withdraw, restrict or suspend certificates.	
494.	**1.5. Financial requirements** The notified body shall have at its disposal the financial resources required to conduct its conformity assessment activities and related business operations. It shall document and provide evidence of its financial capacity and its sustainable economic viability, taking into account specific circumstances during an initial start-up phase.	**1.5. Financial requirements** The notified body, including its subsidiaries, shall have at its disposal the financial resources required to conduct its conformity assessment activities and related business operations. It shall document and provide evidence of its financial capacity and its sustainable economic viability, taking into account specific circumstances during an initial start-up phase.	**1.5. Financial requirements** The notified body shall have at its disposal the financial resources required to conduct its conformity assessment activities within its scope of designation and related business operations. It shall document and provide evidence of its financial capacity and its sustainable economic viability, taking in to account specific circumstances during an initial start-up phase.	
495.	**1.6. Participation in coordination activities**	**1.6. Participation in coordination activities**	**1.6. Participation in coordination activities**	
496.	1.6.1. The notified body shall participate in, or ensure that its assessment personnel is informed of the relevant standardisation activities and the activities of the notified body coordination group and that its assessment and decision making personnel are informed of all relevant legislation, guidance and best practice documents adopted in the framework of this Regulation.	1.6.1. The notified body shall participate in, or ensure that its assessment personnel including subcontractors, is informed of and trained on the relevant standardisation activities and the activities of the notified body coordination group and that its assessment and decision making personnel are informed of all relevant legislation, guidance and best practice documents adopted in the framework of this Regulation.	1.6.1. The notified body shall participate in, or ensure that its assessment personnel is informed of the relevant standardisation activities and the activities of the notified body coordination group and that its assessment and decision making personnel are informed of all relevant legislation, guidance and best practice documents adopted in the framework of this Regulation.	No change

Row	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
497.		The notified body shall keep a record of the actions it takes to inform its personnel.		
498.	1.6.2. The notified body shall adhere to a code of conduct, addressing among other things, ethical business practices for notified bodies in the field of in vitro diagnostic medical devices that is accepted by the national authorities responsible for notified bodies. The code of conduct shall provide for a mechanism of monitoring and verification of its implementation by notified bodies.	1.6.2. The notified body shall adhere to a code of conduct, addressing among other things, ethical business practices for notified bodies in the field of in vitro diagnostic medical devices that is accepted by the national authorities responsible for notified bodies. The code of conduct shall provide for a mechanism of monitoring and verification of its implementation by notified bodies.	1.6.1a. The notified body shall take into consideration guidance and best practice documents.	
499.	**2. QUALITY MANAGEMENT REQUIREMENTS**	**2. QUALITY MANAGEMENT REQUIREMENTS**	**2. QUALITY MANAGEMENT REQUIREMENTS**	
500.	2.1. The notified body shall establish, document, implement, maintain and operate a quality management system that is appropriate to the nature, area and scale of its conformity assessment activities and capable of supporting and demonstrating the consistent achievement of the requirements of this Regulation.	2.1. The notified body shall establish, document, implement, maintain and operate a quality management system that is appropriate to the nature, area and scale of its conformity assessment activities and capable of supporting and demonstrating the consistent achievement of the requirements of this Regulation.	2.1. The notified body shall establish, document, implement, maintain and operate a quality management system that is appropriate to the nature, area and scale of its conformity assessment activities and capable of supporting and demonstrating the consistent achievement of the requirements of this Regulation.	No change
501.	2.2. The quality management system of the notified body shall at least address the following:	2.2. The quality management system of the notified body and its subcontractors shall at least address the following:	2.2. The quality management system of the notified body shall at least address the following:	
502.			- management system structure and documentation, including policies and	

Row	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
			objectives for its activities;	
503.	- policies for assignment of personnel to activities and their responsibilities;	- policies for assignment of personnel to activities and their responsibilities;	- policies for assignment of personnel to activities and their responsibilities,	
504.	- decision-making process in accordance with the tasks, responsibilities and role of the top-level management and other notified body personnel;	- decision-making process in accordance with the tasks, responsibilities and role of the top-level management and other notified body personnel;	- assessment and decision-making process in accordance with the tasks, responsibilities and role of the top-level management and other notified body personnel;	
505.			- planning, conducting, evaluating and, if necessary, adapting its conformity assessment procedures;	
506.	- control of documents;	- control of documents;	- control of documents;	
507.	- control of records;	- control of records;	- control of records;	
508.	- management review;	- management review;	- management review;	
509.	- internal audits;	- internal audits;	- internal audits;	
510.	- corrective and preventive actions;	- corrective and preventive actions;	- corrective and preventive actions;	
511.	- complaints and appeals.	- complaints and appeals;	- complaints and appeals.	
512.		- continuous training.		
513.			If documents are used in various languages the notified body shall ensure and control that they have the same	

Row	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
			content.	
514.			2.3. The notified body top management shall ensure that the quality management system is fully understood, implemented and maintained throughout the notified body organisation including subsidiaries and subcontractors being involved in conformity assessment activities according to this Regulation.	
515.			2.4. The notified body shall require all personnel to formally commit themselves by a signature or equivalent to comply with the procedures defined by the notified body. The commitment shall consider aspects relating to confidentiality and to independence from commercial and other interests, and any existing or prior association with clients. The personnel will be required to complete written statements indicating their compliance to confidentiality, independence and impartiality principles.	
516.	**3. RESOURCE REQUIREMENTS**	**3. RESOURCE REQUIREMENTS**	**3. RESOURCE REQUIREMENTS**	
517.	**3.1. General**	**3.1. General**	**3.1. General**	
518.	3.1.1. A notified body shall be capable of carrying out all the tasks assigned to it by this Regulation with the highest degree of professional integrity and the requisite technical competence in the specific field,	3.1.1. A notified body and its subcontractors shall be capable of carrying out all the tasks assigned to it by this Regulation with the highest degree of professional integrity and the requisite	3.1.1. A notified body shall be capable of carrying out all the tasks assigned to it by this Regulation with the highest degree of professional integrity and the requisite competence in the specific field, whether	No change

Row	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
	whether those tasks are carried out by the notified body itself or on its behalf and under its responsibility.	technical competence in the specific field, whether those tasks are carried out by the notified body itself or on its behalf and under its responsibility.	those tasks are carried out by the notified body itself or on its behalf and under its responsibility.	
519.		In accordance with Article 35, this requirement shall be monitored to ensure that it is of the requisite quality.		
520.	In particular, it shall have the necessary personnel and shall possess or have access to all equipment and facilities needed to perform properly the technical and administrative tasks entailed in the conformity assessment activities in relation to which it has been notified.	In particular, it shall have the necessary personnel and shall possess or have access to all equipment and facilities needed to perform properly the technical and administrative tasks entailed in the conformity assessment activities in relation to which it has been notified.	In particular, it shall have the necessary personnel and possess or have access to all equipment, facilities and competence needed to perform properly the technical, scientific and administrative tasks entailed in the conformity assessment activities in relation to which it has been designated.	
521.	This presupposes the availability within its organisation of sufficient scientific personnel who possess experience and knowledge sufficient to assess the medical functionality and performance of devices for which it has been notified, having regard to the requirements of this Regulation and, in particular, those set out in Annex I.	This presupposes the permanent availability within its organisation of sufficient scientific personnel who possess experience, a university degree and the knowledge sufficient to assess the medical functionality and performance of devices for which it has been notified, having regard to the requirements of this Regulation and, in particular, those set out in Annex I.	This presupposes at all times and for each conformity assessment procedure and each kind or category of products in relation to which it has been designated, the notified body shall have permanent availability at its disposal sufficient administrative, technical and scientific personnel who possess experience and knowledge relating to the relevant devices and the corresponding technologies. These shall be sufficient to ensure that the notified body can perform the conformity assessment tasks including the assessment of the medical functionality, performance evaluations and the performance and safety of devices, for which it has been	

Row	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
			designated, having regard to the requirements of this Regulation, in particular, those set out in Annex I.	
522.			A specific notified body's cumulative competence must enable it to assess the specific devices for which it is designated. The notified body retains full responsibility for the results of its conformity assessment activities and must have sufficient internal competence to critically evaluate assessments conducted by key external expertise for specific devices in which it has only a general competence. Specific tasks which a notified body cannot subcontract are outlined in Section 3.4 of this Annex.	
523.		Permanent "in house" staff shall be used. However, in accordance with Article 30, notified bodies may hire external experts on an ad hoc and temporary basis provided they can make publicly available the list of these experts, as well as their declarations of interest and the specific tasks for which they are responsible. Notified bodies shall conduct unannounced inspections at least once a year of all premises at which the medical devices coming within their remit are manufactured. The notified body responsible for carrying out the assessment tasks shall notify the other Member States of the findings of the annual inspections carried out. Those		

Row	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
		findings shall be set out in a report. It shall also forward a record of the annual inspections carried out to the relevant national authority responsible.		
524.	3.1.2. At all times and for each conformity assessment procedure and each kind or category of products in relation to which it has been notified, a notified body shall have within its organisation the necessary administrative, technical and scientific personnel with technical knowledge and sufficient and appropriate experience relating to in vitro diagnostic medical devices and the corresponding technologies to perform the conformity assessment tasks, including the assessment of clinical data.	3.1.2. At all times and for each conformity assessment procedure and each kind or category of products in relation to which it has been notified, a notified body shall have within its organisation the necessary administrative, technical and scientific personnel with medical, technical and the needed pharmacological knowledge and sufficient and appropriate experience relating to in vitro diagnostic medical devices and the corresponding technologies to perform the conformity assessment tasks, including the assessment of clinical data or the evaluation of an assessment made by a subcontractor.	***Cf row 497***	
525.			Personnel involved in the management of the operation of the notified body's conformity assessment activities for devices shall have appropriate knowledge to set up and operate a system for the selection of the assessment and verification staff, verification of their competence, authorisation for and allocation of their tasks, their initial and ongoing training, their instruction and monitoring to ensure that personnel who administered and	No bullet n°

Row	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
			perform assessment and verification operations are competent to fulfil the tasks required of them. The notified body shall identify at least one individual within its top-level management having overall responsibility for all conformity assessment activities in relation to in vitro diagnostic medical devices.	
526.			3.1.2a. The notified body shall ensure that personnel involved in conformity assessment activities maintain their qualification and expertise by implementing a system for exchange of experience and a continuous training and education programme.	
527.	3.1.3. The notified body shall clearly document the extent and the limits of the duties, responsibilities and authorities in relation of the personnel involved in conformity assessment activities and inform the personnel concerned about it.	3.1.3. The notified body shall clearly document the extent and the limits of the duties, responsibilities and authorities in relation of the personnel, including any subcontractors, subsidiaries and external experts, involved in conformity assessment activities and inform the personnel concerned about it.	3.1.3. The notified body shall clearly document the extent and the limits of the duties, responsibilities and authorities in relation to the personnel, including any subcontractors and external experts**,** involved in conformity assessment activities and inform the these personnel accordingly.	
528.		3.1.3a.The notified body shall make available the list of its personnel involved in conformity assessment activities and their expertise to the Commission and, upon request, to other parties. That list shall be kept up to date.		

Row	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
529.	**3.2. Qualification criteria in relation to personnel**	**3.2. Qualification criteria in relation to personnel**	**3.2. Qualification criteria in relation to personnel**	
530.	3.2.1. The notified body shall establish and document qualification criteria 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 training).	3.2.1. The MDCG shall establish and document the principles of high level competence and qualification criteria 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 training).	3.2.1. The Notified Body shall establish and document qualification criteria 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 training).	
531.	The qualification criteria shall address the various functions within the conformity assessment process (e.g. auditing, product evaluation/testing, design dossier/file review, decision-making) as well as the devices, technologies and areas covered by the scope of designation.	The qualification criteria shall address the various functions within the conformity assessment process (e.g. auditing, product evaluation/testing, design dossier/file review, decision-making) as well as the devices, technologies and areas (e.g. biocompatibility, sterilisation, tissues and cells of human and animal origin, clinical evaluation, risk management) covered by the scope of designation.	The qualification criteria shall address the various functions within the conformity assessment process (e.g. auditing, product evaluation/testing, technical documentation /file review, decision-making, batch release) as well as the devices, technologies and areas (e.g. biocompatibility, sterilisation, self and near patient-testing, companion diagnostics, performance evaluation) covered by the scope of designation.	
532.	3.2.2. The qualification criteria shall refer to the scope of the notified body's designation in accordance with the scope description used by the Member State for the notification referred to in Article 31, providing sufficient level of detail for the required qualification within the subdivisions of the scope description.	3.2.2 The qualification criteria shall refer to the scope of the notified body's designation in accordance with the scope description used by the Member State for the notification referred to in Article 31, providing sufficient level of detail for the required qualification within the subdivisions of the scope description.	3.2.2. The qualification criteria shall refer to the scope of the notified body's designation in accordance with the scope description used by the Member State for the notification referred to in Article 31, providing sufficient level of detail for the required qualification within the subdivisions of the scope description.	

Row	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
533.	Specific qualification criteria shall be defined for the assessment of biocompatibility aspects, clinical evaluation and the different types of sterilisation processes.	Specific qualification criteria shall be defined for the assessment of biocompatibility aspects, safety, clinical evaluation and the different types of sterilisation processes.	Specific qualification criteria shall be defined at least for the assessment of biological safety, performance evaluation, devices for self and near patient testing, companion diagnostics, functional safety, software, packaging and the different types of sterilisation processes.	
534.	3.2.3. The personnel responsible for authorising other personnel to perform specific conformity assessment activities and the personnel with overall responsibility for the final review and decision-making on certification shall be employed by the notified body itself and shall not be subcontracted.	3.2.3. The personnel responsible for authorising other personnel to perform specific conformity assessment activities and the personnel with overall responsibility for the final review and decision-making on certification shall be employed by the notified body itself and shall not be subcontracted.	3.2.3. The personnel responsible for establishing qualification criteria and for authorising other personnel to perform specific conformity assessment activities shall be employed by the notified body itself and shall not be subcontracted.	
535.	This personnel altogether shall have proven knowledge and experience in the following:	This personnel altogether shall have proven knowledge and experience in the following:	They shall have proven knowledge and experience in the following:	
536.	- Union in vitro diagnostic medical devices legislation and relevant guidance documents;	- Union in vitro diagnostic medical devices legislation and relevant guidance documents;	- Union in vitro diagnostic medical devices legislation and relevant guidance documents;	
537.	- the conformity assessment procedures in accordance with this Regulation;	- the conformity assessment procedures in accordance with this Regulation;	- the conformity assessment procedures in accordance with this Regulation;	
538.	- a broad base of in vitro diagnostic medical device technologies, the in vitro diagnostic medical device industry and the design and manufacture of in vitro diagnostic medical devices;	- a broad base of in vitro diagnostic medical device technologies, the in vitro diagnostic medical device industry and the design and manufacture of in vitro diagnostic medical devices;	- a broad base of in vitro diagnostic medical device technologies, and the design and manufacture of in vitro diagnostic medical devices;	

Row	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
539.	- the notified body's quality management system and related procedures;	- the notified body's quality management system and related procedures;	- the notified body's quality management system, related procedures and the required qualification criteria;	
540.	- the types of qualifications (knowledge, experience and other competence) required for carrying out conformity assessments in relation to in vitro diagnostic medical devices as well as the relevant qualification criteria;	- the types of qualifications (knowledge, experience and other competence) required for carrying out conformity assessments in relation to in vitro diagnostic medical devices as well as the relevant qualification criteria;		
541.	- training relevant to personnel involved in conformity assessment activities in relation to in vitro diagnostic medical devices;	- training relevant to personnel involved in conformity assessment activities in relation to in vitro diagnostic medical devices;	- training relevant to personnel involved in conformity assessment activities in relation to in vitro diagnostic medical devices;	
542.	- the ability to draw up certificates, records and reports demonstrating that the conformity assessments have been appropriately carried out.	- the ability to draw up certificates, records and reports demonstrating that the conformity assessments have been appropriately carried out.	***Cf. 3.2.5 (row 444), 3.2.6 (row 453), 3.2.7 (row 460)***	
543.		- at least three years' appropriate experience in the field of conformity assessments within a notified body,		
544.		- adequate seniority / experience in conformity assessments under this Regulation or previously applicable directives during a period of at least three years within a notified body. The notified body staff involved in certification decisions shall not have been involved in the conformity assessment on which a certification decision needs to be taken.		

Row	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
545.	3.2.4. Notified bodies shall have available personnel with clinical expertise. This personnel shall be integrated in the notified body's decision-making process in a steady way in order to:	3.2.4 Clinical experts: notified bodies shall have available personnel with expertise in clinical investigation design, medical statistics, clinical patient management, Good Clinical Practice in the field of clinical investigations. Permanent "in house" staff shall be used. However, in accordance with Article 28, notified bodies may hire external experts on an ad hoc and temporary basis provided they can make publicly available the list of these experts, as well as the specific tasks for which they are responsible. This personnel shall be integrated in the notified body's decision-making process in a steady way in order to:	3.2.4. The notified body shall have available personnel with relevant clinical expertise. These personnel shall be integrated throughout the notified body's assessment and decision-making process in order to:	
546.	- identify when specialist input is required for the assessment of the clinical evaluation conducted by the manufacturer and identify appropriately qualified experts;	- identify when specialist input is required for the assessment of the clinical investigation plans and the clinical evaluation conducted by the manufacturer and identify appropriately qualified experts;	- identify when specialist input is required for the assessment of the performance evaluation conducted by the manufacturer and identify appropriately qualified experts;	
547.	- appropriately train external clinical experts in the relevant requirements of this Regulation, delegated and/or implementing acts, harmonised standards, CTS and guidance documents and ensure that the external clinical experts are fully aware of the context and implication of their assessment and advice provided;	- appropriately train external clinical experts in the relevant requirements of this Regulation, delegated and/or implementing acts, harmonised standards, CTS and guidance documents and ensure that the external clinical experts are fully aware of the context and implication of their assessment and advice provided;	- appropriately train external clinical experts in the relevant requirements of regulation, CS, guidance and harmonised standards and ensure that the external clinical experts are fully aware of the context and implication of their assessment and advice provided;	

Row	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
548.	- be able to discuss the clinical data contained within the manufacturer's clinical evaluation with the manufacturer and with external clinical experts and to appropriately guide external clinical experts in the assessment of the clinical evaluation;	- be able to discuss the rationale of the planned study design, the clinical investigation plans and the selection of the control intervention with the manufacturer and with external clinical experts and to appropriately guide external clinical experts in the assessment of the clinical evaluation;	- be able to review and scientifically challenge the clinical data contained within the performance evaluation, and appropriately guide external clinical experts in the assessment of the performance evaluation presented by the manufacturer;	
549.	- be able to scientifically challenge the clinical data presented, and the results of the external clinical experts' assessment of the manufacturer's clinical evaluation;	- be able to scientifically challenge the clinical investigation plans and the clinical data presented, and the results of the external clinical experts' assessment of the manufacturer's clinical evaluation;	- be able to scientifically evaluate and, if necessary, challenge the performance evaluation presented, and the results of the external clinical experts' assessment of the manufacturer's performance evaluation;	
550.	- be able to ascertain the comparability and consistency of the clinical assessments conducted by clinical experts;		- be able to ascertain the comparability and consistency of the assessments of performance evaluation conducted by clinical experts;	
551.	- be able to make an objective clinical judgement about the assessment of the manufacturer's clinical evaluation and make a recommendation to the notified body's decision maker.	- be able to make an objective clinical judgement about the assessment of the manufacturer's clinical evaluation and make a recommendation to the notified body's decision maker.	- be able to make an assessment of the manufacturer's performance evaluation and a clinical judgement of the opinion provided by any external expert and make a recommendation to the notified body's decision maker.	
552.		- ensure independence and objectivity and disclose potential conflicts of interest.		
553.	3.2.5. The personnel responsible for carrying out product related review (e.g.	3.2.5 Product assessors: the personnel responsible for carrying out	3.2.5. The personnel (Product Reviewers) responsible for carrying out	

Row	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
	design dossier review, technical documentation review or type examination including aspects such as clinical evaluation, sterilisation, software validation) shall have the following proven qualification:	product related reviews (e.g. design dossier review, technical documentation review or type examination including aspects such as clinical evaluation, biological safety, sterilisation, software validation) shall have the specialist qualifications, which should include:	product related review (e.g. technical documentation review or type examination including aspects such as performance evaluation, biological safety, sterilisation, software validation) shall have the following proven qualifications:	
554.	- successful completion of a university or a technical college degree or equivalent qualification in relevant studies, e.g. medicine, natural science or engineering;	- successful completion of a university or a technical college degree or equivalent qualification in relevant studies, e.g. medicine, natural science or engineering;	- successful completion of a university or a technical college degree or equivalent qualification in relevant studies, e.g. medicine, pharmacy engineering or other relevant sciences;	
555.	- four years professional experience in the field of healthcare products or related sectors (e.g. industry, audit, healthcare, research experience) whilst two years of this experience shall be in the design, manufacture, testing or use of the device or technology to be assessed or related to the scientific aspects to be assessed;	- four years professional experience in the field of healthcare products or related sectors (e.g. industry, audit, healthcare, research experience) whilst two years of this experience shall be in the design, manufacture, testing or use of the device or technology to be assessed or related to the scientific aspects to be assessed;	- four years professional experience in the field of healthcare products or related sectors (e.g. industry, audit, healthcare, research experience) whilst two years of this experience shall be in the design, manufacture, testing or use of the device or technology to be assessed or related to the scientific aspects to be assessed;	
556.	- appropriate knowledge of the general safety and performance requirements laid down in Annex I as well as related delegated and/or implementing acts, harmonised standards, CTS and guidance documents;	- appropriate knowledge of the general safety and performance requirements laid down in Annex I as well as related delegated and/or implementing acts, harmonised standards, CTS and guidance documents;	- knowledge of the in vitro diagnostic medical device legislation, including the general safety and performance requirements laid down in Annex I;	
557.			- appropriate knowledge and experience of relevant harmonised standards, CS and guidance documents;	
558.		- qualification based on technical or scientific fields (e.g. sterilization,		

Row	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
		biocompatibility, animal tissue, human tissue, software, functional safety, clinical evaluation, electrical safety, packaging);		
559.	- appropriate knowledge and experience of risk management and related in vitro diagnostic medical device standards and guidance documents;	- appropriate knowledge and experience of risk management and related in vitro diagnostic medical device standards and guidance documents;	- appropriate knowledge and experience of risk management and related in vitro diagnostic medical device standards and guidance documents;	
560.		- appropriate knowledge and experience of clinical evaluation;	- appropriate knowledge and experience of performance evaluation;	
561.			- appropriate knowledge of the devices which they are assessing;	
562.	- appropriate knowledge and experience of the conformity assessment procedures laid down in Annexes VIII to X, in particular of those aspects for which they are authorised, and adequate authority to carry out those assessments.		- appropriate knowledge and experience of the conformity assessment procedures laid down in Annexes VIII to X, in particular of those aspects for which they are authorised, and adequate authority to carry out those assessments.	
563.			- the ability to draw up records and reports demonstrating that the relevant conformity assessment activities have been appropriately carried out.	
564.	3.2.6. The personnel responsible for carrying out audits of the manufacturer's quality management system shall have the following proven qualification:	3.2.7. The personnel responsible for carrying out audits of the manufacturer's quality management system shall have the following proven qualification:	3.2.6. The personnel (Site Auditors) responsible for carrying out audits of the manufacturer's quality management system shall have the following proven qualifications:	

Row	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
565.	- successful completion of a university or a technical college degree or equivalent qualification in relevant studies, e.g. medicine, natural sciences or engineering;	- successful completion of a university or a technical college degree or equivalent qualification in relevant studies, e.g. medicine, natural sciences or engineering;	- successful completion of a university or a technical college degree or equivalent qualification in relevant studies, e.g. medicine, pharmacy, engineering or other relevant sciences;	
566.	- four years professional experience in the field of healthcare products or related sectors (e.g. industry, audit, healthcare, research experience) whilst two years of this experience shall be in the area of quality management;	- four years professional experience in the field of healthcare products or related sectors (e.g. industry, audit, healthcare, research experience) whilst two years of this experience shall be in the area of quality management;	- four years professional experience in the field of healthcare products or related sectors (e.g. industry, audit, healthcare, research experience) whilst two years of this experience shall be in the area of quality management;	
567.	- appropriate knowledge of the in vitro diagnostic medical devices legislation as well as related delegated and/or implementing acts, harmonised standards, CTS and guidance documents;	- appropriate knowledge of the in vitro diagnostic medical devices legislation as well as related delegated and/or implementing acts, harmonised standards, CTS and guidance documents;	- appropriate knowledge of the in vitro diagnostic medical devices legislation as well as related harmonised standards, CTS and guidance documents;	
568.	- appropriate knowledge and experience of risk management and related in vitro diagnostic medical device standards and guidance documents;	- appropriate knowledge and experience of risk management and related in vitro diagnostic medical device standards and guidance documents;	- appropriate knowledge and experience of risk management and related in vitro diagnostic medical device standards and guidance documents;	
569.	- appropriate knowledge of quality management systems and related standards and guidance documents;	- appropriate knowledge of quality management systems and related standards and guidance documents;	- appropriate knowledge of quality management systems and related in vitro diagnostic medical devices standards and guidance documents;	
570.	- appropriate knowledge and experience of the conformity assessment procedures laid down in Annexes VIII to X, in particular of those aspects for which they	- appropriate knowledge and experience of the conformity assessment procedures laid down in Annexes VIII to X, in particular of those aspects for which they	- appropriate knowledge and experience of the conformity assessment procedures laid down in Annexes VIII to X, in particular of those aspects for which they	

Row	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
	are authorised, and adequate authority to carry out the audits;	are authorised, and adequate authority to carry out the audits;	are authorised, and adequate authority to carry out those audits;	
571.	- training in auditing techniques enabling them to challenge quality management systems.	- training in auditing techniques enabling them to challenge quality management systems.	- training in auditing techniques enabling them to challenge quality management systems.;	
572.			- the ability to draw up records and reports demonstrating that the relevant conformity assessment activities have been appropriately carried out.	
573.		***3.2.6*** Auditor: The personnel responsible for carrying out audits of the manufacturer's quality assurance system shall have specialist qualifications, which should include:		
574.		- successful completion of a university or a technical college degree or equivalent qualification in relevant studies, e.g. medicine, natural sciences or engineering;		
575.		- four years professional experience in the field of healthcare products or related sectors (e.g. industry, audit, healthcare, research experience) whilst two years of this experience shall be in the area of quality management;		
576.		- appropriate knowledge of technologies such as those defined by IAF/EAC coding or equivalent.		

Row	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
577.			3.2.7. The personnel with overall responsibility for final review and decision-making on certification shall be employee of the notified body and not be external expert or be subcontracted. These personnel, together, shall have proven knowledge and comprehensive experience of the following:	
578.			- the in vitro diagnostic medical devices legislation and relevant guidance documents;	
579.			- the in vitro diagnostic medical device conformity assessments relevant to this Regulation;	
580.			- the types of qualifications, experience and expertise relevant to medical device conformity assessment;	
581.			- a broad base of in vitro diagnostic medical device technologies, including sufficient experience of the conformity assessment of the devices being reviewed for final certification, the in vitro diagnostic medical device industry and the design and manufacture of devices;	
582.			- the notified body's quality system, related procedures and the required qualification criteria;	
583.			- the ability to draw up records and	

Row	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
			reports demonstrating that the conformity assessment activities have been appropriately carried out.	
584.	**3.3. Documentation of qualification, training and authorisation of personnel**	**3.3. Documentation of qualification, training and authorisation of personnel**	**3.3. Documentation of qualification, training and authorisation of personnel**	
585.	3.3.1. The notified body shall have a process in place to fully document the qualification of each personnel involved in conformity assessment activities and the satisfaction of the qualification criteria referred to in Section 3.2.	3.3.1. The notified body shall have a process in place to fully document the qualification of each personnel involved in conformity assessment activities and the satisfaction of the qualification criteria referred to in Section 3.2.	3.3.1. The notified body shall have a process in place to fully document the qualification of each personnel involved in conformity assessment activities and the satisfaction of the qualification criteria referred to in Section 3.2.	
586.	Where in exceptional circumstances the fulfilment of the qualification criteria set out in Section 3.2 cannot be fully demonstrated, the notified body shall appropriately justify the authorisation of this personnel to carry out specific conformity assessment activities.	Where in exceptional circumstances the fulfilment of the qualification criteria set out in Section 3.2 cannot be fully demonstrated, the notified body shall appropriately justify the authorisation of this personnel to carry out specific conformity assessment activities.	Where in exceptional circumstances the fulfilment of the qualification criteria set out in Section 3.2 cannot be fully demonstrated, the notified body shall justify to the national authority responsible for notified bodies the authorisation of these personnel to carry out specific conformity assessment activities	
587.	3.3.2. For its personnel referred to in Sections 3.2.3 to 3.2.6, the notified body shall establish and maintain up to date:	3.3.2. For its personnel referred to in Sections 3.2.3 to 3.2.6, the notified body shall establish and maintain up to date:	3.3.2. For all of its personnel referred to in Sections 3.2.3. to 3.2.7., the notified body shall establish and maintain up to date:	
588.	- a matrix detailing the responsibilities of the personnel in respect of the conformity assessment activities;	- a matrix detailing the responsibilities of the personnel in respect of the conformity assessment activities;	- a matrix detailing the authorisations and responsibilities of the personnel in respect of the conformity assessment activities;	

Row	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
589.	- records demonstrating the required knowledge and experience for the conformity assessment activity for which they are authorised.	- records demonstrating the required knowledge and experience for the conformity assessment activity for which they are authorised.	- records demonstrating the required knowledge and experience for the conformity assessment activity for which they are authorised.	
590.			The records shall contain a rationale for defining the scope of the responsibilities for each of the assessment personnel and records of the conformity assessment activities carried out by each of them.	
591.	**3.4. Subcontractors and external experts**	**3.4. Subcontractors and external experts**	**3.4. Subcontractors and external experts**	
592.	3.4.1. Without prejudice to the limitations emanating from Section 3.2., the notified bodies may subcontract clearly defined parts of the conformity assessment activities.	3.4.1. Without prejudice to the limitations emanating from Section 3.2., the notified bodies may subcontract clearly defined parts of the conformity assessment activities in particular where clinical expertise is limited.	3.4.1. Without prejudice to the limitations emanating from Section 3.2., notified bodies may subcontract certain clearly defined component parts of a conformity assessment activity.	
593.	The subcontracting of the auditing of quality management systems or of product related reviews as a whole is not allowed.	The subcontracting of the auditing of quality management systems or of product related reviews as a whole is not allowed.	The subcontracting of the auditing of quality management systems or of product related reviews as a whole is not allowed, but nevertheless these activities can be conducted by subcontractors and external experts working on behalf of the notified body.	
594.			The notified body retains the full responsibility for being able to produce appropriate evidence of the competence of subcontractors and experts to fulfil	

Row	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
			their specific tasks, retains responsibility for making a decision based on a subcontractor's assessment and full responsibility for the work conducted by subcontractors and experts on its behalf.	
595.			The following activities may not be subcontracted by the notified body: - review of the qualification and the monitoring of the performance of external experts; - auditing and certification activities to auditing or certification organisations; - allocation of work to external experts for specific conformity assessment activities; - final review and decision making functions.	
596.	3.4.2. Where a notified body subcontracts conformity assessment activities either to an organisation or an individual, it shall have a policy describing the conditions under which subcontracting may take place.	3.4.2. Where a notified body subcontracts conformity assessment activities either to an organisation or an individual, it shall have a policy describing the conditions under which subcontracting may take place.	3.4.2. Where a notified body subcontracts certain conformity assessment activities either to an organisation or an individual, it shall have a policy describing the conditions under which subcontracting may take place, and shall ensure that:	
597.			- the subcontractor meets the relevant requirements of this Annex;	
598.			- subcontractors and external experts do not further subcontract work to organisations or personnel;	
599.			- where the notified body subcontracts conformity assessment activities, the	

Row	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
			client has been informed of this and has given consent.	
600.	Any subcontracting or consultation of external experts shall be properly documented and be subject to a written agreement covering, among others, confidentiality and conflict of interests.	Any subcontracting or consultation of external experts shall be properly documented, be publicly available and be subject to a written agreement covering, among others, confidentiality and conflict of interests.	Any subcontracting or consultation of external personnel shall be properly documented and shall be subject to a direct written agreement covering, among others, confidentiality and conflict of interests.	
601.			The notified body shall take full responsibility for the tasks performed by subcontractors.	
602.	3.4.3. Where subcontractors or external experts are used in the context of the conformity assessment, the notified body shall have adequate own competence in each product area for which it is designated to lead the conformity assessment, to verify the appropriateness and validity of expert opinions and make the decision on the certification.	3.4.3. Where subcontractors or external experts are used in the context of the conformity assessment, the notified body shall have adequate own competence in each product area, each treatment or medical specialty for which it is designated to lead the conformity assessment, to verify the appropriateness and validity of expert opinions and make the decision on the certification.	3.4.3. Where subcontractors or external experts are used in the context of the conformity assessment, in particular regarding novel in vitro diagnostic medical devices or technologies the notified body shall have adequate own competence in each product area for which it is designated to lead the overall conformity assessment, to verify the appropriateness and validity of expert opinions and make the decision on the certification.	
603.	3.4.4. The notified body shall establish procedures for assessing and monitoring the competence of all subcontractors and external experts used.	3.4.4. The notified body shall establish procedures for assessing and monitoring the competence of all subcontractors and external experts used.		
604.		3.4.4a. The policy and procedures under points 3.4.2 and 3.4.4 shall be		

Row	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
		communicated to the national authority before any subcontracting takes place.		
605.	**3.5. Monitoring of competences and training**	**3.5. Monitoring of competences and training**	**3.5. Monitoring of competences ~~and~~, training and exchange of experience**	
606.	3.5.1. The notified body shall appropriately monitor the satisfactory performance of the conformity assessment activities by its personnel.	3.5.1. The notified body shall appropriately monitor the satisfactory performance of the conformity assessment activities by its personnel.	3.5.1. The notified body shall establish procedures for the initial evaluation and on-going monitoring of the competence, conformity assessment activities and performance of all internal and external personnel and subcontractors, involved in conformity assessment activities.	
607.	3.5.2. It shall review the competence of its personnel and identify training needs in order to maintain the required level of qualification and knowledge.	3.5.2. It shall review the competence of its personnel and identify training needs and ensure that necessary measures are taken accordingly, in order to maintain the required level of qualification and knowledge.	3.5.2. It shall review at regular intervals, the competence of its personnel, identify training needs and draw up a training plan to maintain the required level of qualification and knowledge of individual personnel.	
608.			This review shall at a minimum, verify that personnel: - are aware of the current in vitro diagnostic medical device Regulation, relevant harmonised standards, CS, guidance documents and the results of the coordination activities according to Section 1.6 of this Annex; - take part in the internal exchange of experience and the continuous training and education programme according to Section 3.1.2a.	

Row	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
609.		**3.5 a 1. Clinical Experts for Special Notified Bodies**		
610.		Notified bodies shall have available personnel with expertise in clinical investigation design, medical statistics, clinical patient management, Good Clinical Practice in the field of clinical investigations and pharmacology. Permanent "in house" staff shall be used. However, in accordance with Article 30, notified bodies may hire external experts on an ad hoc and temporary basis provided they can make publicly available the list of these experts, as well as the specific tasks for which they are responsible. This personnel shall be integrated in the notified body's decision-making process in a steady way in order to:		
611.		- identify when specialist input is required for the assessment of the clinical investigation plans and the clinical evaluation conducted by the manufacturer and identify appropriately qualified experts;		
612.		- appropriately train external clinical experts in the relevant requirements of this Regulation, delegated and/or implementing acts, harmonised standards, CTS and guidance documents and ensure that the external clinical experts are fully aware of the context and		

Row	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
		implication of their assessment and advice provided;		
613.		- be able to discuss the rationale of the planned study design, the clinical investigation plans and the selection of the control intervention with the manufacturer and with external clinical experts and to appropriately guide external clinical experts in the assessment of the clinical evaluation;		
614.		- be able to scientifically challenge the clinical investigation plans and the clinical data presented, and the results of the external clinical experts' assessment of the manufacturer's clinical evaluation;		
615.		- be able to ascertain the comparability and consistency of the clinical assessments conducted by clinical experts;		
616.		- be able to make an objective clinical judgement about the assessment of the manufacturer's clinical evaluation and make a recommendation to the notified body's decision maker.		
617.		- have an understanding of active substances.		
618.		- ensure independence and objectivity and disclose potential conflicts of interest		

Row	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
619.		**3.5.a.2. Training for Product Specialists for Special Notified Bodies**		
620.		The personnel responsible for carrying out product related reviews (e.g. design dossier review, technical documentation review or type examination) for devices referred to in Article 41 a shall have the following proven Product Specialist qualifications:		
621.		- Meet the requirement for Product Assessors;		
622.		- Have an advanced academic degree in a field relevant to medical devices, or alternatively have six years of relevant experience in in vitro diagnostics medical devices or related sectors;		
623.		- Have an ability to identify key risks of products with the specialist's product categories without prior reference to manufacturer's specifications or risk analyses;		
624.		- Have an ability to assess the essential requirements in the absence of harmonised or established national standards;		
625.		- The professional experience should be gained in the first product category their qualification is based on, relevant to the		

Row	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
		product category of designation of the notified body, providing sufficient knowledge and experience to thoroughly analyse the design, the validation and verification testing and the clinical use, with a sound understanding of the design, manufacture, testing, clinical use and risks associated with such a device;		
626.		- Missing professional experience for further product categories closely related to the first product category, may be substituted by internal product specific training programmes;		
627.		- For product specialists with qualification in specific technology, professional experience should be gained in the specific technology area, relevant to the scope of designation of the notified body.		
628.		For each designated product category, the Special notify body shall have a minimum of two product specialists of which at least one in house, to review devices referred to in Article 41a(1). For those devices, product specialists shall be available in house for the designated technology fields covered by the scope of the notification.		
629.		**3.5.a.3. Maintenance Qualification for Product Specialists**		

Row	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
630.		Qualifications of Product Specialists shall be reviewed on an annual basis; a minimum of four Design Dossier reviews, independent of the number of product categories qualified for shall be demonstrated as a four-year rolling average. Reviews of significant changes to the approved design (not full design examinations) count for 50%, as do reviews supervised.		
631.		On an ongoing basis, the product Specialist needs to show evidence of stateof- art product knowledge, review experience in each product category for which qualification exists. Annual training with regard to latest status of Regulations, harmonized standards, relevant guidance documents, clinical evaluation, performance evaluation, CTS requirements needs to be demonstrated. If the requirements for renewal of qualification are not met, the qualification shall be suspended. Then the first upcoming Design Dossier review shall be done under supervision, and requalification confirmed based on the outcome of this review.		
632.	**4. PROCESS REQUIREMENTS**	**4. PROCESS REQUIREMENTS**	**4. PROCESS REQUIREMENTS**	
633.	4.1. The notified body's decision-making process shall be clearly documented, including the process for the issue, suspension, reinstatement, withdrawal or			

Row	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
	refusal of conformity assessment certificates, their modification or restriction and the issue of supplements.			
634.	4.2. The notified body shall have in place a documented process for the conduct of the conformity assessment procedures for which it is designated taking into account their respective specificities, including legally required consultations, in respect of the different categories of devices covered by the scope of notification, ensuring transparency and the ability of reproduction of those procedures.	4.2. The notified body's decision-making process shall be transparent and clearly documented and its outcome publicly available, including the process for the issue, suspension, reinstatement, withdrawal or refusal of conformity assessment certificates, their modification or restriction and the issue of supplements.	4.2. General The notified body shall have in place documented processes and sufficiently detailed procedures for the conduct of each conformity assessment activity for which it is designated, comprising the individual steps from pre-application activities until decision making and surveillance and taking into account, when necessary, their respective specificities of the devices.	
635.			The requirements outlined in Sections 4.4., 4.5., 4.8. and 4.9. shall be internal activities of the notified body and shall not be subcontracted.	
636.	4.3. The notified body shall	**4.4** The notified body shall	4.3. Notified body quotations and pre-application activities The notified body shall	
637.			- publish a publicly available description of the application procedure by which manufacturers can obtain certification by the notified body.	
638.	have in place documented procedures covering at least:	have in place documented procedures that are publicly available covering at least:	- have documented procedures relating to, and documented details about fees charged for specific conformity assessment activities and any other	

Row	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
			financial conditions relating to its assessment activities for devices,	
639.	- the application for conformity assessment by a manufacturer or by an authorised representative,	- the application for conformity assessment by a manufacturer or by an authorised representative,	**4.4, § 1** The notified body shall require a formal application signed by the manufacturer or an authorised representative containing all of the information and manufacturer's declarations required by the relevant conformity assessment annexes VIII to X.	
640.	- the processing of the application, including the verification of the completeness of the documentation, the qualification of the product as in vitro diagnostic medical device and its classification,	- the processing of the application, including the verification of the completeness of the documentation, the qualification of the product as in vitro diagnostic medical device and its classification, as well as the recommended duration for conducting its conformity assessment,	***4.4*** - the completeness with respect to the requirements provided in the respective Annex under which approval has been sought, - the verification of the qualification of the products covered by the application as devices and their specific classification(s),	
641.	- the language of the application, of the correspondence and of the documentation to be submitted,	- the language of the application, of the correspondence and of the documentation to be submitted,	**4.3, 1st bullet** This description shall include which languages are acceptable for submission of documentation and for any related correspondence,	
642.	- the terms of the agreement with the manufacturer or authorised representative,	- the terms of the agreement with the manufacturer or authorised representative,	**4.4** This contract shall have clear terms and conditions and contain obligations that enable the notified body to act as required by this Regulation, including an obligation on the manufacturer to inform the notified body of vigilance reports, the right of the notified body to suspend,	

Row	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
			restrict or withdraw certificates issued and to fulfil its information obligations.	
643.	- the fees to be charged for conformity assessment activities,	- the fees to be charged for conformity assessment activities,	**Cf. row 594**	
644.	- the assessment of relevant changes to be submitted for prior approval,	- the assessment of relevant changes to be submitted for prior approval,		
645.	- the planning of surveillance,	- the planning of surveillance,		
646.	- the renewal of certificates.	- the renewal of certificates.		
647.			- have documented procedures in relation to advertising of its conformity assessment services. These shall ensure that advertising or promotional activities in no way imply or could lead to inference that their conformity assessment will offer manufacturers earlier market access or be quicker, easier or less stringent than other notified bodies,	
648.			- have documented procedures requiring the review of pre-application information including the preliminary verification that the product is covered by this Regulation and its classification prior to issuing any quotation to the manufacturer relating to a specific conformity assessment,	
649.			- ensure that all contracts relating to the conformity assessment activities covered by this Regulation are established directly	

Row	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
			between the manufacturer and the notified body and not with any other organisation.	
650.		4.3 The notified body shall have in place a documented process for the conduct of the conformity assessment procedures for which it is designated taking into account their respective specificities, including legally required consultations, in respect of the different categories of devices covered by the scope of notification, ensuring transparency and the ability of reproduction of those procedures.		
651.			**4.4. Application and contract review**	
652.			The contract between the notified body and the manufacturer shall take the form of a written agreement signed by both parties. It shall be kept by the notified body.	
653.			The notified body shall have documented procedures to review applications, addressing: - the legal applicability of the conformity assessment route chosen by the applicant, - the ability of the notified body to assess the application based on their designation, and - the availability of sufficient and	

Row	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
			appropriate resources.	
654.			The outcome of this review shall be documented. Refusals or withdrawals of applications shall be notified to the European databank and shall be accessible to other notified bodies.	
655.			**4.5. Allocation**	
656.			The notified body shall have documented procedures to ensure that all conformity assessment activities are conducted by appropriately authorised and qualified personnel who are sufficiently experienced in the evaluation of the devices, systems and processes and related documentation that are subject to conformity assessment.	
657.			For each application, the notified body shall determine the resource needs and identify one individual responsible for ensuring that the assessment of each application is conducted in accordance with the relevant procedures and for ensuring that the appropriate resources/personnel are utilised for individual tasks of the assessment. The allocation of tasks required for the conformity assessment and any changes subsequently made to this allocation shall be documented.	

Row	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
658.			**4.6. Conformity assessment activities**	
659.			**4.6.1. General**	
660.			The notified body and its personnel shall carry out the conformity assessment activities with the highest degree of professional integrity and the requisite technical and scientific competence in the specific fields.	
661.			The notified body shall have sufficient expertise, facilities and detailed documented procedures to effectively conduct the conformity assessment activities, taking account of the specific requirements set out in Annex VIII, IX and X of this Regulation for which it is designated, including the requirements:	
662.			- to appropriately plan the conduct of each individual project; these shall ensure that the composition of the assessment teams assures experience with the technology concerned, continuous objectivity and independence, which shall include provision for rotation of the members of the assessment team at appropriate intervals,	
663.			- to detail the rationale for fixing time limits for completion of conformity assessment activities,	

Row	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
664.			- to assess the manufacturer's technical documentation and the solutions adopted to meet the Requirements laid out in Annex I,	
665.			- to review manufacturer's procedures and documentation relating to performance evaluation,	
666.			- to address the interface with the risk management process and the appraisal and analysis of the, performance evaluation and its relevance to demonstrate conformity to the relevant requirements in Annex I,	
667.			- to carry out the "specific procedures" in the case of devices incorporating medicinal substances, human blood derivatives or in the case of devices manufactured utilising non-viable tissues or cells,	
668.			- to assess, in the case of devices falling into class B or C, on a representative basis the technical documentation,	
669.			- to plan and periodically carry out appropriate surveillance audits and assessments, to carry out or request certain tests to verify the proper functioning of the quality management system and to perform unannounced factory visits,	

Row	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
670.			- relating to the sampling of devices to verify that the manufactured device is in conformity with the technical documentation, these shall define the relevant sampling criteria and testing procedure prior to sampling,	
671.			- to evaluate and verify a manufacturer's compliance with relevant Annexes.	
672.			Specific requirements of a notified body in conducting conformity assessment activities, including quality system audits, technical documentation assessment and performance evaluation can be found in the relevant conformity assessment Annexes VIII to X. The notified body shall, when relevant, take into consideration harmonised standards, even if the manufacturer doesn't claim compliance, available CS, guidance and best practice documents.	
673.			**4.6.2. Quality management system audits**	
674.			(a) As part of the quality system assessment activity, the notified body shall prior to the audit and in accordance with its documented procedures:	
675.			- assess the documentation submitted according the relevant conformity assessment Annex and establish an audit	

Row	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
			programme which clearly identifies the number and sequence of activities required to demonstrate complete coverage of a manufacturer's quality management system and to determine whether it meets the requirements of this Regulation,	
676.			- determine interfaces and responsibilities between different manufacturer sites, as well as the identification of relevant suppliers and/or subcontractors of the manufacturer, including consideration of the need to specifically audit any of these suppliers and/or subcontractors,	
677.			- clearly define, for each audit identified in the audit programme, the objectives, criteria and scope of the audit and shall draw up an audit plan adequately addressing and taking account of the specific requirements for the devices, technologies and processes covered,	
678.			- establish and maintain, for class B and C devices, a sampling plan for the assessment of technical documentation as referred to in Annex II covering the range of such devices comprised by the manufacturer's application. This plan shall ensure that all devices covered by the certificate are sampled over the period of validity of the certificate,	

Row	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
679.			- select and assign appropriately qualified and authorised personnel for conducting the individual audits. The respective roles, responsibilities and authorities of the team members shall be clearly defined and documented.	
680.			(b) According to the audit programme established, the notified body shall, in accordance with its documented procedures:	
681.			- audit the manufacturer's quality management system, which must ensure that the devices covered conform to the relevant provisions of this Regulation, which apply to devices at every stage, from design through final inspection to ongoing surveillance, and determine if the requirements of this Regulation are met,	
682.			- review and audit the manufacturer's processes/subsystems, based on relevant technical documentation – in particular for design and development, production and process controls, product documentation, purchasing controls including verification of purchased devices, corrective and preventive actions including post-market surveillance and post-market performance follow-up, requirements and provisions adopted by the manufacturer including those in relation to fulfilling the	

Row	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
			general safety and performance requirements to determine whether the manufacturer meets the requirements referred to in the relevant conformity assessment annex. Documentation shall be sampled to reflect the risks associated with the intended use for the device, the complexity of the manufacturing technologies, the range and classes of devices produced and any available post-market surveillance information.	
683.			- if not already covered by the audit programme, audit the control of processes on the premises of the manufacturer's suppliers, when the conformity of finished devices is significantly influenced by the activity of suppliers and, in particular when the manufacturer cannot demonstrate sufficient control over its suppliers,	
684.			- conduct assessments of the technical documentations according to the established sampling plan and taking account of Section 4.6.4. of this Annex for performance evaluation.	
685.			- the notified body shall ensure that audit findings are appropriately and consistently classified in accordance with the requirements of this Regulation and with relevant standards/best practice documents developed or adopted by the MDCG.	

Row	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
686.			**4.6.3. Product verification**	
687.			For assessment of the technical documentation conducted in accordance with Annex VIII Chapter II, the notified body shall have sufficient expertise, facilities and detailed documented procedures providing for:	
688.			- the allocation of appropriately qualified and authorised personnel for the examination of the individual aspects (use of the device, biocompatibility, performance evaluation, risk management, sterilisation, etc.),	
689.			- the assessment of the technical documentation taking account of Sections 4.6.4. and 4.6.5. of this Annex and the assessment of conformity of the design with the provisions of this Regulation. This examination shall include the assessment of the implementation and the results of incoming, in-process and final inspections. If further tests or other evidence is required to allow for the assessment of conformity with the requirements of the Regulation, the notified body shall carry out adequate physical or laboratory tests in relation to the device or request the manufacturer to carry out such tests.	

Row	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
690.			**Type-examinations** The notified body shall have detailed documented procedures, sufficient expertise and facilities for the type-examination of devices according to Annex IX including capacity to:	
691.			**-** examine and assess the technical documentation taking account of Sections 4.6.4. and 4.6.5. of this Annex and verify that the type has been manufactured in conformity with that documentation.	
692.			- establish a test plan identifying all relevant and critical parameters which need to be tested by the notified body or under its responsibility.	
693.			- document its rationale for the selection of those parameters.	
694.			- carry out the appropriate examinations and tests in order to verify that the solutions adopted by the manufacturer meet the general safety and performance requirements of this Regulation. This shall include all necessary tests to verify that the manufacturer has applied the relevant standards.	
695.			- agree with the applicant as to where the necessary tests will be performed if they are not to be carried out directly by the	

Row	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
			notified body.	
696.			- assume full responsibility for test results. Test reports submitted by the manufacturer can only be taken into account if they have been issued by conformity assessment bodies which are competent and independent of the manufacturer.	
697.			**Verification by examination and testing of every product** The notified body shall:	
698.			- have detailed documented procedures, sufficient expertise and facilities for the verification by examination and testing of every product according to Annex X	
699.			- establish a test plan identifying all relevant and critical parameters which need to be tested by the notified body or under its responsibility in order to:	
700.			- for devices in class C: verify the conformity of the device with the type described in the EU type-examination certificate and with the requirements of this Regulation which apply to them,	
701.			- for devices in class B: confirm the conformity with the technical documentation referred to in Annex II and with the requirements of this Regulation	

Row	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
			which apply to them.	
702.			- document its rationale for the selection of those parameters.	
703.			- have documented procedures to carry out the appropriate assessments and tests in order to verify the conformity of the device with the requirements of the Regulation by examining and testing of manufactured devices or every product each batch of devices as specified in Annex X, Section 5.	
704.			- have documented procedures providing for agreement with the applicant as to where the necessary tests will be performed if they are not to be carried out directly by the notified body.	
705.			- shall assume full responsibility for test results in accordance with documented procedures. Test reports submitted by the manufacturer can only be taken into account if they have been issued by conformity assessment bodies which are competent and independent of the manufacturer.	
706.			4.6.4. Performance evaluation assessment	
707.			The notified body assessment of procedures and documentation shall	

Row	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
			address the results of literature search and all validation, verification and testing performed and conclusions drawn and shall typically include considerations of alternative materials and substances to be used and of the packaging, stability/shelf life of the finished device. Where no new testing has been undertaken by the manufacturer or for deviations from procedures, the notified body shall appropriately challenge the justification presented by the manufacturer.	
708.			The notified body shall have documented procedures in place relating to the review of a manufacturer's procedures and documentation relating to performance evaluation both for initial conformity assessment and on an ongoing basis. The notified body shall examine, validate and verify that the manufacturer's procedures and documentation adequately address:	
709.			- the planning, conduct, assessment, reporting and updating of the performance evaluation according to Annex XII,	
710.			- post-market surveillance and post-market performance follow up,	
711.			- the interface with the risk management	

Row	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
			process,	
712.			- the appraisal and analysis of the available data and its relevance to demonstrate conformity to the relevant requirements in Annex I,	
713.			- the conclusions drawn with regard to the clinical evidence and elaboration of the performance evaluation report .	
714.			These procedures shall take into consideration available CS, guidance and best practice documents.	
715.			The notified body assessment of performance evaluation according to Annex XII shall include specified intended use and claims for the device defined by the manufacturer, the planning of the performance evaluation, the methodology for the literature search, relevant documentation to the literature search, the performance studies, post-market surveillance and of post-market performance follow up, validity of claimed equivalence to other devices, the demonstration of equivalence, the suitability and conclusions data from equivalent and similar devices, justifications presented for deviations from their procedures) and the performance evaluation report.	

Row	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
716.			In relation to data from performance studies included within the performance evaluation, the notified body shall ensure that the conclusions drawn by the manufacturer are valid in the light of the performance studies submitted to the competent authority.	
717.			The notified body shall ensure that the performance evaluation adequately addresses the relevant safety and performance requirements in Annex I, that it is appropriately aligned with the risk management, performed in accordance with Annex XII and that it is appropriately reflected in the information provided relating to the device.	
718.			4.6.5. “Specific Procedures”	
719.			The notified body shall have detailed documented procedures, sufficient expertise and facilities for the “ specific types of devices” according to Annex VIII, Sections 6, for which it is designated.	
720.			In the case of companion diagnostics the notified body shall have document procedure in place that relate to the requirements of this Regulation for consultation of the European Medicines Agency or a medicinal products competent authority during its assessment of such a device.	

Row	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
721.			4.7. Reporting	
722.			The notified body shall: - ensure all steps of the conformity assessment are documented so that the conclusions of the assessment are clear and demonstrate compliance with the requirements of this Regulation and can provide objective evidence of this to personnel not directly involved in the assessment, for example designating authorities, - ensure that records for quality management system audits are available that are sufficient to provide a discernible audit trail, - clearly document the conclusions of its assessment of the performance evaluation in a performance evaluation assessment report, - for each specific project provide a detailed report which shall be based on a standard format containing a minimum set of content determined by the Medical Device Coordination Group.	
723.			The notified body reports shall: - clearly document the outcome of, their assessments and draw clear conclusions on verifying the manufacturer's conformity to the requirements of this Regulation, - make a recommendation for review and final decision making by the notified	

Row	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
			body; this recommendation shall be clearly signed off by the responsible notified body personnel, - be provided to the manufacturer.	
724.			4.8. Review	
725.			The notified body shall prior to making a final decision ensure: - that personnel assigned for review and decision making on specific projects are appropriately authorised and are different from those personnel who have conducted the assessments, - that the report(s) and supporting documentation needed for decision making, including close out of nonconformities raised during assessment, are complete and sufficient with respect to the scope of the application, - that no unresolved nonconformities exist that prevent issuance of an EU certificate.	
726.			4.9. Decisions and certifications	
727.			The notified body shall have documented procedures for decision making including responsibilities for decision making and the issuance, suspension, restriction and withdrawal of certificates. These procedures shall include the notification requirements according to Chapter V of	

Row	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
			this Regulation. These procedures shall allow it to: - decide, based on the assessment documentation and additional information available whether the requirements of the Regulation are fulfilled, decide based on the results of their assessment of the performance evaluation and risk management if the PMS plan, including whether the PMPF is adequate and on specific milestones for further review by the notified body of the up to date performance evaluation, - decide whether specific conditions or provisions need to be defined for the certification, - decide, based on the novelty, risk classification, performance evaluation and outputs from the risk analysis of the device, on a period for certification not exceeding five years, - clearly document decision making and approval steps including approval by signature of the responsible individuals, - clearly document responsibilities and mechanisms for communication of decisions, in particular, if the final signatory of a certificate differs from the decision maker(s) and does not fulfil the requirements outlined in Section 3.2.7. of this Annex, - issue a certificate(s) according to the minimum requirements defined in Annex XI for a period of validity not exceeding five years and shall indicate if there are	

Row	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
			specific conditions or limitations associated with the certification, - issue a certificate(s) for the applicant alone and shall not issue certificates covering multiple entities, - ensure that the outcome of the assessment and the resultant decision is notified to the manufacturer and entered into the European databank according to Article 43(4).	
728.			4.10. Changes and modifications	
729.			The notified body shall have documented procedures and contractual arrangements with manufacturers in place relating to the information obligations and the assessment of changes to:	
730.			- the approved quality management system(s) or the product-range covered,	
731.			- the approved design of a device,	
732.			- the approved type of a device,	
733.			- any substance incorporated in or utilised for the manufacturing of a device and being subject to "specific procedures" according to Section 4.6.5.	
734.			These procedures and contractual	

Row	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
			arrangements shall include processes for checking the significance of changes.	
735.			In accordance with its documented procedures, the notified body shall: - ensure that manufacturers submit plans for such changes and relevant information relating to the change for prior approval, - assess the changes proposed and verify whether after these changes the quality management system or the design/type of a device still meets the requirements of this Regulation, - notify the manufacturer of its decision and provide a (supplement) report, which shall contain the justified conclusions of its assessment/audit.	
736.			4.11. Surveillance activities and post-certification monitoring	
737.			The notified body shall have documented procedures:	
738.			- defining how and when surveillance activities of manufacturers are to be conducted. These shall include provisions for unannounced visits to manufacturers and when applicable subcontractors and suppliers, carrying out product tests and the monitoring of compliance to any conditions on manufacturers associated with	

Row	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
			certification decisions, e.g. updates to clinical data at defined intervals,	
739.			- for screening relevant sources of scientific, clinical and post-market information relating to the scope of its designation. Such information shall be taken into account in the planning and conducting of surveillance activities,	
740.			- to review vigilance information accessible according to Article 60 in order to estimate its impact, if any, on the validity of existing certificates. The results of the evaluation and any decisions taken shall be thoroughly documented.	
741.			The notified body shall, upon receipt of information about vigilance cases from the manufacturer or the competent authorities, decide about the following options:	
742.			- that no action is required as the vigilance case is clearly not related to the certification granted,	
743.			- observation of the manufacturer's and competent authorities activities and the results of the manufacturer's investigation to allow a conclusion that the certification granted is not endangered or adequate corrective action has been performed,	

Row	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
744.			- performance of extraordinary surveillance measures (document review, short-notice or unannounced audit, product testing, etc.) if it is likely that certification granted is endangered	
745.			- increasing the frequency of surveillance audits	
746.			- reviewing specific products or processes during the next audit of the manufacturer, or	
747.			- any other relevant measure.	
748.			In relation to surveillance audits of manufacturers, the notified body shall have documented procedures to:	
749.			- conduct surveillance audits of the manufacturer on at least an annual basis which shall be planned and conducted in line with the relevant requirements in 4.6.,	
750.			- ensure that it adequately assesses the manufacturer's documentation on, and application of, the provisions on vigilance, the post-market surveillance plan (including post-market performance follow-up),	
751.			- sample and test devices and technical	

Row	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
			documentations, during audits, according to pre-defined sampling criteria and testing procedures to ensure that the manufacturer continuously applies the approved quality management system,	
752.			- ensure that that manufacturer complies with the documentation and information obligations laid down in the respective Annex(es) of this Regulation and that his procedures take into account best practices in implementation of quality management systems,	
753.			- ensure that the manufacturer does not use quality management system or device approvals in a misleading manner,	
754.			- gather sufficient information to determine if the quality management system continues to comply with the requirements of this Regulation,	
755.			- if non-conformities are detected ask the manufacturer for corrections, corrective actions, when applicable preventative actions, and	
756.			- when necessary, impose specific restrictions on the relevant certificate or suspend or withdraw it.	
757.			The notified body shall, if listed as part of the conditions for certification :	

Row	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
758.			- conduct an in depth review of the up to date performance evaluation of the manufacturer based on post-market surveillance, post-market performance follow up and clinical literature relevant to the condition being treated or similar devices,	
759.			- clearly document the outcome of this review and address any specific concerns or conditions to the manufacturer,	
760.			- ensure that the updated performance evaluation is appropriately reflected in the Instructions For Use and Summary of Safety and Performance Data.	
761.			4.12. Re-certification	
762.			The notified body shall have documented procedures in place relating to the re-certification reviews and the renewal of certificates. Re-certification of approved quality management systems or EU technical documentation assessment or EU type-examination certificates shall occur at least every 5 years.	
763.			The notified body shall have documented procedures relating to EU technical documentation assessment renewals and EU type-examination renewals that shall require the manufacturer to submit a	

Row	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
			summary on changes and scientific findings for the device, including:	
764.			- all changes to the originally approved device, including changes not yet notified,	
765.			- experience gained from post -market surveillance,	
766.			- experience from risk-management,	
767.			- experience from updating the proof of compliance with the general safety and performance requirements,	
768.			- experience from reviews of the performance evaluation, including the results of any clinical investigations and post-market clinical follow up,	
769.			- changes of the requirements, of components of the device or of the scientific or regulatory environment,	
770.			- changes of applied or new (harmonised) standards, CS or equivalent documents,	
771.			- changes in medicine, scientific and technical knowledge, such as: = new treatments, = changes in test methods, = new scientific findings on materials,	

Row	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
			components, etc., also with respect to biocompatibility, = experience from market research on comparable devices, = data from registers/registries, = experience from performance studies with comparable devices.	
772.			The notified body shall have documented procedures to assess this information and shall pay particular attention to clinical data from post-market surveillance and PMPF activities undertaken during this period, including appropriate updates to manufacturer's performance evaluation reports.	
773.			For the decision on the extension the notified body shall use the same methods and principles as for the initial decision. If necessary, separate forms shall be established taking into account the above mentioned steps, e.g. for application and application review.	
774.		**4 A. A RECOMMENDED DURATION FOR CONFORMITY ASSESSMENTS CONDUCTED BY NOTIFIED BODIES**		
775.		4.1 Notified bodies shall identify the audit duration for the stage 1 and stage 2 initial audits, and surveillance audits for each applicant and certified client		

Row	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
776.		4.2 An audit duration shall be based, inter alia, on the effective number of personnel of the organization, the complexity of the processes within the organization, the nature and the characteristics of the medical devices included in the scope of the audit and the different technologies that are employed to manufacture and control the medical devices. The audit duration may be adjusted based on any significant factors that uniquely apply to the organization to be audited. The notified body shall ensure that any variation in audit duration does not compromise the effectiveness of audits		
777.		4.3 The duration of any scheduled on site audit shall not be less than one auditor/day.		
778.		4.4 Certification of multiple sites under one quality assurance system shall not be based on a sampling system.		
779.	**ANNEX VII** **CLASSIFICATION CRITERIA**	**ANNEX VII** **CLASSIFICATION CRITERIA**	**ANNEX VII** **CLASSIFICATION CRITERIA**	
780.	**1. IMPLEMENTING RULES FOR THE CLASSIFICATION RULES**	**1. IMPLEMENTING RULES FOR THE CLASSIFICATION RULES**	**1. IMPLEMENTING RULES FOR THE CLASSIFICATION RULES**	
781.	1.1. Application of the classification rules shall be governed by the intended purpose of the devices.	1.1. Application of the classification rules shall be governed by the intended purpose, novelty, complexity and inherent risk of the devices.	1.1. Application of the classification rules shall be governed by the intended purpose of the devices.	---

Row	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
782.	1.2. If the device is intended to be used in combination with another device, the classification rules shall apply separately to each of the devices.	1.2. If the device is intended to be used in combination with another device, the classification rules shall apply separately to each of the devices.	1.2. If the device is intended to be used in combination with another device, the classification rules shall apply separately to each of the devices.	---
783.	1.3. Accessories are classified in their own right separately from the device with which they are used.	1.3. Accessories are classified in their own right separately from the device with which they are used.	1.3. Accessories are classified in their own right separately from the device with which they are used.	---
784.	1.4. Standalone software, which drives a device or influences the use of a device, falls automatically in the same class as the device. If standalone software is independent of any other device, it is classified in its own right.	1.4. Standalone software, which drives a device or influences the use of a device, falls automatically in the same class as the device. If standalone software is independent of any other device, it is classified in its own right.	1.4. Software, which drives a device or influences the use of a device, falls automatically in the same class as the device. If the software is independent of any other device, it is classified in its own right.	No significant change
785.	1.5. Calibrators intended to be used with a device shall be classified in the same class as the device.	1.5. Calibrators intended to be used with a device shall be classified in the same class as the device.	1.5. Calibrators intended to be used with a device shall be classified in the same class as the device.	---
786.	1.6. Standalone control materials with quantitative or qualitative assigned values intended for one specific analyte or multiple analytes shall be classified in the same class as the device.	1.6. Standalone control materials with quantitative or qualitative assigned values intended for one specific analyte or multiple analytes shall be classified in the same class as the device.	1.6. Control materials with quantitative or qualitative assigned values intended for one specific analyte or multiple analytes shall be classified in the same class as the device.	Standalone control materials are different from control materials but this can be explained in interpretation.
787.	1.7. The manufacturer shall take into consideration all the rules in order to establish the proper classification for the device.	1.7. The manufacturer shall take into consideration all the rules in order to establish the proper classification for the device.	1.7. The manufacturer shall take into consideration all the rules in order to establish the proper classification for the device.	---
788.	1.8. Where a device has multiple intended purposes stated by the	1.8. Where a device has multiple intended purposes stated by the	1.8. Where a device has multiple intended purposes stated by the	---

Row	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
	manufacturer, which place the device into more than one class, it shall be classified in the higher class.	manufacturer, which place the device into more than one class, it shall be classified in the higher class.	manufacturer, which place the device into more than one class, it shall be classified in the higher class.	
789.	1.9. If several classification rules apply to the same device the rule resulting in the higher classification shall apply.	1.9. If several classification rules apply to the same device the rule resulting in the higher classification shall apply.	1.9. If several classification rules apply to the same device the rule resulting in the higher classification shall apply.	---
790.			1.10. Each of the rules applies to first line assays, confirmatory assays and supplemental assays.	Not needed, but has no major impact.
791.	**2. CLASSIFICATION RULES**	**2. CLASSIFICATION RULES**	**2. CLASSIFICATION RULES**	Changes to classification may all have an impact on convergence with GHTF principles.
792.	**2.1. Rule 1** Devices intended for the following purposes are classified as **class D**:	**2.1. Rule 1** Devices intended for the following purposes are classified as **class D**:	**2.1. Rule 1** Devices intended for the following purposes are classified as **class D**:	**---**
793.	- Devices intended to be used to detect the presence of, or exposure to, a transmissible agent in blood, blood components, cells, tissues or organs, or in any of their derivatives, in order to assess their suitability for transfusion or transplantation.	- Devices intended to be used to detect the presence of, or exposure to, a transmissible agent in blood, blood components, cells, tissues or organs, or in any of their derivatives, in order to assess their suitability for transfusion or transplantation.	- Devices intended to be used to detect the presence of, or exposure to, a transmissible agent in blood, blood components, cells, tissues or organs, or in any of their derivatives, in order to assess their suitability for transfusion, or transplantation or cell administration.	Added cell administration to the list.
794.	- Devices intended to be used to detect the presence of, or exposure to, a transmissible agent that causes a life-threatening disease with a high or currently undefined risk of propagation.	- Devices intended to be used to detect the presence of, or exposure to, a transmissible agent that causes a life-threatening disease with a high or currently undefined risk of propagation.	- Devices intended to be used to detect the presence of, or exposure to, a transmissible agent that causes a life-threatening disease with a high or suspected high risk of propagation.	**---**

Row	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
795.			- Devices intended to be used to determine the infectious load of a life-threatening disease where its monitoring is critical in the process of patient management.	**Concern –** This is a divergence from the principles of classification as these kind of assays have only a risk for the individual patient.
796.	This rule applies to first line assays, confirmatory assays and supplemental assays.	This rule applies to first line assays, confirmatory assays and supplemental assays.		
797.			All assays for the clinical diagnosis and monitoring of infection by HIV 1/2, Hepatitis C virus, Hepatitis B virus and HTLV I/II devices should be classified as class D.	**Concern –** This is a divergence from the principles of classification as these kind of assays have only a risk for the individual patient.
798.			Assays for the clinical diagnosis of Hepatitis B virus are taken to include the following infectious disease markers: Hepatitis B surface antigen (HBsAg), Hepatitis B core total antibodies (anti-HBc total) and Hepatitis B virus nucleic acid detection (HBV NAT).	**---**
799.	**2.2. Rule 2** Devices intended to be used for blood grouping, or tissue typing to ensure the immunological compatibility of blood, blood components, cells, tissue or organs that are intended for transfusion or transplantation, are classified as **class C,** except when intended to determine any of the following markers: - ABO system [A (ABO1), B (ABO2), AB	**2.2. Rule 2** Devices intended to be used for blood grouping, or tissue typing to ensure the immunological compatibility of blood, blood components, cells, tissue or organs that are intended for transfusion or transplantation, are classified as **class C,** except when intended to determine any of the following markers: - ABO system [A (ABO1), B (ABO2), AB	**2.2. Rule 2** Devices intended to be used for blood grouping, or tissue typing to ensure the immunological compatibility of blood, blood components, cells, tissue or organs that are intended for transfusion or transplantation or cell administration, are classified as **class C**, except when intended to determine any of the following markers:	Added cell administration.

Row	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
	(ABO3)]; - Rhesus system [RH1 (D), RH2 (C), RH3 (E), RH4 (c), RH5 (e)]; - Kell system [Kel1 (K)]; - Kidd system [JK1 (Jka), JK2 (Jkb)]; - Duffy system [FY1 (Fya), FY2 (Fyb)] in which case they are classified as **class D.**	(ABO3)]; - Rhesus system [RH1 (D), RH2 (C), RH3 (E), RH4 (c), RH5 (e)]; - Kell system [Kel1 (K)]; - Kidd system [JK1 (Jka), JK2 (Jkb)]; - Duffy system [FY1 (Fya), FY2 (Fyb)] in which case they are classified as **class D.**	- ABO system [A (ABO1), B (ABO2), AB (ABO3)]; - Rhesus system [RH1 (D), RHW_1, RH2 (C), RH3 (E), RH4 (c), RH5 (e)]; - Kell system [Kel1 (K)]; - Kidd system [JK1 (Jka), JK2 (Jkb)]; - Duffy system [FY1 (Fya), FY2 (Fyb)] in which case they are classified as **class D**.	
800.	**2.3. Rule 3** Devices are classified as **class C** if they are intended for:	**2.3. Rule 3** Devices are classified as **class C** if they are intended for:	**2.3. Rule 3** Devices are classified as **class C** if they are intended for:	**---**
801.	(a) detecting the presence of, or exposure to, a sexually transmitted agent;	(a) detecting the presence of, or exposure to, a sexually transmitted agent;	(a) detecting the presence of, or exposure to, a sexually transmitted agent;	**---**
802.	(b) detecting the presence in cerebrospinal fluid or blood of an infectious agent with a risk of limited propagation;	(b) detecting the presence in cerebrospinal fluid or blood of an infectious agent with a risk of limited propagation;	(b) detecting the presence in cerebrospinal fluid or blood of an infectious agent without a high or suspected high risk of propagation;	Wording better clarifies that these are the cases which are not covered by rule 1.
803.	(c) detecting the presence of an infectious agent, if there is a significant risk that an erroneous result would cause death or severe disability to the individual or foetus being tested, or to the individual's offspring;	(c) detecting the presence of an infectious agent, if there is a significant risk that an erroneous result would cause death or severe disability to the individual or foetus or embryo being tested, or to the individual's offspring;	(c) detecting the presence of an infectious agent, if there is a significant risk that an erroneous result would cause death or severe disability to the individual or foetus being tested, or to the individual's offspring;	**---**
804.	(d) pre-natal screening of women in order to determine their immune status towards transmissible agents;	(d) pre-natal screening of women in order to determine their immune status towards transmissible agents;	(d) pre-natal screening of women in order to determine their immune status towards transmissible agents;	**---**

Row	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
805.	(e) determining infective disease status or immune status, if there is a risk that an erroneous result would lead to a patient management decision resulting in an imminent life-threatening situation for the patient or for the patient's offspring;	(e) determining infective disease status or immune status, if there is a risk that an erroneous result would lead to a patient management decision resulting in an imminent life-threatening situation for the patient or for the patient's offspring;	(e) determining infective disease status or immune status, if there is a risk that an erroneous result would lead to a patient management decision resulting in a life-threatening situation for the patient or for the patient's offspring;	---
806.	(f) selection of patients, i.e.	(f) selection of patients, i.e.		---
807.	(i) Devices intended to be used as companion diagnostics; or	(i) Devices intended to be used as companion diagnostics; or	(f) Devices intended to be used as companion diagnostics;	---
808.	(ii) Devices intended to be used for disease staging; or	(ii) Devices intended to be used for disease staging or prognosis; or	(fa)Devices intended to be used for disease staging, if there is a risk that an erroneous result would lead to a patient management decision resulting in a life-threatening situation for the patient or for the patient's offspring; or	Restricted the scope of this rule.
809.	(iii) Devices intended to be used in screening for or in the diagnosis of cancer.	(iii) Devices intended to be used in screening for or in the diagnosis of cancer.	(fb) Devices intended to be used in screening, diagnosis, or staging of cancer;	---
810.	(g) human genetic testing;	(g) human genetic testing;	(g) human genetic testing;	---
811.	(h) monitoring of levels of medicinal products, substances or biological components, when there is a risk that an erroneous result will lead to a patient management decision resulting in an imminent life-threatening situation for the patient or for the patient's offspring;	(h) monitoring of levels of medicinal products, substances or biological components, when there is a risk that an erroneous result will lead to a patient management decision resulting in an imminent life-threatening situation for the patient or for the patient's offspring;	(h) monitoring of levels of medicinal products, substances or biological components, when there is a risk that an erroneous result will lead to a patient management decision resulting in life-threatening situation for the patient or for the patient's offspring;	---

Row	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
812.	(i) management of patients suffering from a life-threatening infectious disease;	(i) management of patients suffering from a life-threatening infectious disease;	(i) management of patients suffering from a life-threatening disease or condition;	**---**
813.	(j) screening for congenital disorders in the foetus.	(j) screening for congenital disorders in the foetus or embryo.	(j) screening for congenital disorders in the foetus;	**---**
814.			(k) screening for congenital disorders in new-born where failure to detect and treat such disorders could lead to life-threatening situations or severe disabilities.	No comment
815.	**2.4. Rule 4** (a) Devices intended for self-testing are classified as class C, except those devices from which the result is not determining a medically critical status, or is preliminary and requires follow-up with the appropriate laboratory test in which case they are Class B.	**2.4. Rule 4** (a) Devices intended for self-testing are classified as class C, except those devices from which the result is not determining a medically critical status, or is preliminary and requires follow-up with the appropriate laboratory test in which case they are Class B.	**2.4. Rule 4** (a) Devices intended for self-testing are classified as class C.	**Concern –** All self tests become class C – hard to justify for pregnancy tests or similar assays.
816.	(b) Devices intended for blood gases and blood glucose determinations for near-patient testing are class C. Other devices that are intended for near-patient testing shall be classified in their own right.	(b) Devices intended for blood gases and blood glucose determinations for near-patient testing are class C. Other devices that are intended for near-patient testing shall be classified in their own right.	(b) Devices intended for near-patient testing are classified in their own right.	Simpler rule, but diverges from GHTF.
817.	**2.5. Rule 5** The following devices are classified as **class A**:	**2.5. Rule 5** The following devices are classified as **class A**:	**2.5. Rule 5** The following devices are classified as **class A**:	**---**
818.	(a) reagents or other articles which possess specific characteristics, intended	(a) reagents or other articles which possess specific characteristics, intended	(a) products for general laboratory use accessories which possess no critical	Change in rule – seems to exclude culture media, general

Row	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
	by the manufacturer to make them suitable for in vitro diagnostic procedures related to a specific examination;	by the manufacturer to make them suitable for in vitro diagnostic procedures related to a specific examination;	characteristics buffer solutions, washing solutions, intended by the manufacturer to make them suitable for in vitro diagnostic procedures related to a specific examination ;	laboratory reagents are excluded by definition from the regulation thus it is a difficult to use the concept in classification.
819.	(b) instruments intended by the manufacturer specifically to be used for in vitro diagnostic procedures;	(b) instruments intended by the manufacturer specifically to be used for in vitro diagnostic procedures;	(b) instruments intended by the manufacturer specifically to be used for in vitro diagnostic procedures;	**---**
820.	(c) specimen receptacles.	(c) specimen receptacles.	(c) specimen receptacles.	**---**
821.	**2.6. Rule 6** Devices not covered by the above-mentioned classification rules are classified as **class B**.	**2.6. Rule 6** Devices not covered by the above-mentioned classification rules are classified as **class B**.	**2.6. Rule 6** Devices not covered by the above-mentioned classification rules are classified as **class B**.	**---**
822.	**2.7. Rule 7** Devices which are controls without a quantitative or qualitative assigned value are classified as **class B**.	**2.7. Rule 7** Devices which are controls without a quantitative or qualitative assigned value are classified as **class B**.	**2.7. Rule 7** Devices which are controls without a quantitative or qualitative assigned value are classified as **class B**.	**---**
823.	**ANNEX VIII** **CONFORMITY ASSESSMENT BASED ON FULL QUALITY ASSURANCE AND DESIGN EXAMINATION**	**ANNEX VIII** **CONFORMITY ASSESSMENT BASED ON FULL QUALITY ASSURANCE AND DESIGN EXAMINATION**	**ANNEX VIII** **CONFORMITY ASSESSMENT BASED ON A QUALITY MANAGEMENT SYSTEM ASSURANCE AND ASSESSMENT OF TECHNICAL DOCUMENTATION**	**Under Assessment**
824.	**Chapter I: Full Quality Assurance System**	**Chapter I: Full Quality Assurance System**	**Chapter I: Quality Management System Assurance**	
825.	1. The manufacturer shall ensure	1. The manufacturer shall ensure	1. The manufacturer shall establish,	

Row	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
	application of the quality management system approved for the design, manufacture and final inspection of the devices concerned, as specified in Section 3, and is subject to audit as laid down in Sections 3.3 and 3.4 and to the surveillance as specified in Section 4.	application of the quality management system approved for the design, manufacture and final inspection of the devices concerned, as specified in Section 3, and is subject to audit as laid down in Sections 3.3 and 3.4 and to the surveillance as specified in Section 4.	document and implement a quality management system as described in Article 8.5 of this Regulation and maintain its effectiveness through the life cycle of the devices concerned,. The manufacturer shall ensure the application of the quality management system as specified in Section 3, and is subject to audit as laid down in Sections 3.3. and 3.4. and to the surveillance as specified in Section 4.	
826.	2. The manufacturer who fulfils the obligations imposed by Section 1 shall draw up and keep an EU declaration of conformity in accordance with Article 15 and Annex III for the device model covered by the conformity assessment procedure. By issuing a declaration of conformity, the manufacturer ensures and declares that the devices concerned meet the provisions of this Regulation which apply to them.	2. The manufacturer who fulfils the obligations imposed by Section 1 shall draw up and keep an EU declaration of conformity in accordance with Article 15 and Annex III for the device model covered by the conformity assessment procedure. By issuing a declaration of conformity, the manufacturer ensures and declares that the devices concerned meet the provisions of this Regulation which apply to them.		
827.	**3. Quality management system**	**3. Quality management system**	**3. Quality management system assessment**	
828.	3.1. The manufacturer shall lodge an application for assessment of his quality management system with a notified body. The application shall include:	3.1. The manufacturer shall lodge an application for assessment of his quality management system with a notified body. The application shall include:	3.1. The manufacturer shall lodge an application for assessment of his quality management system with a notified body. The application shall include:	
829.	- the name and address of the manufacturer and any additional	- the name and address of the manufacturer and any additional	- the name and address of the registered place of business of the manufacturer	

Row	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
	manufacturing site covered by the quality management system, and, if the application is lodged by the authorised representative, his name and address as well,	manufacturing site covered by the quality management system, and, if the application is lodged by the authorised representative, his name and address as well,	and any additional manufacturing site covered by the quality management system, and, if the application is lodged by the authorised representative, his name and address of registered place of business as well,	
830.	- all the relevant information on the device or device category covered by the procedure,	- all the relevant information on the device or device category covered by the procedure,	- all the relevant information on the device or group of devices covered by the quality management system,	
831.	- a written declaration that no application has been lodged with any other notified body for the same device-related quality management system, or information about any previous application for the same device-related quality management system that has been refused by another notified body,	- a written declaration that no application has been lodged with any other notified body for the same device-related quality management system, or information about any previous application for the same device-related quality management system that has been refused by another notified body,	- a written declaration that no application has been lodged with any other notified body for the same device-related quality management system, or information about any previous application for the same device-related quality management system,	
832.			- a draft of an EU declaration of conformity in accordance with Article 15 and Annex III for the device model covered by the conformity assessment procedure,	
833.	- the documentation on the quality management system,	- the documentation on the quality management system,	- the documentation on the quality management system,	
834.	- a description of the procedures in place to fulfil the obligations imposed by the quality management system approved and the undertaking by the manufacturer to apply these procedures,	- a description of the procedures in place to fulfil the obligations imposed by the quality management system approved and the undertaking by the manufacturer to apply these procedures,	- documented procedures in place to fulfil the obligations imposed by the quality management system and required by this Regulation and the undertaking by the manufacturer to apply these procedures,	

Row	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
835.	- a description of the procedures in place to keep the approved quality management system adequate and efficacious and an undertaking by the manufacturer to apply these procedures,	- a description of the procedures in place to keep the approved quality management system adequate and efficacious and an undertaking by the manufacturer to apply these procedures,	- a description of the procedures in place to keep the quality management system adequate and efficacious and an undertaking by the manufacturer to apply these procedures,	
836.	- the documentation on the post-market surveillance plan, including, when applicable, a plan for the post-market follow-up, and the procedures put in place to ensure compliance with the obligations emanating from the provisions on vigilance set out in Articles 59 to 64,	- the documentation on the post-market surveillance plan, including, when applicable, a plan for the post-market follow-up, and the procedures put in place to ensure compliance with the obligations emanating from the provisions on vigilance set out in Articles 59 to 64,	- the documentation on the post-market surveillance plan, including, when applicable, a post-market performance follow-up plan, and the procedures put in place to ensure compliance with the obligations emanating from the provisions on vigilance set out in Articles 59 to 64,	
837.	- a description of the procedures in place to keep up to date the post-market surveillance plan, including, when applicable, a plan for the post-market follow-up, and the procedures ensuring compliance with the obligations emanating from the provisions on vigilance set out in Articles 59 to 64, as well as the undertaking by the manufacturer to apply these procedures.	- a description of the procedures in place to keep up to date the post-market surveillance plan, including, when applicable, a plan for the post-market follow-up, and the procedures ensuring compliance with the obligations emanating from the provisions on vigilance set out in Articles 59 to 64, as well as the undertaking by the manufacturer to apply these procedures.	- a description of the procedures in place to keep up to date the post-market surveillance system, including, when applicable, a plan for the post-market performance follow-up plan, and the procedures ensuring compliance with the obligations emanating from the provisions on vigilance set out in Articles 59 to 64, as well as the undertaking by the manufacturer to apply these procedures.	
838.			- documentation on the performance evaluation plan,	
839.			- a description of the procedures in place to keep up to date the performance evaluation plan taking into account the state of the art.	
840.	3.2. Application of the quality	3.2. Application of the quality	3.2. Implementation of the quality	

Row	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
	management system shall ensure that the devices conform to the provisions of this Regulation which apply to them at every stage, from design to final inspection. All the elements, requirements and provisions adopted by the manufacturer for his quality management system shall be documented in a systematic and orderly manner in the form of written policies and procedures, such as quality programmes, quality plans, quality manuals and quality records.	management system shall ensure that the devices conform to the provisions of this Regulation which apply to them at every stage, from design to final inspection. All the elements, requirements and provisions adopted by the manufacturer for his quality management system shall be documented in a systematic and orderly manner in the form of written policies and procedures, such as quality programmes, quality plans, quality manuals and quality records.	management system shall ensure the compliance with the provisions of this Regulation. All the elements, requirements and provisions adopted by the manufacturer for his quality management system shall be documented in a systematic and orderly manner in the form of a quality manual and written policies and procedures, such as quality programmes, quality plans, and quality records.	
841.	Moreover, the documentation to be submitted for the assessment of the quality management system shall include an adequate description of, in particular:	Moreover, the documentation to be submitted for the assessment of the quality management system shall include an adequate description of, in particular:	Moreover, the documentation to be submitted for the assessment of the quality management system shall include an adequate description of, in particular:	
842.	(a) the manufacturer's quality objectives;	(a) the manufacturer's quality objectives;	(a) the manufacturer's quality objectives;	No change
843.	(b) the organisation of the business and in particular:	(b) the organisation of the business and in particular:	(b) the organisation of the business and in particular:	
844.	- the organisational structures, the responsibilities of the managerial staff and their organisational authority where quality of design and manufacture of the products is concerned,	- the organisational structures, the responsibilities of the managerial staff and their organisational authority where quality of design and manufacture of the products is concerned,	- the organisational structures with clear assignment to critical procedures, the responsibilities of the managerial staff and their organisational authority,	
845.	- the methods of monitoring the efficient operation of the quality management system and in particular its ability to achieve the desired quality of design and	- the methods of monitoring the efficient operation of the quality management system and in particular its ability to achieve the desired quality of design and	- the methods of monitoring the efficient operation of the quality management system and in particular its ability to achieve the desired quality of design and	

Row	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
	of product, including control of products which fail to conform,	of product, including control of products which fail to conform,	of device, including control of devices which fail to conform,	
846.	- where the design, manufacture and/or final inspection and testing of the products, or elements thereof, is carried out by another party, the methods of monitoring the efficient operation of the quality management system and in particular the type and extent of control applied to the other party,	- where the design, manufacture and/or final inspection and testing of the products, or elements thereof, is carried out by another party, the methods of monitoring the efficient operation of the quality management system and in particular the type and extent of control applied to the other party,	- where the design, manufacture, and/or final verification and testing of the devices, the performance evaluation, or elements of any of these, is carried out by another party, the methods of monitoring the efficient operation of the quality management system and in particular the type and extent of control applied to the other party,	
847.	- where the manufacturer does not have a registered place of business in a Member State, the draft mandate for the designation of an authorised representative and a letter of intention of the authorised representative to accept the mandate;	- where the manufacturer does not have a registered place of business in a Member State, the draft mandate for the designation of an authorised representative and a letter of intention of the authorised representative to accept the mandate;	- where the manufacturer does not have a registered place of business in a Member State, the draft mandate for the designation of an authorised representative and a letter of intention of the authorised representative to accept the mandate;	No change
848.	(c) the procedures and techniques for monitoring, verifying, validating and controlling the design of the devices, including the corresponding documentation as well as the data and records arising from those procedures and techniques;	(c) the procedures and techniques for monitoring, verifying, validating and controlling the design of the devices, including the corresponding documentation as well as the data and records arising from those procedures and techniques;	(c) the procedures and techniques for monitoring, verifying, validating and controlling the design and performance evaluation of the devices, and the corresponding documentation as well as the data and records arising from those procedures and techniques; where these procedures and techniques shall specifically address:	
849.			- the strategy for regulatory compliance, including processes for identification of relevant legal requirements, qualification, classification, handling of equivalence**,**	

Row	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
			choice of and compliance with conformity assessment procedures,	
850.			- identification of applicable general safety and performance requirements and solutions to address these, under consideration of applicable CS and harmonized standards or equivalent solutions,	
851.			- the risk management according to Section I.2 of Annex I,	
852.			- the performance evaluation, according to Article 47 and Annex XII, including post-market performance follow-up planning,	
853.			- the solutions to address the applicable specific requirements regarding design and construction, including appropriate preclinical evaluation, addressing specifically section II of Annex I,	
854.			- the solutions to address the applicable specific requirements regarding the information to be supplied with the device, addressing specifically section III of Annex I,	
855.			- the device identification procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of	

Row	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
			manufacture,	
856.			- management of design or quality management system changes.	
857.	(d) the inspection and quality assurance techniques at the manufacturing stage and in particular:	(d) the inspection and quality assurance techniques at the manufacturing stage and in particular:	(d) the verification and quality assurance techniques at the manufacturing stage and in particular:	
858.	- the processes and procedures which will be used, particularly as regards sterilisation, purchasing and the relevant documents,	- the processes and procedures which will be used, particularly as regards sterilisation, purchasing and the relevant documents,	- the processes and procedures which will be used and the relevant documents,	
859.	- the product identification procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture	- the product identification and traceability procedures drawn up and kept up to date from drawings, specifications or other relevant documents at every stage of manufacture		
860.	(e) the appropriate tests and trials which will be carried out before, during and after manufacture, the frequency with which they will take place, and the test equipment used; it shall be possible to trace back the calibration of the test equipment adequately.	(e) the appropriate tests and trials which will be carried out before, during and after manufacture, the frequency with which they will take place, and the test equipment used; it shall be possible to trace back the calibration of the test equipment adequately.	(e) the appropriate tests and trials which will be carried out before, during and after manufacture, the frequency with which they will take place, and the test equipment used; it shall be possible to trace back the calibration of the test equipment adequately.	No change
861.	In addition, the manufacturer shall grant the notified body access to the technical documentation referred to in Annex II.	In addition, the manufacturer shall grant the notified body access to the technical documentation referred to in Annex II.	In addition, the manufacturer shall grant the notified body access to the technical documentation referred to in Annex II.	No change
862.	**3.3. Audit**	**3.3. Audit**	**3.3. Audit**	

Row	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
863.	(a) The notified body shall audit the quality system to determine whether it meets the requirements referred to in Section 3.2.	(a) The notified body shall audit the quality system to determine whether it meets the requirements referred to in Section 3.2.	(a) The notified body shall audit the quality management system to determine whether it meets the requirements referred to in Section 3.2.	
864.			Where the manufacturer uses a harmonised standard or a CS related to quality management system, it shall assess conformity with those standards.	
865.	Unless duly substantiated, it shall presume that quality management systems which satisfy the relevant harmonised standards or CTS conform to the requirements covered by the standards or CTS.	Unless duly substantiated, it shall presume that quality management systems which satisfy the relevant harmonised standards or CTS conform to the requirements covered by the standards or CTS.	Unless duly substantiated, it shall presume that quality management systems which satisfy the relevant harmonised standards or CS conform to the requirements covered by the standards or CS.	
866.	(b) The assessment team shall include at least one member with past experience of assessments of the technology concerned.	(b) The assessment team shall include at least one member with past experience of assessments of the technology concerned.	(b) The audit team shall include at least one member with past experience of assessments of the technology concerned in accordance with Section 4.4. of Annex VI. In circumstances where this experience is not immediately obvious or applicable the notified body must provide a documented rationale for the allocation of this auditor.	
867.	The assessment procedure shall include an audit on the manufacturer's premises and, if appropriate, on the premises of the manufacturer's suppliers and/or subcontractors to inspect the manufacturing and other relevant processes.	The assessment procedure shall include an audit on the manufacturer's premises and, if appropriate, on the premises of the manufacturer's suppliers and/or subcontractors to inspect the manufacturing and other relevant processes.	The assessment procedure shall include an audit on the manufacturer's premises and, if appropriate, on the premises of the manufacturer's suppliers and/or subcontractors to verify the manufacturing and other relevant processes.	

Row	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
868.	(c) Moreover, in the case of devices classified as class C, the audit procedure shall include an assessment, on a representative basis, of the design documentation within the technical documentation as referred to in Annex II of the device(s) concerned.	(c) Moreover, in the case of devices classified as class C, the audit procedure shall include an assessment, on a representative basis, of the design documentation within the technical documentation as referred to in Annex II of the device(s) concerned.	(c) Moreover, in the case of devices classified as class C, the quality management system assessment shall be accompanied by the assessment of the technical documentation in accordance with provisions 5.3a to 5.30e of Chapter II of this Annex, for the selected devices.	
869.	In choosing representative sample(s) the notified body shall take into account the novelty of the technology, similarities in design, technology, manufacturing and sterilisation methods, the intended purpose and the results of any previous relevant assessments that have been carried out in accordance with this Regulation.	In choosing representative sample(s) the notified body shall take into account the novelty of the technology, similarities in design, technology, manufacturing and sterilisation methods, the intended purpose and the results of any previous relevant assessments that have been carried out in accordance with this Regulation.	In choosing representative sample(s) the notified body shall take into account the guidance developed and published by the MDCG according to Article 77 and in particular the novelty of the technology, the potential impact on the patient and practice of medicine, similarities in design, technology, manufacturing methods, the intended purpose and the results of any previous relevant assessments that have been carried out in accordance with this Regulation.	
870.	The notified body shall document its rationale for the sample(s) taken	The notified body shall document its rationale for the sample(s) taken	The notified body shall document its rationale for the sample(s) taken.	
871.	(d) If the quality management system conforms to the relevant provisions of this Regulation, the notified body shall issue an EU full quality assurance certificate.	(d) If the quality management system conforms to the relevant provisions of this Regulation, the notified body shall issue an EU full quality assurance certificate.	(d) If the quality management system conforms to the relevant provisions of this Regulation, the notified body shall issue an EU quality management system certificate.	
872.	The decision shall be notified to the manufacturer.	The decision shall be notified to the manufacturer.	The decision shall be notified to the manufacturer.	

Row	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
873.	It shall contain the conclusions of the audit and a reasoned assessment.	It shall contain the conclusions of the audit and a reasoned assessment.	It shall contain the conclusions of the audit and a reasoned report.	
874.	3.4. The manufacturer shall inform the notified body which approved the quality management system of any plan for substantial changes to the quality management system or the product-range covered.	3.4. The manufacturer shall inform the notified body which approved the quality management system of any plan for substantial changes to the quality management system or the product-range covered.	3.4. The manufacturer shall inform the notified body which approved the quality management system of any plan for substantial changes to the quality management system, or the device-range covered.	
875.	The notified body shall assess the changes proposed and verify whether after these changes the quality management system still meets the requirements referred to in Section 3.2.	The notified body shall assess the changes proposed and verify whether after these changes the quality management system still meets the requirements referred to in Section 3.2.	The notified body shall assess the changes proposed, determine the need for additional audits and verify whether after these changes the quality management system still meets the requirements referred to in Section 3.2.	
876.	It shall notify the manufacturer of its decision which shall contain the conclusions of the audit and a reasoned assessment.	It shall notify the manufacturer of its decision which shall contain the conclusions of the audit and a reasoned assessment.	It shall notify the manufacturer of its decision which shall contain the conclusions of the assessment, and where applicable, conclusions of additional audits.	
877.	The approval of any substantial change to the quality management system or the product-range covered shall take the form of a supplement to the EU full quality assurance certificate.	The approval of any substantial change to the quality management system or the product-range covered shall take the form of a supplement to the EU full quality assurance certificate.	The approval of any substantial change to the quality management system or the device-range covered shall take the form of a supplement to the EU quality management system certificate.	
878.	**4. Surveillance assessment applicable to devices classified as class C and D**	**4. Surveillance assessment applicable to devices classified as class C and D**	**4. Surveillance assessment applicable to devices classified as class C and D**	
879.	4.1. The aim of surveillance is to ensure that the manufacturer duly fulfils the	4.1. The aim of surveillance is to ensure that the manufacturer duly fulfils the	4.1. The aim of surveillance is to ensure that the manufacturer duly fulfils the	

Row	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
	obligations imposed by the approved quality management system.	obligations imposed by the approved quality management system.	obligations imposed by the approved quality management system.	
880.	4.2. The manufacturer shall authorise the notified body to carry out all the necessary audits, including inspections, and supply it with all relevant information, in particular:	4.2. The manufacturer shall authorise the notified body to carry out all the necessary audits, including inspections, and supply it with all relevant information, in particular:	4.2. The manufacturer shall authorise the notified body to carry out all the necessary audits, including on-site audits, and supply it with all relevant information, in particular:	
881.	- the documentation on the quality management system,	- the documentation on the quality management system,	- the documentation on the quality management system,	
882.	- the documentation on the post-market surveillance plan, including a post-market follow-up, as well as, if applicable, any findings resulting from the application of the post-market surveillance plan, including the post-market follow-up, and of the provisions on vigilance set out in Articles 59 to 64,	- the documentation on the post-market surveillance plan, including a post-market follow-up, as well as, if applicable, any findings resulting from the application of the post-market surveillance plan, including the post-market follow-up, and of the provisions on vigilance set out in Articles 59 to 64,	- the documentation on any findings and conclusions resulting from the application of the post-market surveillance plan, including the post-market performance follow-up plan for a selection of devices and of the provisions on vigilance set out in Articles 59 to 64,	
883.	- the data stipulated in the part of the quality management system relating to design, such as the results of analyses, calculations, tests and the solutions adopted regarding the risk-management as referred to in Section 2 of Annex I,	- the data stipulated in the part of the quality management system relating to design, such as the results of analyses, calculations, tests and the solutions adopted regarding the risk-management as referred to in Section 2 of Annex I,	- the data stipulated in the part of the quality management system relating to design, such as the results of analyses, calculations, tests and the solutions adopted regarding the risk-management as referred to in Section 2 of Annex I,	
884.	- the data stipulated in the part of the quality management system relating to manufacture, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.	- the data stipulated in the part of the quality management system relating to manufacture, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.	- the data stipulated in the part of the quality management system relating to manufacture, such as inspection reports and test data, calibration data, qualification reports of the personnel concerned, etc.	

Row	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
885.	4.3. The notified body shall periodically, at least every 12 months, carry out appropriate audits and assessments to make sure that the manufacturer applies the approved quality management system and the post-market surveillance plan, and shall supply the manufacturer with an assessment report.	4.3. The notified body shall periodically, at least every 12 months, carry out appropriate audits and assessments to make sure that the manufacturer applies the approved quality management system and the post-market surveillance plan, and shall supply the manufacturer with an assessment report.	4.3. The notified body shall periodically, at least once every 12 months, carry out appropriate audits and assessments to make sure that the manufacturer applies the approved quality management system and the post-market surveillance plan.	
886.	This shall include inspections on the premises of the manufacturer and, if appropriate, of the manufacturer's suppliers and/or subcontractors.	This shall include inspections on the premises of the manufacturer and, if appropriate, of the manufacturer's suppliers and/or subcontractors.	This shall include audits on the premises of the manufacturer and, if appropriate, of the manufacturer's suppliers and/or subcontractors.	
887.	At the time of such inspections, the notified body shall, where necessary, carry out or ask for tests in order to check that the quality management system is working properly. It shall provide the manufacturer with an inspection report and, if a test has been carried out, with a test report.	At the time of such inspections, the notified body shall, where necessary, carry out or ask for tests in order to check that the quality management system is working properly. It shall provide the manufacturer with an inspection report and, if a test has been carried out, with a test report.	At the time of such on-site audits, the notified body shall, where necessary, carry out or ask for tests in order to check that the quality management system is working properly. It shall provide the manufacturer with surveillance audit report and, if a test has been carried out, with a test report.	
888.	4.4. The notified body shall randomly perform unannounced factory inspections to the manufacturer and, if appropriate, of the manufacturer's suppliers and/or subcontractors, which may be combined with the periodic surveillance assessment referred to in Section 4.3. or be performed in addition to this surveillance assessment.	4.4. The notified body shall randomly perform for each manufacturer and generic device group unannounced factory inspections at the relevant manufacturing sites and, if appropriate, of the manufacturer's suppliers and/or subcontractors.	4.4. The notified body shall randomly perform unannounced factory on-site audits to the manufacturer and, if appropriate, of the manufacturer's suppliers and/or subcontractors, which may be combined with the periodic surveillance assessment referred to in Section 4.3. or be performed in addition to this surveillance assessment.	
889.	The notified body shall establish a plan	The notified body shall establish a plan	The notified body shall establish a plan	

Row	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
	for the unannounced inspections which shall not be disclosed to the manufacturer.	for the unannounced inspections which may not be disclosed to the manufacturer.	for the unannounced on-site audits which shall not be disclosed to the manufacturer.	
890.		At the time of such inspections, the notified body shall carry out the tests or ask to carry them in order to check that the quality management system is working properly. It shall provide the manufacturer with an inspection report and with a test report. The notified body shall carry out such inspections at least once every three years.		
891.	Within the context of such unannounced inspections, the notified body shall check an adequate sample from the production or the manufacturing process to verify that the manufactured device is in conformity with the technical documentation and/or design dossier.	Within the context of such unannounced inspections, the notified body shall check an adequate sample from the production or the manufacturing process to verify that the manufactured device is in conformity with the technical documentation and/or design dossier.	Within the context of such unannounced on-site audits, the notified body shall check an adequate sample from the production or the manufacturing process to verify that the manufactured device is in conformity with the technical documentation.	
892.	Prior to the unannounced inspection, the notified body shall specify the relevant sampling criteria and testing procedure.	Prior to the unannounced inspection, the notified body shall specify the relevant sampling criteria and testing procedure.	Prior to the unannounced on-site audits, the notified body shall specify the relevant sampling criteria and testing procedure.	
893.	Instead of, or in addition to, the sampling from the production, the notified body shall take samples of devices from the market to verify that the manufactured device is in conformity with the technical documentation and/or design dossier.	Instead of, or in addition to, the sampling from the production, the notified body shall take samples of devices from the market to verify that the manufactured device is in conformity with the technical documentation and/or design dossier.	Instead of, or in addition to, the sampling from the production, the notified body shall take samples of devices from the market to verify that the manufactured device is in conformity with the technical documentation.	

Row	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
894.	Prior to the sampling, the notified body shall specify the relevant sampling criteria and testing procedure.	Prior to the sampling, the notified body shall specify the relevant sampling criteria and testing procedure.	Prior to the sampling, the notified body shall specify the relevant sampling criteria and testing procedure.	
895.	The notified body shall provide the manufacturer with an inspection report which shall include, if applicable, the result of the sample check.	The notified body shall provide the manufacturer with an inspection report which shall include, if applicable, the result of the sample check.	The notified body shall provide the manufacturer with an on-site audits report which shall include, if applicable, the result of the sample test.	
896.	4.5. In the case of devices classified as class C, the surveillance assessment shall also include the assessment of the design documentation within the technical documentation of the device(s) concerned on the basis of further representative sample(s) chosen in accordance with the rationale documented by the notified body in accordance with point (c) of Section 3.3.	4.5. In the case of devices classified as class C, the surveillance assessment shall also include the assessment of the design documentation within the technical documentation of the device(s) concerned on the basis of further representative sample(s) chosen in accordance with the rationale documented by the notified body in accordance with point (c) of Section 3.3.	4.5. In the case of devices classified as class C, the surveillance assessment shall also include an assessment of technical documentation in accordance with the provisions 5.3a to 5.3e of Chapter II of this Annex of the device(s) concerned on the basis of further representative sample(s) chosen in accordance with the rationale documented by the notified body in accordance with point (c) of Section 3.3.	
897.	4.6. The notified body shall ensure that the composition of the assessment team assures experience with the technology concerned, continuous objectivity and neutrality; this shall include a rotation of the members of the assessment team at appropriate intervals.	4.6. The notified body shall ensure that the composition of the assessment team assures experience with the technology concerned, continuous objectivity and neutrality; this shall include a rotation of the members of the assessment team at appropriate intervals.	4.6. The notified body shall ensure that the composition of the assessment team assures experience with the evaluation of the devices, systems and processes concerned, continuous objectivity and neutrality; this shall include a rotation of the members of the assessment team at appropriate intervals.	
898.	As a general rule, a lead auditor shall not lead and attend an audit for more than three consecutive years in respect to the same manufacturer.	As a general rule, a lead auditor shall not lead and attend an audit for more than three consecutive years in respect to the same manufacturer.	As a general rule, a lead auditor shall not lead and attend an audit for more than three consecutive years in respect to the same manufacturer.	

Row	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
899.	4.7. If the notified body establishes a divergence between the sample taken from the production or from the market and the specifications laid down in the technical documentation or the approved design, it shall suspend or withdraw the relevant certificate or impose restrictions on it.	4.7. If the notified body establishes a divergence between the sample taken from the production or from the market and the specifications laid down in the technical documentation or the approved design, it shall suspend or withdraw the relevant certificate or impose restrictions on it.	4.7. If the notified body establishes a divergence between the sample taken from the production or from the market and the specifications laid down in the technical documentation or the approved design, it shall suspend or withdraw the relevant certificate or impose restrictions on it.	
900.	**Chapter II: Design dossier examination**	**Chapter II: Design dossier examination**	**Chapter II: Assessment of the technical documentation**	
901.	**5. Examination of the design of the device and batch verification applicable to devices in class D**	**5. Examination of the design of the device and batch verification applicable to devices in class D**	**5. Assessment of the technical documentation of the device and batch verification applicable to devices in class D**	
902.	5.1. In addition to the obligation imposed by Section 3, the manufacturer of devices classified as class D shall lodge with the notified body referred to in Section 3.1 an application for the examination of the design dossier relating to the device which he plans to manufacture and which falls into the device category covered by the quality management system referred to in Section 3.	5.1. In addition to the obligation imposed by Section 3, the manufacturer of devices classified as class D shall lodge with the notified body referred to in Section 3.1 an application for the examination of the design dossier relating to the device which he plans to manufacture and which falls into the device category covered by the quality management system referred to in Section 3.	5.1. In addition to the obligation imposed by Section 3, the manufacturer of devices classified as class D shall lodge with the notified body referred to in Section 3.1 an application for the assessment of the technical documentation relating to the device which he plans to place on the market or put into service and is covered by the quality management system referred to in Section 3.	
903.	5.2. The application shall describe the design, manufacture and performances of the device in question. It shall include the technical documentation as referred to in Annex II;	5.2. The application shall describe the design, manufacture and performances of the device in question. It shall include the technical documentation as referred to in Annex II;	5.2. The application shall describe the design, manufacture and performances of the device in question. It shall include the technical documentation as referred to in Annex II.	

Row	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
904.	where the technical documentation is voluminous and/or held in different locations, the manufacturer shall submit a summary technical documentation (STED) and grant access to the full technical documentation upon request.	where the technical documentation is voluminous and/or held in different locations, the manufacturer shall submit a summary technical documentation (STED) and grant access to the full technical documentation upon request.		
905.	In the case of devices for self-testing or near-patient testing, the application shall also include the aspects referred to in Section 6.1, point b).	In the case of devices for self-testing or near-patient testing, the application shall also include the aspects referred to in Section 6.1, point b).	In the case of devices for self-testing or near-patient testing, the application shall also include the aspects referred to in Section 6.1, point b).	
906.	5.3. The notified body shall examine the application employing staff with proven knowledge and experience regarding the technology concerned.	5.3. The notified body shall examine the application employing staff with proven knowledge and experience regarding the technology concerned.	5.3. The notified body shall examine the application employing staff with proven knowledge and experience in the evaluation of the technology, and the devices concerned and the evaluation of clinical evidence.	
907.		The notified body shall ensure that the manufacturer's application adequately describes the design, manufacture and performance of the device, allowing assessment of whether the product conforms with the requirements set out in this Regulation.		
908.		The notified bodies shall comment on the conformity of the following: - general description of the product, - design specifications, including a description of the solutions adopted to fulfil the essential requirements, - systematic procedures used for the		

Row	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
		design process and techniques used to control, monitor and verify the design of the device.		
909.	The notified body may require the application to be completed by further tests or other evidence to allow assessment of conformity with the requirements of this Regulation.	The notified body may require the application to be completed by further tests or other evidence to allow assessment of conformity with the requirements of this Regulation.	The notified body may require the application to be completed by further tests or other evidence to allow assessment of conformity with the relevant requirements of this Regulation.	
910.	The notified body shall carry out adequate physical or laboratory tests in relation to the device or request the manufacturer to carry out such tests.	The notified body shall carry out adequate physical or laboratory tests in relation to the device or request the manufacturer to carry out such tests.	The notified body shall carry out adequate physical or laboratory tests in relation to the device or request the manufacturer to carry out such tests.	
911.			5.3a. The notified body shall in particular review the clinical evidence presented by the manufacturer in the performance evaluation report according to Annex XII 1.4.2.	
912.			The notified body shall employ device reviewers with sufficient clinical expertise, including the use of external clinical expertise with direct and current experience on the clinical application of the device in question for the purposes of this review.	
913.			5.3b. The notified body shall, in circumstances when the clinical evidence is based on data, in total or in part, from devices which are claimed to be similar or equivalent to the device under	

Row	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
			assessment, assess the suitability of this route, taking into account factors such as new indications and innovation.	
914.			The notified body shall clearly document its conclusions on the claimed equivalency, the relevance and adequacy of the data to demonstrate conformity.	
915.			5.3c. The notified body shall ensure the adequacy of the clinical evidence and the clinical evaluation and verify the conclusions drawn by the manufacturer on the conformity with the relevant general safety and performance requirements.	
916.			This review should include consideration of the adequacy of the benefit-risk assessment, instructions for use, user training, manufacturer's post-market surveillance plan, and include the need for, and adequacy of the post-market performance follow up proposed, where applicable.	
917.			5.3d. The notified body shall consider based on its assessment of the clinical evidence, the performance evaluation, and the benefit-risk assessment if specific milestones are required to be defined to allow for review by the notified body on updates to the clinical evidence based on post-market surveillance and	

Row	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
			post-market performance follow up data.	
918.			5.3e. The notified body shall clearly document the outcome of its assessment in the performance evaluation assessment report.	
919.	5.4. Before issuing an EU design-examination certificate, the notified body shall request a reference laboratory, where designated in accordance with Article 78, to verify compliance of the device with the CTS, when available, or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent.	5.4. Before issuing an EU design-examination certificate, the notified body shall request a reference laboratory, where designated in accordance with Article 78, to verify compliance of the device with the CTS, when available, or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent.	5.4. Before issuing an technical documentation assessment certificate, the notified body shall request a reference laboratory**,** where designated in accordance with Article 78, to verify whether the performance of the device is in compliance with the available CS.	
920.			The verification shall include laboratory tests by the reference laboratory according to Article 40(2).	
921.	The reference laboratory shall provide a scientific opinion within 30 days.	The reference laboratory shall provide a scientific opinion within 30 days.	The reference laboratory shall provide a scientific opinion within 60 days.	
922.	The scientific opinion of the reference laboratory and any possible updates shall be included in the documentation of the notified body concerning the device. The notified body shall give due consideration to the views expressed in the scientific opinion when making its decision.	The scientific opinion of the reference laboratory and any possible updates shall be included in the documentation of the notified body concerning the device. The notified body shall give due consideration to the views expressed in the scientific opinion when making its decision.	The scientific opinion of the reference laboratory and any possible updates shall be included in the documentation of the notified body concerning the device. The notified body shall give due consideration to the views expressed in the scientific opinion when making its decision.	
923.	The notified body shall not deliver the	The notified body shall not deliver the	The notified body shall not deliver the	

Row	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
	certificate if the scientific opinion is unfavourable.	certificate if the scientific opinion is unfavourable.	certificate if the scientific opinion is unfavourable.	
924.	5.5. The notified body shall provide the manufacturer with an EU design-examination report.	5.5. The notified body shall provide the manufacturer with an EU design-examination report.	5.5. The notified body shall provide the manufacturer with an EU technical documentation assessment report, including a performance evaluation assessment report.	
925.	If the device conforms to the relevant provisions of this Regulation, the notified body shall issue an EU design-examination certificate.	If the device conforms to the relevant provisions of this Regulation, the notified body shall issue an EU design-examination certificate.	If the device conforms to the relevant provisions of this Regulation, the notified body shall issue an EU technical documentation assessment certificate.	
926.	The certificate shall contain the conclusions of the examination, the conditions of validity, the data needed for identification of the approved design, where appropriate, a description of the intended purpose of the device.	The certificate shall contain the conclusions of the examination, the conditions of validity, the data needed for identification of the approved design, where appropriate, a description of the intended purpose of the device.	The certificate shall contain the conclusions of the assessment, the conditions of validity, the data needed for identification of the approved device, where appropriate, a description of the intended purpose of the device.	
927.	5.6. Changes to the approved design shall receive further approval from the notified body which issued the EU design-examination certificate, wherever the changes could affect conformity with the general safety and performance requirements of this Regulation or with the conditions prescribed for use of the device.	5.6. Changes to the approved design shall receive further approval from the notified body which issued the EU design-examination certificate, wherever the changes could affect conformity with the general safety and performance requirements of this Regulation or with the conditions prescribed for use of the device.	5.6. Changes to the approved device shall receive further approval from the notified body which issued the EU technical documentation assessment certificate, wherever the changes could affect the safety and performance of the device or the conditions prescribed for use of the device.	
928.	The applicant shall inform the notified body which issued the EU design-examination certificate of any planned	The applicant shall inform the notified body which issued the EU design-examination certificate of any planned	Where the applicant plans to introduce any of the above mentioned changes he shall inform the notified body which	

Row	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
	changes to the approved design.	changes to the approved design.	issued the EU technical documentation assessment certificate thereof.	
929.	The notified body shall examine the planned changes, notify the manufacturer of its decision and provide him with a supplement to the EU design-examination report.	The notified body shall examine the planned changes, notify the manufacturer of its decision and provide him with a supplement to the EU design-examination report.	The notified body shall examine the planned changes and decide whether the planned changes require a new conformity assessment in accordance with Article 40 or whether they could be addressed by means of a supplement to the EU technical documentation assessment certificate.	
930.			In the latter case, the notified body shall assess the changes, notify the manufacturer of its decision and, where the changes are approved, provide him with a supplement to the EU technical documentation assessment certificate.	
931.	Where the changes could affect compliance with the CTS or with other solutions chosen by the manufacturer which were approved through the EU design-examination certificate, the notified body shall consult the reference laboratory that was involved in the initial consultation, in order to confirm that compliance with the CTS or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent are maintained.	Where the changes could affect compliance with the CTS or with other solutions chosen by the manufacturer which were approved through the EU design-examination certificate, the notified body shall consult the reference laboratory that was involved in the initial consultation, in order to confirm that compliance with the CTS or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent are maintained.	Where the changes could affect compliance with the CS or with other solutions chosen by the manufacturer which were approved through the EU technical documentation assessment certificate, the notified body shall consult the reference laboratory that was involved in the initial consultation, in order to confirm that compliance with the CS or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent are maintained.	
932.	The reference laboratory shall provide a	The reference laboratory shall provide a	The reference laboratory shall provide a	

Row	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
	scientific opinion within 30 days.	scientific opinion within 30 days.	scientific opinion within 60 days.	
933.	The approval of any change to the approved design shall take the form of a supplement to the EU design-examination certificate.	The approval of any change to the approved design shall take the form of a supplement to the EU design-examination certificate.	The approval of any change to the approved device shall take the form of a supplement to the EU technical documentation assessment certificate.	
934.	5.7. To verify conformity of manufactured devices classified as class D, the manufacturer shall carry out tests on the manufactured devices or each batch of devices.	5.7. To verify conformity of manufactured devices classified as class D, the manufacturer shall carry out tests on the manufactured devices or each batch of devices.	5.7. To verify conformity of manufactured devices classified as class D, the manufacturer shall carry out tests on each manufactured batch of devices.	
935.	After the conclusion of the controls and tests he shall forward to the notified body without delay the relevant reports on these tests.	After the conclusion of the controls and tests he shall forward to the notified body without delay the relevant reports on these tests.	After the conclusion of the controls and tests he shall forward to the notified body without delay the relevant reports on these tests.	
936.	Furthermore, the manufacturer shall make the samples of manufactured devices or batches of devices available to the notified body in accordance with pre-agreed conditions and modalities which shall include that the notified body or the manufacturer, in regular intervals, shall send samples of the manufactured devices or batches of devices to a reference laboratory, where designated in accordance with Article 78, to carry out appropriate tests.	Furthermore, the manufacturer shall make the samples of manufactured devices or batches of devices available to the notified body in accordance with pre-agreed conditions and modalities which shall include that the notified body or the manufacturer shall send samples of the manufactured devices or batches of devices to a reference laboratory, where designated in accordance with Article 78, to carry out appropriate tests.	Furthermore, the manufacturer shall make the samples of manufactured batches of devices available to the notified body in accordance with pre-agreed conditions and modalities which shall include that the notified body or the manufacturer shall send samples of the manufactured batches of devices to a reference laboratory, where designated in accordance with Article 78, to carry out appropriate tests.	
937.	The reference laboratory shall inform the notified body about its findings.	The reference laboratory shall inform the notified body about its findings.	The reference laboratory shall inform the notified body about its findings.	

Row	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
938.	5.8. The manufacturer may place the devices on the market, unless the notified body communicates to the manufacturer within the agreed time-frame, but not later than 30 days after reception of the samples, any other decision, including in particular any condition of validity of delivered certificates.	5.8. The manufacturer may place the devices on the market, unless the notified body communicates to the manufacturer within the agreed time-frame, but not later than 30 days after reception of the samples, any other decision, including in particular any condition of validity of delivered certificates.	5.8. The manufacturer may place the devices on the market, unless the notified body communicates to the manufacturer within the agreed time-frame, but not later than 30 days after reception of the samples, any other decision, including in particular any condition of validity of delivered certificates.	
939.	**6. Examination of the design of specific types of devices**	**6. Examination of the design of specific types of devices**	**6. Assessment of the technical documentation of specific types of devices**	
940.	6.1. Examination of the design of devices for self-testing and near-patient testing classified as class A, B or C	6.1. Examination of the design of devices for self-testing classified as class A, B or C and of devices for near patient testing classified as class C	6.1. Assessment of the technical documentation of devices for self-testing and near-patient testing classified as class A, B or C	
941.	(a) The manufacturer of devices for self-testing or near-patient testing classified as class A, B and C shall lodge with the notified body referred to in Section 3.1 an application for the examination of the design.	(a) The manufacturer of devices for self-testing classified as class A, B and C and of devices for near patient testing classified as class C shall lodge with the notified body referred to in Section 3.1 an application for the examination of the design.	(a) The manufacturer of devices for self-testing or near-patient testing classified as class A, B and C shall lodge with the notified body referred to in Section 3.1 an application for the assessment of the technical documentation.	
942.	(b) The application shall enable the design of the device to be understood and shall enable conformity with the design-related requirements of this Regulation to be assessed. It shall include:	(b) The application shall enable the design of the device to be understood and shall enable conformity with the design-related requirements of this Regulation to be assessed. It shall include:	(b) The application shall enable the design of the device to be understood and shall enable conformity with the design related requirements of this Regulation to be assessed. It shall include:	
943.	- test reports, including results of studies	- test reports, including results of studies	- test reports, including results of studies	

Row	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
	carried out with intended users;	carried out with intended users;	carried out with intended users;	
944.	- where practicable, an example of the device; if required, the device shall be returned on completion of the design examination;	- where practicable, an example of the device; if required, the device shall be returned on completion of the design examination;	- where practicable, an example of the device; if required, the device shall be returned on completion of the technical documentation assessment;	
945.	- data showing the handling suitability of the device in view of its intended purpose for self-testing or near patient-testing;	- data showing the handling suitability of the device in view of its intended purpose for self-testing or near patient-testing;	- data showing the suitability of the device in view of its intended purpose for self-testing or near patient-testing;	
946.	- the information to be provided with the device on its label and its instructions for use.	- the information to be provided with the device on its label and its instructions for use.	- the information to be provided with the device on its label and its instructions for use.	
947.	The notified body may require the application to be completed by further tests or proof to allow assessment of conformity with the requirements of this Regulation.	The notified body may require the application to be completed by further tests or proof to allow assessment of conformity with the requirements of this Regulation.	The notified body may require the application to be completed by further tests or proof to allow assessment of conformity with the requirements of this Regulation.	
948.			(ba) The notified body shall verify the compliance of the devices with the relevant requirements set out in Annex I of this Regulation.	
949.	(c) The notified body shall examine the application employing staff with proven knowledge and experience regarding the technology concerned and provide the manufacturer with an EU design-examination report.	(c) The notified body shall examine the application employing staff with proven knowledge and experience regarding the technology concerned and provide the manufacturer with an EU design-examination report.	(c) The notified body shall assess the application employing staff with proven knowledge and experience regarding the technology concerned and the intended purpose of the device and provide the manufacturer with technical documentation assessment report.	

Row	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
950.	(d) If the device conforms to the relevant provisions of this Regulation, the notified body shall issue an EU design-examination certificate. The certificate shall contain the conclusions of the examination, the conditions of validity, the data needed for the identification of the approved design and, where appropriate, a description of the intended purpose of the device.	(d) If the device conforms to the relevant provisions of this Regulation, the notified body shall issue an EU design-examination certificate. The certificate shall contain the conclusions of the examination, the conditions of validity, the data needed for the identification of the approved design and, where appropriate, a description of the intended purpose of the device.	(d) If the device conforms to the relevant provisions of this Regulation, the notified body shall issue an EU technical documentation assessment certificate. The certificate shall contain the conclusions of the assessment, the conditions of validity, the data needed for the identification of the approved devices and, where appropriate, a description of the intended purpose of the device.	
951.	(e) Changes to the approved design shall receive further approval from the notified body which issued the EU design-examination certificate, wherever the changes could affect conformity with the general safety and performance requirements of this Regulation or with the conditions prescribed for use of the device	(e) Changes to the approved design shall receive further approval from the notified body which issued the EU design-examination certificate, wherever the changes could affect conformity with the general safety and performance requirements of this Regulation or with the conditions prescribed for use of the device	(e) Changes to the approved device shall receive further approval from the notified body which issued the EU technical documentation assessment certificate, wherever the changes could affect the safety and performance of the device or the conditions prescribed for use of the device.	
952.	The applicant shall inform the notified body which issued the EU design-examination certificate of any planned changes to the approved design.	The applicant shall inform the notified body which issued the EU design-examination certificate of any planned changes to the approved design.	Where the applicant plans to introduce any of above mentioned changes he shall inform the notified body which issued the EU technical documentation assessment certificate thereof.	
953.	The notified body shall examine the planned changes, notify the manufacturer of its decision and provide him with a supplement to the EU design-examination report.	The notified body shall examine the planned changes, notify the manufacturer of its decision and provide him with a supplement to the EU design-examination report.	The notified body shall assess the planned changes and decide whether the planned changes require a new conformity assessment in accordance with Article 40 or whether they could be addressed by means of a supplement to the EU technical documentation	

Row	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
			assessment certificate.	
954.	The approval of any change to the approved design shall take the form of a supplement to the EU design-examination certificate.	The approval of any change to the approved design shall take the form of a supplement to the EU design-examination certificate.	In the latter case, the notified body shall assess the changes, notify the manufacturer of its decision and, where the changes are approved, provide him with a supplement to the EU technical documentation assessment certificate.	
955.	6.2. Examination of the design of companion diagnostics	6.2. Examination of the design of companion diagnostics	6.2. Assessment of the technical documentation of companion diagnostics	
956.	(a) The manufacturer of a companion diagnostic shall lodge with the notified body referred to in Section 3.1 an application for the examination of the design.	(a) The manufacturer of a companion diagnostic shall lodge with the notified body referred to in Section 3.1 an application for the examination of the design.	(a) The manufacturer of a companion diagnostic shall lodge with the notified body referred to in Section 3.1 an application for the assessment of the technical documentation.	
957.	(b) The application shall enable the design of the device to be understood and shall enable conformity with the design-related requirements of this Regulation to be assessed, in particular, with regard to the suitability of the device in relation to the medicinal product concerned.	(b) The application shall enable the design of the device to be understood and shall enable conformity with the design-related requirements of this Regulation to be assessed, in particular, with regard to the suitability of the device in relation to the medicinal product concerned.	(b) The application shall enable the characteristics and performance(s) of the device to be understood and shall enable conformity with the design-related requirements of this Regulation to be assessed, in particular, with regard to the suitability of the device in relation to the medicinal product concerned.	
958.	(c) 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 before issuing an EU design-examination certificate and on the basis of the draft summary of safety and performance and	(c) 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 before issuing an EU design-examination certificate and on the basis of the draft summary of safety and performance and	(c) For companion diagnostic, the notified body shall consult before issuing an EU technical documentation assessment certificate and on the basis of the draft summary of safety and performance and the draft instructions for use, the medicinal product authorising authority,	

Row	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
	the draft instructions for use, one of the competent authorities designated by the Member States in accordance with Directive 2001/83/EC (hereinafter referred to as 'medicinal products competent authority') or the European Medicines Agency (hereinafter referred to as 'EMA') established by the Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, regarding the suitability of the device in relation to the medicinal product concerned. Where the medicinal product falls exclusively within the scope of the Annex of Regulation (EC) No 726/2004, the notified body shall consult the EMA.	the draft instructions for use, one of the competent authorities designated by the Member States in accordance with Directive 2001/83/EC (hereinafter referred to as 'medicinal products competent authority') or the European Medicines Agency (hereinafter referred to as 'EMA') established by the Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, regarding the suitability of the device in relation to the medicinal product concerned. Where the medicinal product falls exclusively within the scope of the Annex of Regulation (EC) No 726/2004, the notified body shall consult the EMA.	designated by the Member States in accordance with Directive 2001/83/EC (hereinafter referred to as 'medicinal products competent authority') or the European Medicines Agency (hereinafter referred to as 'EMA') established by the Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency in case of centralized authorisation procedure**,** regarding the suitability of the device in relation to the medicinal product concerned. Where the medicinal product falls exclusively within the scope of the Annex of Regulation (EC) No 726/2004, the notified body shall consult the EMA.	
959.	(d) The medicinal products competent authority or the EMA shall give its opinion, if any, within 60 days after receipt of valid documentation. This 60-day period may be extended only once for a further 60 days on scientifically valid grounds. The opinion of the medicinal products authority or of the EMA and any possible update shall be included in the documentation of the notified body concerning the device.	(d) The medicinal products competent authority or the EMA shall give its opinion, if any, within 60 days after receipt of valid documentation. This 60-day period may be extended only once for a further 60 days on scientifically valid grounds. The opinion of the medicinal products authority or of the EMA and any possible update shall be included in the documentation of the notified body concerning the device.	(d) The medicinal product authorizing authority shall give its opinion within 60 days after receipt of valid documentation. This 60-day period may be extended only once for a further 60 days on justified grounds. The opinion of this authority and any possible update shall be included in the documentation of the notified body concerning the device.	
960.	(e) The notified body shall give due consideration to the opinion, if any,	(e) The notified body shall give due consideration to the opinion, if any,	(e) The notified body shall give due consideration to the opinion expressed by	

Row	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
	expressed by the medicinal products competent authority concerned or the EMA when making its decision. It shall convey its final decision to the medicinal products competent authority concerned or to the EMA	expressed by the medicinal products competent authority concerned or the EMA on the scientific suitability of the companion diagnostic when making its decision. If the notified body deviates from that position, It shall justify its decision to the medicinal products competent authority concerned or to the EMA. If no agreement is reached, the notified body shall inform the MDCG thereof.	the medicinal product authorizing authority when making its decision. The notified body It shall convey its final decision to this authority.	
961.	The design-examination certificate shall be delivered in accordance with point (d) of Section 6.1.	The design-examination certificate shall be delivered in accordance with point (d) of Section 6.1.	The EU technical documentation assessment certificate shall be delivered in accordance with point (d) of Section 6.1.	
962.	(f) Before changes affecting the suitability of the device in relation to the medicinal product concerned are made, the manufacturer shall inform the notified body of the changes, which shall consult the medicinal products competent authority that was involved in the initial consultation or the EMA.	(f) Before changes affecting the suitability of the device in relation to the medicinal product concerned are made, the manufacturer shall inform the notified body of the changes, which shall consult the medicinal products competent authority that was involved in the initial consultation or the EMA.	(f) Before changes affecting the performance and/or the intended use and/or the suitability of the device in relation to the medicinal product concerned are made, the manufacturer shall inform the notified body of the changes. The notified body shall assess the planned changes and decide whether the planned changes require a new conformity assessment in accordance with Article 40 or whether they could be addressed by means of a supplement to the EU technical documentation assessment certificate. In the latter case the notified body shall assess changes and, shall consult the medicinal product authorizing authority	

Row	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
			that was involved in the initial consultation.	
963.	The medicinal products competent authority or the EMA shall give its opinion, if any, within 30 days after receipt of the valid documentation regarding the changes. A supplement to the EU design-examination certificate shall be issued in accordance with point (e) of Section 6.1.	The medicinal products competent authority or the EMA shall give its opinion, if any, within 30 days after receipt of the valid documentation regarding the changes. A supplement to the EU design-examination certificate shall be issued in accordance with point (e) of Section 6.1.	The medicinal product authorizing authority shall give its opinion within 30 days after receipt of the valid documentation regarding the changes. A supplement to the EU technical documentation assessment certificate shall be issued in accordance with point (e) of Section 6.1.	
964.	**Chapter III: Administrative provisions**	**Chapter III: Administrative provisions**	**Chapter III: Administrative provisions**	
965.	7. The manufacturer or his authorised representative shall, for a period ending at least five years after the last device has been placed on the market, keep at the disposal of the competent authorities:	7. The manufacturer or his authorised representative shall, for a period ending at least five years after the last device has been placed on the market, keep at the disposal of the competent authorities:	7. The manufacturer or where the manufacturer does not have a registered place of business in a Member State his authorised representative shall, for a period ending at least five years after the last device has been placed on the market, keep at the disposal of the competent authorities:	
966.	- the declaration of conformity,	- the declaration of conformity,	- the declaration of conformity,	
967.	- the documentation referred to in the fourth indent of Section 3.1 and in particular the data and records arising from the procedures referred to in point (c) of Section 3.2.,	- the documentation referred to in the fourth indent of Section 3.1 and in particular the data and records arising from the procedures referred to in point (c) of Section 3.2.,	- the documentation referred to in the fifth indent of Section 3.1. and in particular the data and records arising from the procedures referred to in point (c) of Section 3.2.,	
968.	- the changes referred to in Section 3.4,	- the changes referred to in Section 3.4,	- the changes referred to in Section 3.4.,	

Row	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
969.	- the documentation referred to in Sections 5.2 and point (b) of Section 6.1, and	- the documentation referred to in Sections 5.2 and point (b) of Section 6.1, and	- the documentation referred to in Sections 5.2. and point (b) of Section 6.1., and	
970.	- the decisions and reports from the notified body as referred to in Sections 3.3, 4.3, 4.4, 5.5, 5.6, 5.8, points (c), (d) and (e) of Section 6.1, point (e) of Section 6.2 and point (f) of Section 6.2.	- the decisions and reports from the notified body as referred to in Sections 3.3, 4.3, 4.4, 5.5, 5.6, 5.8, points (c), (d) and (e) of Section 6.1, point (e) of Section 6.2 and point (f) of Section 6.2.	- the decisions and reports from the notified body as referred to in Sections 3.3., 4.3., 4.4., 5.5., 5.6., 5.8., points (c), (d) and (e) of Section 6.1., point (e) of Section 6.2. and point (f) of Section 6.2.	
971.	8. Each Member State shall make provision that this documentation is kept at the disposal of the competent authorities for the period indicated in the first sentence of the preceding paragraph in case the manufacturer, or his authorised representative, established within its territory goes bankrupt or ceases its business activity prior to the end of this period.	8. Each Member State shall make provision that this documentation is kept at the disposal of the competent authorities for the period indicated in the first sentence of the preceding paragraph in case the manufacturer, or his authorised representative, established within its territory goes bankrupt or ceases its business activity prior to the end of this period.	8. Each Member State shall make provision that this documentation is kept at the disposal of the competent authorities for the period indicated in the first sentence of the preceding paragraph in case the manufacturer, or his authorised representative, established within its territory goes bankrupt or ceases its business activity prior to the end of this period.	
972.	**ANNEX IX** **CONFORMITY ASSESSMENT BASED ON TYPE EXAMINATION**	**ANNEX IX** **CONFORMITY ASSESSMENT BASED ON TYPE EXAMINATION**	**ANNEX IX** **CONFORMITY ASSESSMENT BASED ON TYPE EXAMINATION**	**Under Assessment**
973.	1. EU type-examination is the procedure whereby a notified body ascertains and certifies that a representative sample of the production covered fulfils the relevant provisions of this Regulation.	1. EU type-examination is the procedure whereby a notified body ascertains and certifies that a representative sample of the production covered fulfils the relevant provisions of this Regulation.	1. EU type-examination is the procedure whereby a notified body ascertains and certifies that a device, including its technical documentation and relevant life cycle processes and a corresponding representative sample of the production covered fulfils the relevant provisions of this Regulation including those covering the performance evaluation and the	

Row	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
			PMS-planning.	
974.	**1. Application**	**1. Application**	**2. Application**	
975.	The application shall include:	The application shall include:	The application shall include:	
976.	- the name and address of the manufacturer and, if the application is lodged by the authorised representative, the name and address of the authorised representative,	- the name and address of the manufacturer and, if the application is lodged by the authorised representative, the name and address of the authorised representative,	- the name and address of the registered place of business of the manufacturer and, if the application is lodged by the authorised representative, the name and address of the registered place of business of the authorised representative,	
977.	- the technical documentation referred to in Annex II needed to assess the conformity of the representative sample of the production in question, hereinafter referred to as the 'type', with the requirements of this Regulation; where the technical documentation is voluminous and/or held in different locations, the manufacturer shall submit a summary technical documentation (STED) and grant access to the full technical documentation upon request.	- the technical documentation referred to in Annex II needed to assess the conformity of the representative sample of the production in question, hereinafter referred to as the 'type', with the requirements of this Regulation; where the technical documentation is voluminous and/or held in different locations, the manufacturer shall submit a summary technical documentation (STED) and grant access to the full technical documentation upon request.	- the technical documentation referred to in Annex II suitable to assess the conformity of the representative sample of the production in question, hereinafter referred to as the 'type', with the requirements of this Regulation, including those covering the performance evaluation and the PMS-planning.	
978.	The applicant shall make a 'type' available to the notified body.	The applicant shall make a 'type' available to the notified body.	The applicant shall make a representative sample of the production in question, hereinafter referred to as 'type' available to the notified body.	
979.	The notified body may request other samples as necessary,	The notified body may request other samples as necessary,	The notified body may request other samples as necessary,	

Row	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
980.	- in the case of devices for self-testing or near-patient testing, test reports, including results of studies carried out with intended users, and data showing the handling suitability of the device in view of its intended purpose for self-testing or near patient-testing,	- in the case of devices for self-testing or near-patient testing, test reports, including results of studies carried out with intended users, and data showing the handling suitability of the device in view of its intended purpose for self-testing or near patient-testing,	- in the case of devices for self-testing or near-patient testing, test reports, including results of studies carried out with intended users, and data showing the handling suitability of the device in view of its intended purpose for self-testing or near patient-testing,	No change
981.			- where practicable, an example of the device. If required, the device shall be returned on completion of the technical documentation assessment;	
982.			- data showing the suitability of the device in view of its intended purpose for self-testing or near-patient-testing,	
983.			- the information to be provided with the device on its label and its instructions for use.	
984.	- a written declaration that no application has been lodged with any other notified body for the same type, or information about any previous application for the same type that has been refused by another notified body.	- a written declaration that no application has been lodged with any other notified body for the same type, or information about any previous application for the same type that has been refused by another notified body.	- a written declaration that no application has been lodged with any other notified body for the same type, or information about any previous application for the same type that has been refused or withdrawn by another notified body.	
985.	**3. Assessment**	**3. Assessment**	3. **Assessment**	
986.	The notified body shall:	The notified body shall:	The notified body shall:	
987.			3.1. examine the application employing	

Row	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
			staff with proven knowledge and experience in the evaluation of the technology, and the devices concerned and the evaluation of clinical evidence. The notified body may require the application to be completed by further tests or other evidence to allow assessment of conformity with the relevant requirements of this Regulation. The notified body shall carry out adequate physical or laboratory tests in relation to the device or request the manufacturer to carry out such tests.	
988.	3.1. examine and assess the technical documentation and verify that the type has been manufactured in conformity with that documentation;	3.1. examine and assess the technical documentation and verify that the type has been manufactured in conformity with that documentation;	3.1a. examine and assess the technical documentation for conformity with the requirements of this regulation applicable to the device, including assessment of the performance evaluation and the PMS-planning and verify that the type has been manufactured in conformity with that documentation;	
989.	it shall also record the items designed in conformity with the applicable specifications of the standards referred to in Article 6 or CTS, as well as the items not designed on the basis of the relevant provisions of the abovementioned standards;	it shall also record the items designed in conformity with the applicable specifications of the standards referred to in Article 6 or CTS, as well as the items not designed on the basis of the relevant provisions of the abovementioned standards;	it shall also record the items designed in conformity with the applicable specifications of the standards referred to in Article 6 or CS, as well as the items not designed on the basis of the relevant provisions of the abovementioned standards;	
990.			3.1b. The notified body shall in particular review the clinical evidence presented by the manufacturer in the performance evaluation report according to Annex XII	

Row	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
			1.4.2. The notified body shall employ device reviewers with sufficient clinical expertise, including the use of external clinical expertise with direct and current experience on the clinical application of the device in question for the purposes of this review.	
991.			3.1c. The notified shall, in circumstances when the clinical evidence is based on data, in total or in part, from devices which are claimed to be similar or equivalent to the device under assessment, assess the suitability of this route, taking into account factors such as new indications and innovation. The notified body shall clearly document its conclusions on the claimed equivalency, the relevance and adequacy of the data to demonstrate conformity.	
992.			3.1d. clearly document the outcome of its assessment in the performance evaluation assessment report as defined in Annex XII.	
993.	3.2. carry out or arrange for the appropriate assessments and the physical or laboratory tests necessary to verify whether the solutions adopted by the manufacturer meet the general safety and performance requirements of this Regulation if the standards referred to in Article 6 or CTS have not been applied; if the device is to be connected to other	3.2. carry out or arrange for the appropriate assessments and the physical or laboratory tests necessary to verify whether the solutions adopted by the manufacturer meet the general safety and performance requirements of this Regulation if the standards referred to in Article 6 or CTS have not been applied; if the device is to be connected to other	3.2. carry out or arrange for the appropriate assessments and the physical or laboratory tests necessary to verify whether the solutions adopted by the manufacturer meet the general safety and performance requirements of this Regulation if the standards referred to in Article 6 or CS have not been applied; if the device is to be connected to other	No change

Row	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
	equipment in order to operate as intended, proof shall be provided that it conforms to the general safety and performance requirements when connected to any such equipment having the characteristics specified by the manufacturer;	equipment in order to operate as intended, proof shall be provided that it conforms to the general safety and performance requirements when connected to any such equipment having the characteristics specified by the manufacturer;	equipment in order to operate as intended, proof shall be provided that it conforms to the general safety and performance requirements when connected to any such equipment having the characteristics specified by the manufacturer;	
994.	3.3. carry out or arrange for the appropriate assessments and the physical or laboratory tests necessary to verify whether, if the manufacturer has chosen to apply the relevant standards, these have actually been applied;	3.3. carry out or arrange for the appropriate assessments and the physical or laboratory tests necessary to verify whether, if the manufacturer has chosen to apply the relevant standards, these have actually been applied;	3.3. carry out or arrange for the appropriate assessments and the physical or laboratory tests necessary to verify whether, if the manufacturer has chosen to apply the relevant standards, these have actually been applied;	No change
995.	3.4. agree with the applicant on the place where the necessary assessments and tests will be carried out;	3.4. agree with the applicant on the place where the necessary assessments and tests will be carried out;	3.4. agree with the applicant on the place where the necessary assessments and tests will be carried out; and	
996.			3.4a. draw up an EU type-examination report on the results of the assessments and tests carried out under paragraphs 3.1. to 3.3., including a clinical evaluation assessment report;	
997.	3.5. in the case of devices classified as class D, request a reference laboratory, where designated in accordance with Article 78, to verify compliance of the device with the CTS or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent.	3.5. in the case of devices classified as class D, or for companion diagnostics, request a reference laboratory, where designated in accordance with Article 78, to verify compliance of the device with the CTS or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least	3.5. in the case of devices classified as class D, request a reference laboratory, where designated in accordance with Article 78, to verify compliance of the device with the CS The verification should include laboratory tests by the reference laboratory according to Article 40(2).	

Row	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
		equivalent.		
998.	The reference laboratory shall provide a scientific opinion within 30 days.	The reference laboratory shall provide a scientific opinion within 30 days.	The reference laboratory shall provide a scientific opinion within 60 days.	
999.	The scientific opinion of the reference laboratory and any possible update shall be included in the documentation of the notified body concerning the device.	The scientific opinion of the reference laboratory and any possible update shall be included in the documentation of the notified body concerning the device.	The scientific opinion of the reference laboratory and any possible update shall be included in the documentation of the notified body concerning the device.	
1000.	The notified body shall give due consideration to the views expressed in the scientific opinion when making its decision. The notified body shall not deliver the certificate if the scientific opinion is unfavourable;	The notified body shall give due consideration to the views expressed in the scientific opinion when making its decision. The notified body shall not deliver the certificate if the scientific opinion is unfavourable;	The notified body shall give due consideration to the views expressed in the scientific opinion when making its decision. The notified body shall not deliver the certificate if the scientific opinion is unfavourable;	
1001.	3.6. For companion diagnostic intended to be used to assess the patient eligibility to a treatment with a specific medicinal product, seek the opinion, on the basis of the draft summary of safety and performance and the draft instructions for use, of a one of the competent authorities designated by the Member States in accordance with Directive 2001/83/EC (hereinafter referred to as 'medicinal products competent authority') or the European Medicines Agency (hereinafter referred to as 'EMA') on the suitability of the device in relation to the medicinal product concerned.		3.6. For companion diagnostic seek the opinion, on the basis of the draft summary of safety and performance and the draft instructions for use, of a one of the competent authorities designated by the Member States in accordance with Directive 2001/83/EC (hereinafter referred to as 'medicinal products competent authority') or the European Medicines Agency (hereinafter referred to as 'EMA') on the suitability of the device in relation to the medicinal product concerned.	

Row	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
1002.	Where the medicinal product falls exclusively within the scope of the Annex of Regulation (EC) No 726/2004, the notified body shall consult the EMA. The medicinal products authority or the European Medicines Agency shall deliver its opinion, if any, within 60 days upon receipt of the valid documentation. This 60-day period may be extended only once for a further 60 days on scientifically valid grounds.		Where the medicinal product falls exclusively within the scope of the Annex of Regulation (EC) No 726/2004, the notified body shall consult the EMA. The medicinal products authority or the European Medicines Agency shall deliver its opinion, if any, within 60 days upon receipt of the valid documentation. This 60-day period may be extended only once for a further 60 days on scientifically valid grounds.	
1003.	The opinion of the medicinal products authority or of the EMA and any possible update shall be included in the documentation of the notified body concerning the device. The notified body shall give due consideration to the opinion, if any, expressed by the medicinal products competent authority concerned or the EMA when making its decision. It shall convey its final decision to the medicinal products competent authority concerned or to the EMA.		The opinion of the medicinal products authority or of the EMA and any possible update shall be included in the documentation of the notified body concerning the device. The notified body shall give due consideration to the opinion, if any, expressed by the medicinal products competent authority concerned or the EMA when making its decision. It shall convey its final decision to the medicinal products competent authority concerned or to the EMA, and	
1004.			3.7. draw up an EU type-examination report on the results of the assessments, tests and scientific opinions under paragraphs 3.1. to 3.6., including a performance evaluation report for devices classified as class C or D or Section 2, third indent.	

Row	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
1005.	**4. Certificate**	**4. Certificate**	**4. Certificate**	
1006.	If the type conforms to the provisions of this Regulation, the notified body shall issue an EU type-examination certificate.	If the type conforms to the provisions of this Regulation, the notified body shall issue an EU type-examination certificate.	If the type conforms to the provisions of this Regulation, the notified body shall issue an EU type-examination certificate.	
1007.	The certificate shall contain the name and address of the manufacturer, the conclusions of the assessment, the conditions of validity and the data needed for identification of the type approved.	The certificate shall contain the name and address of the manufacturer, the conclusions of the assessment, the conditions of validity and the data needed for identification of the type approved.	The certificate shall contain the name and address of the manufacturer, the conclusions of the assessment, the conditions of validity and the data needed for identification of the type approved. The certificate shall be drawn up in accordance with Annex XI.	
1008.	The relevant parts of the documentation shall be annexed to the certificate and a copy kept by the notified body.	The relevant parts of the documentation shall be annexed to the certificate and a copy kept by the notified body.	The relevant parts of the documentation shall be annexed to the certificate and a copy kept by the notified body.	
1009.	**5. Changes to the type**	**5. Changes to the type**	5. **Changes to the type**	
1010.	5.1. The applicant shall inform the notified body which issued the EU type-examination certificate of any planned change to the approved type.	5.1. The applicant shall inform the notified body which issued the EU type-examination certificate of any planned change to the approved type.	5.1. The applicant shall inform the notified body which issued the EU type-examination certificate of any planned change to the approved type or its intended use.	
1011.	5.2. Changes to the approved product shall receive further approval from the notified body which issued the EU type-examination certificate wherever the changes may affect conformity with the general safety and performance requirements or with the conditions prescribed for use of the product.	5.2. Changes to the approved product shall receive further approval from the notified body which issued the EU type-examination certificate wherever the changes may affect conformity with the general safety and performance requirements or with the conditions prescribed for use of the product.	5.2. Changes to the approved product including limitations of its intended purpose and use shall receive further approval from the notified body which issued the EU type-examination certificate wherever the changes may affect conformity with the general safety and performance requirements or with	

Row	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
			the conditions prescribed for use of the product.	
1012.	The notified body shall examine the planned changes, notify the manufacturer of its decision and provide him with a supplement to the EU type-examination report. The approval of any change to the approved type shall take the form of a supplement to the initial EU type-examination certificate.	The notified body shall examine the planned changes, notify the manufacturer of its decision and provide him with a supplement to the EU type-examination report. The approval of any change to the approved type shall take the form of a supplement to the initial EU type-examination certificate.	The notified body shall examine the planned changes, notify the manufacturer of its decision and provide him with a supplement to the EU type-examination report. The approval of any change to the approved type shall take the form of a supplement to the initial EU type-examination certificate.	
1013.	5.3. Where the changes could affect compliance with the CTS or with other solutions chosen by the manufacturer which were approved through the EU type-examination certificate, the notified body shall consult the reference laboratory that was involved in the initial consultation, in order to confirm that compliance with the CTS, when available, or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent are maintained.	5.3. Where the changes could affect compliance with the CTS or with other solutions chosen by the manufacturer which were approved through the EU type-examination certificate, the notified body shall consult the reference laboratory that was involved in the initial consultation, in order to confirm that compliance with the CTS, when available, or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent are maintained.	5.3. Where the changes could affect the claimed performance or compliance with the CS or with other solutions chosen by the manufacturer which were approved through the EU type-examination certificate, the notified body shall consult the reference laboratory that was involved in the initial consultation, in order to confirm that compliance with the CS, when available, or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent are maintained.	
1014.	The reference laboratory shall provide a scientific opinion within 30 days.	The reference laboratory shall provide a scientific opinion within 30 days.	The reference laboratory shall provide a scientific opinion within 60 days.	
1015.	5.4. Where the changes affect a companion diagnostic approved through the EU type-examination certificate with regard to its suitability in relation to a medicinal product, the notified body shall consult the medicinal products competent		5.4. Where the changes affect the performance or the intended use of a companion diagnostic approved through the EU type-examination certificate or its suitability in relation to a medicinal product, the notified body shall consult	

Row	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
	authority that was involved in the initial consultation or the EMA.		the medicinal products competent authority that was involved in the initial consultation or the EMA.	
1016.	The medicinal products competent authority or the EMA shall give its opinion, if any, within 30 days after receipt of the valid documentation regarding the changes. The approval of any change to the approved type shall take the form of a supplement to the initial EU type-examination certificate.		The medicinal products competent authority or the EMA shall give its opinion, if any, within 30 days after receipt of the valid documentation regarding the changes. The approval of any change to the approved type shall take the form of a supplement to the initial EU type-examination certificate.	
1017.	**6. Administrative provisions**	**6. Administrative provisions**	6. **Administrative provisions**	
1018.	The manufacturer or his authorised representative shall, for a period ending at least five years, after the last device has been placed on the market, keep at the disposal of the competent authorities:	The manufacturer or his authorised representative shall, for a period ending at least five years, after the last device has been placed on the market, keep at the disposal of the competent authorities:	The manufacturer or his authorised representative where the manufacturer does not have a registered place of business in a Member State shall, for a period ending at least five years, after the last device has been placed on the market, keep at the disposal of the competent authorities:	
1019.	- the documentation referred to in the second indent of Section 2,	- the documentation referred to in the second indent of Section 2,	- the documentation referred to in the second indent of Section 2,	
1020.	- the changes referred to in Section 5,	- the changes referred to in Section 5,	- the changes referred to in Section 5,	
1021.	- copies of EU type-examination certificates and their additions.	- copies of EU type-examination certificates and their additions.	- copies of EU type-examination certificates, scientific opinions and reports and their additions/supplements**.**	

Row	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
1022.	Section 8 of Annex VIII shall apply.	Section 8 of Annex VIII shall apply.	Section 8 of Annex VIII shall apply.	
1023.	**ANNEX X** **CONFORMITY ASSESSMENT BASED ON PRODUCTION QUALITY ASSURANCE**	**ANNEX X** **CONFORMITY ASSESSMENT BASED ON PRODUCTION QUALITY ASSURANCE**	**ANNEX X** **CONFORMITY ASSESSMENT BASED ON PRODUCTION QUALITY ASSURANCE**	**Under Assessment**
1024.	1. The manufacturer shall ensure application of the quality management system approved for the manufacture of the devices concerned and carry out the final inspection, as specified in Section 3, and is subject to the surveillance referred to in Section 4.	1. The manufacturer shall ensure application of the quality management system approved for the manufacture of the devices concerned and carry out the final inspection, as specified in Section 3, and is subject to the surveillance referred to in Section 4.	1. The manufacturer shall ensure application of the quality management system approved for the manufacture of the devices concerned and for continuous life cycle processes including risk management, performance evaluation and PMS and carry out the final inspection, as specified in Section 3, and is subject to the surveillance referred to in Section 4.	
1025.	2. The manufacturer who fulfils the obligations imposed by Section 1 shall draw up and keep an EU declaration of conformity in accordance with Article 15 and Annex III for the device model covered by the conformity assessment procedure. By issuing an EU declaration of conformity, the manufacturer ensures and declares that the devices concerned conform to the type described in the EU type-examination certificate and meet the provisions of this Regulation which apply to them.	2. The manufacturer who fulfils the obligations imposed by Section 1 shall draw up and keep an EU declaration of conformity in accordance with Article 15 and Annex III for the device model covered by the conformity assessment procedure. By issuing an EU declaration of conformity, the manufacturer ensures and declares that the devices concerned conform to the type described in the EU type-examination certificate and meet the provisions of this Regulation which apply to them.	2. The manufacturer who fulfils the obligations imposed by Section 1 shall draw up and keep an EU declaration of conformity in accordance with Article 15 and Annex III for the device model covered by the conformity assessment procedure. By issuing an EU declaration of conformity, the manufacturer ensures and declares that the devices concerned conform to the type described in the EU type-examination certificate and meet the provisions of this Regulation which apply to them.	No change
1026.	**3. Quality management system**	**3. Quality management system**	**3. Quality management system**	

Row	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
1027.	3.1 The manufacturer shall lodge an application for assessment of his quality management system with a notified body.	3.1 The manufacturer shall lodge an application for assessment of his quality management system with a notified body.	3.1. The manufacturer shall lodge an application for assessment of his quality management system with a notified body.	
1028.	The application shall include:	The application shall include:	The application shall include:	
1029.	- all elements listed in Section 3.1 of Annex VIII,	- all elements listed in Section 3.1 of Annex VIII,	- all elements listed in Section 3.1 of Annex VIII,	
1030.	- the technical documentation as referred to in Annex II for the types approved; where the technical documentation is voluminous and/or held in different locations, the manufacturer shall submit a summary technical documentation (STED) and grant access to the full technical documentation upon request;	- the technical documentation as referred to in Annex II for the types approved; where the technical documentation is voluminous and/or held in different locations, the manufacturer shall submit a summary technical documentation (STED) and grant access to the full technical documentation upon request;	- the technical documentation as referred to in Annex II for the types approved; where the technical documentation is voluminous and/or held in different locations, the manufacturer shall submit a summary technical documentation (STED) and grant access to the full technical documentation upon request;	
1031.	- a copy of the EU-type examination certificates referred to in Section 4 of Annex IX; if the EU-type examination certificates have been issued by the same notified body with which the application is lodged, a reference to the technical documentation and the certificates issued is sufficient.	- a copy of the EU-type examination certificates referred to in Section 4 of Annex IX; if the EU-type examination certificates have been issued by the same notified body with which the application is lodged, a reference to the technical documentation and the certificates issued is sufficient.	- a copy of the EU-type examination certificates referred to in Section 4 of Annex IX; if the EU-type examination certificates have been issued by the same notified body with which the application is lodged, a reference to the technical documentation and its updates and the certificates issued is necessary.	
1032.	3.2 Application of the quality management system shall ensure that the devices conform to the type described in the EU type-examination certificate and to the provisions of this Regulation which apply to them at every stage. All the elements, requirements and	3.2 Application of the quality management system shall ensure that the devices conform to the type described in the EU type-examination certificate and to the provisions of this Regulation which apply to them at every stage. All the elements, requirements and	3.2. Application of the quality management system shall ensure that the devices conform to the type described in the EU type-examination certificate and to the provisions of this Regulation which apply to them at every stage. All the elements, requirements and	

Row	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
	provisions adopted by the manufacturer for his quality management system shall be documented in a systematic and orderly manner in the form of written policies and procedures such as quality programmes, quality plans, quality manuals and quality records.	provisions adopted by the manufacturer for his quality management system shall be documented in a systematic and orderly manner in the form of written policies and procedures such as quality programmes, quality plans, quality manuals and quality records.	provisions adopted by the manufacturer for his quality management system shall be documented in a systematic and orderly manner in the form of written policies and Standard Operating Procedures (SOPs), such as quality programmes, quality plans, quality manuals and quality records.	
1033.	It shall, in particular, include an adequate description of all elements listed in points (a), (b), (d) and (e) of Section 3.2 of Annex VIII.	It shall, in particular, include an adequate description of all elements listed in points (a), (b), (d) and (e) of Section 3.2 of Annex VIII.	It shall, in particular, include an adequate description of all elements listed in points (a), (b), (d) and (e) of Section 3.2. of Annex VIII.	
1034.	3.3 The provisions of points (a) and (b) of Section 3.3 of Annex VIII, apply.	3.3 The provisions of points (a) and (b) of Section 3.3 of Annex VIII, apply.	3.3. The provisions of points (a) and (b) of Section 3.3. of Annex VIII, apply.	
1035.	If the quality system ensures that the devices conform to the type described in the in the EU type-examination certificate and conforms to the relevant provisions of this Regulation, the notified body shall issue an EU quality assurance certificate. The decision shall be notified to the manufacturer. It shall contain the conclusions of the inspection and a reasoned assessment.	If the quality system ensures that the devices conform to the type described in the in the EU type-examination certificate and conforms to the relevant provisions of this Regulation, the notified body shall issue an EU quality assurance certificate. The decision shall be notified to the manufacturer. It shall contain the conclusions of the inspection and a reasoned assessment.	If the quality management system ensures that the devices conform to the type described in the in the EU type-examination certificate and conforms to the relevant provisions of this Regulation, the notified body shall issue an EU production quality assurance certificate. The decision shall be notified to the manufacturer in an EU production quality assurance report. It shall contain the conclusions of the inspection and a reasoned assessment.	
1036.	3.4 The provisions of the Section 3.4 of Annex VIII apply.	3.4 The provisions of the Section 3.4 of Annex VIII apply.	3.4. The provisions of the Section 3.4. of Annex VIII apply.	
1037.	**4. Surveillance**	**4. Surveillance**	**4. Surveillance**	

Row	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
1038.	The provisions of Section 4.1, the first, second and fourth indents of Section 4.2, Section 4.3, Section 4.4, Section 4.6 and Section 4.7 of Annex VIII apply.	The provisions of Section 4.1, the first, second and fourth indents of Section 4.2, Section 4.3, Section 4.4, Section 4.6 and Section 4.7 of Annex VIII apply.	The provisions of Section 4.1., the first, second and fourth indents of Section 4.2., Section 4.3., Section 4.4., Section 4.6. and Section 4.7. of Annex VIII apply.	No change
1039.	**5. Verification of manufactured devices classified as class D**	**5. Verification of manufactured devices classified as class D**	**5. Verification of manufactured devices classified as class D**	
1040.	5.1. In the case of devices classified as class D, the manufacturer shall carry out tests on the manufactured devices or each batch of devices. After the conclusion of the controls and tests he shall forward to the notified body without delay the relevant reports on these tests. Furthermore, the manufacturer shall make the samples of manufactured devices or batches of devices available to the notified body in accordance with pre-agreed conditions and modalities which shall include that the notified body or the manufacturer, in regular intervals, shall send samples of the manufactured devices or batches of devices to a reference laboratory, where designated in accordance with Article 78, to carry out appropriate tests. The reference laboratory shall inform the notified body about its findings	5.1. In the case of devices classified as class D, the manufacturer shall carry out tests on the manufactured devices or each batch of devices. After the conclusion of the controls and tests he shall forward to the notified body without delay the relevant reports on these tests. Furthermore, the manufacturer shall make the samples of manufactured devices or batches of devices available to the notified body in accordance with pre-agreed conditions and modalities which shall include that the notified body or the manufacturer, shall send samples of the manufactured devices or batches of devices to a reference laboratory, where designated in accordance with Article 78, to carry out appropriate laboratory tests. The reference laboratory shall inform the notified body about its findings	5.1. In the case of devices classified as class D, the manufacturer shall carry out tests on the manufactured devices or each batch of devices. After the conclusion of the controls and tests he shall forward to the notified body without delay the relevant reports on these tests. Furthermore, the manufacturer shall make the samples of manufactured devices or batches of devices available to the notified body in accordance with pre-agreed conditions and modalities which shall include that the notified body or the manufacturer, shall send samples of the manufactured devices or batches of devices to a reference laboratory, where designated in accordance with Article 78, to carry out appropriate laboratory tests**.** The reference laboratory shall inform the notified body about its findings.	
1041.	5.2. The manufacturer may place the devices on the market, unless the notified body communicates to the manufacturer within the agreed time-frame, but not later than 30 days after reception of the	5.2. The manufacturer may place the devices on the market, unless the notified body communicates to the manufacturer within the agreed time-frame, but not later than 30 days after reception of the	5.2. The manufacturer may place the devices on the market, unless the notified body communicates to the manufacturer within the agreed time frame, but not later than 30 days after reception of the	No change

Row	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
	samples, any other decision, including in particular any condition of validity of delivered certificates.	samples, any other decision, including in particular any condition of validity of delivered certificates.	samples, any other decision, including in particular any condition of validity of delivered certificates.	
1042.	**6. Administrative provisions**	**6. Administrative provisions**	**6. Administrative provisions**	
1043.	The manufacturer or his authorised representative shall, for a period ending at least five years after the last device has been placed on the market, keep at the disposal of the competent authorities:	The manufacturer or his authorised representative shall, for a period ending at least five years after the last device has been placed on the market, keep at the disposal of the competent authorities:	The manufacturer or his authorised representative shall, for a period ending at least five years after the last device has been placed on the market, keep at the disposal of the competent authorities:	
1044.	- the declaration of conformity,	- the declaration of conformity,	- the declaration of conformity,	
1045.	- the documentation referred to in the fourth indent of Section 3.1 of Annex VIII,	- the documentation referred to in the fourth indent of Section 3.1 of Annex VIII,	- the documentation referred to in the fourth indent of Section 3.1 of Annex VIII,	
1046.	- the documentation referred to in the seventh indent of Section 3.1 of Annex VIII, including the EU type-examination certificate referred to in Annex IX,	- the documentation referred to in the seventh indent of Section 3.1 of Annex VIII, including the EU type-examination certificate referred to in Annex IX,	- the documentation referred to in the seventh indent of Section 3.1 of Annex VIII, including the EU type-examination certificate referred to in Annex IX,	
1047.	- the changes referred to in Section 3.4 of Annex VIII and	- the changes referred to in Section 3.4 of Annex VIII and	- the changes referred to in Section 3.4 of Annex VIII and	
1048.	- the decisions and reports from the notified body as referred to in Sections 3.3, 4.3 and 4.4 of Annex VIII.	- the decisions and reports from the notified body as referred to in Sections 3.3, 4.3 and 4.4 of Annex VIII.	- the decisions and reports from the notified body as referred to in Sections 3.3., 4.3. and 4.4. of Annex VIII.	
1049.	Section 8 of Annex VIII shall apply.	Section 8 of Annex VIII shall apply.	Section 8 of Annex VIII shall apply.	
1050.	**ANNEX XI MINIMUM CONTENT OF**	**ANNEX XI MINIMUM CONTENT OF**	**ANNEX XI CERTIFICATES ISSUED BY A**	**Under Assessment**

Row	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
	CERTIFICATES ISSUED BY A NOTIFIED BODY	**CERTIFICATES ISSUED BY A NOTIFIED BODY**	**NOTIFIED BODY**	
1051.			**I. General Requirements**	
1052.			1. Certificates shall be drawn up in one of the official languages of the Union.	
1053.			2. Each certificate shall refer to only one assessment conformity procedure.	
1054.			3. Certificates shall only be issued to one manufacturer (natural or legal person). The name and address of the manufacturer included in the certificate must be the same as registered in the electronic system referred to in Article 23 of this Regulation.	
1055.			4. The scope of the certificates must unambiguously describe the device(s) covered.	
1056.			(a) EU technical documentation assessment and EU type-examination certificates shall include a clear identification (name, model, type) of the device(s), the intended purpose (the same included by the manufacturer in the instructions for use and that has been assessed by the conformity assessment procedure), risk classification and the unit of use Basic UDI-DI as referred to in	

Row	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
			Article 22.	
1057.			(b) EU quality management system certificates shall include the identification of the devices or groups of devices, the risk classification and for devices classified as Class the intended purpose. 5. Irrespective of the description used in/with the certificate, the Notified Body must be able to demonstrate on request, which (individual) devices are covered by the certificate. The Notified Body must set out a system that enables the determination of the devices, including their classification, covered by the certificate.	
1058.			6. Certificates must contain, if applicable, a note that for the placing on the market of the device(s) covered by this certificate, another certificate according to this Regulation is required.	
1059.			7. EU quality management system certificates for class A devices shall include a statement that the Notified Body has audited the quality system restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions/with the conformity of the device with metrological requirements, as applicable.	
1060.			8. For tracking information, when the certificate replaces a previous one (i.e.	

Row	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
			supplemented, modified, re-issued), a note like "this certificates replaces certificate xyz from dd/mm/yyyy", with the identification of the change shall be include.	
1061.			**II. Minimum content of the certificates**	
1062.	1. Name, address and identification number of the notified body;	1. Name, address and identification number of the notified body;	1. Name, address and identification number of the notified body;	
1063.	2. name and address of the manufacturer and, if applicable, of the authorised representative;	2. name and address of the manufacturer and, if applicable, of the authorised representative;	2. name and address of the manufacturer and, if applicable, of the authorised representative;	
1064.	3. unique number identifying the certificate;	3. unique number identifying the certificate;	3. unique number identifying the certificate ;	
1065.			3a. the single registration number of the manufacturer;	
1066.	4. date of issue;	4. date of issue;	4. date of issue;	
1067.	5. date of expiry;	5. date of expiry;	5. date of expiry;	
1068.	6. data needed for the identification of the device(s) or categories of devices covered by the certificate, including the intended purpose of the device(s) and the GMDN code(s) or internationally recognised nomenclature code(s);	6. data needed for the identification of the device(s) or categories of devices covered by the certificate, including the intended purpose of the device(s) and the GMDN code(s) or internationally recognised nomenclature code(s);	6. data needed for the unambiguous identification of the device(s) or, in case of certificates covering a quality management system, groups of devices covered by the certificate.	Typo

Row	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
1069.	7. if applicable, the manufacturing facilities covered by the certificate;	7. if applicable, the manufacturing facilities covered by the certificate;		
1070.			7a. if applicable, reference to a replaced previous certificate;	
1071.	8. reference to this Regulation and the relevant Annex according to which the conformity assessment has been carried out;	8. reference to this Regulation and the relevant Annex according to which the conformity assessment has been carried out;	8. reference to this Regulation and the relevant Annex according to which the conformity assessment has been carried out;	
1072.	9. examinations and tests performed, e.g. reference to relevant standards / test reports / audit report(s);	9. examinations and tests performed, e.g. reference to relevant standards / test reports / audit report(s);	9. examinations and tests performed, e.g. reference to relevant CS, test reports / audit report(s);	
1073.	10. if applicable, reference to the relevant parts of the technical documentation or other certificates required for the placing on the market of the device(s) covered;	10. if applicable, reference to the relevant parts of the technical documentation or other certificates required for the placing on the market of the device(s) covered;	10. if applicable, reference to the technical documentation or other certificates required for the placing on the market of the device(s) covered;	
1074.	11. if applicable, information about the surveillance by the notified body;	11. if applicable, information about the surveillance by the notified body;	11. if applicable, information about the surveillance by the notified body;	
1075.	12. conclusions of the notified body's assessment, examination or inspection;	12. conclusions of the notified body's assessment, examination or inspection;	12. conclusions of the notified body's conformity assessment with regard to the relevant Annex;	
1076.	13. conditions for or limitations to the validity of the certificate;	13. conditions for or limitations to the validity of the certificate;	13. conditions for or limitations to the validity of the certificate;	
1077.	14. legally binding signature of the notified body according to the applicable national law.	14. legally binding signature of the notified body according to the applicable national law.	14. legally binding signature of the notified body according to the applicable national law.	

Row	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
1078.	**ANNEX XII** **CLINICAL EVIDENCE AND POST-MARKET FOLLOW-UP**	**ANNEX XII** **CLINICAL EVIDENCE AND POST-MARKET FOLLOW-UP**	**ANNEX XII** **CLINICAL EVIDENCE AND POST-MARKET FOLLOW-UP**	**See specific document on Clinical Evidence**
1079.	**PART A: CLINICAL EVIDENCE**	**PART A: CLINICAL EVIDENCE**	**PART A: PERFORMANCE EVALUATION AND CLINICAL PERFORMANCE STUDIES**	
1080.	The demonstration of conformity with the general safety and performance requirements set out in Annex I, under the normal conditions of use of the device, shall be based on clinical evidence. The clinical evidence includes all the information supporting the scientific validity of the analyte, the analytical performance and, where applicable, the clinical performance of the device for its intended purpose as stated by the manufacturer.	The demonstration of conformity with the general safety and performance requirements set out in Annex I, under the normal conditions of use of the device, shall be based on clinical evidence. The clinical evidence includes all the information supporting the scientific validity of the analyte, the analytical performance and, where applicable, the clinical performance of the device for its intended purpose as stated by the manufacturer.		
1081.	**1. SCIENTIFIC VALIDITY DETERMINATION AND PERFORMANCE EVALUATION**	**1. SCIENTIFIC VALIDITY DETERMINATION AND PERFORMANCE EVALUATION**	**1. PERFORMANCE EVALUATION**	
1082.			Performance evaluation of a device is a continuous process by which data are assessed and analysed to demonstrate the scientific validity, analytical performance and clinical performance of that device for its intended purpose as stated by the manufacturer.	

Row	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
1083.			To plan, continuously conduct and document a performance evaluation, the manufacturer shall establish and update a performance evaluation plan. The performance evaluation plan shall specify the characteristics and the performance of the device and the process and criteria applied to generate the necessary clinical evidence.	
1084.			The performance evaluation shall be thorough and objective, considering both favourable and unfavourable data.	
1085.	**1.1. Scientific validity determination**	**1.1. Scientific validity determination**		
1086.	1.1.1. The scientific validity refers to the association of the analyte to a clinical condition or a physiological state.	1.1.1. The scientific validity refers to the association of the analyte to a clinical condition or a physiological state.		
1087.	1.1.2. The determination of the scientific validity may not be necessary where the association of the analyte to a clinical condition or a physiological state is well known, based on available information, such as peer reviewed literature, historical data and experience.	1.1.2. The determination of the scientific validity may not be necessary where the association of the analyte to a clinical condition or a physiological state is well known, based on available information, such as peer reviewed literature, historical data and experience.		
1088.	1.1.3. For a new analyte and/or a new intended purpose, the scientific validity shall be demonstrated based on one or a combination of the following sources:	1.1.3. For a new analyte and/or a new intended purpose, the scientific validity shall be demonstrated based on one or a combination of the following sources:		
1089.	- information on devices measuring the	- information on devices measuring the		

Row	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
	same analyte with the same intended purpose that have marketing history;	same analyte with the same intended purpose that have marketing history;		
1090.	- literature;	- literature;		
1091.	- expert opinions;	- expert opinions;		
1092.	- results from proof of concept studies;	- results from proof of concept studies;		
1093.	- results from clinical performance studies.	- results from clinical performance studies.		
1094.	1.1.4. The information supporting the scientific validity of the analyte shall be summarised as part of the clinical evidence report.	1.1.4. The information supporting the scientific validity of the analyte shall be summarised as part of the clinical evidence report.		
1095.	**1.2. Performance evaluation**	**1.2. Performance evaluation**	**1.2. Performance evaluation plan**	
1096.	The performance evaluation of a device is the process by which generated data are assessed and analysed to demonstrate the analytical performance, and where applicable the clinical performance of that device for its intended purpose as stated by the manufacturer.	The performance evaluation of a device is the process by which generated data are assessed and analysed to demonstrate the analytical performance, and where applicable the clinical performance of that device for its intended purpose as stated by the manufacturer.		
1097.	Interventional performance studies and other clinical performance studies involving risks for the subjects of the studies shall only be performed once the analytical performance of the device has	Interventional performance studies and other clinical performance studies involving risks for the subjects of the studies shall only be performed once the analytical performance of the device has		

Row	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
	been established and determined to be acceptable.	been established and determined to be acceptable.		
1098.			As a general rule, the performance evaluation plan shall include at least:	
1099.			- a specification of the intended purpose of the device according to Article 2 point 2;	
1100.			- a specification of the characteristics of the device as described in Annex I chapter I.II.6 and chapter III 17.3.1. ii;	
1101.			- a specification of the analyte or marker to be determined by the device;	
1102.			- a specification of the intended use of the device;	
1103.			- identification of certified reference materials or reference measurement procedures to allow for metrological traceability;	
1104.			- a clear identification of specified target groups with clear indications, limitations and contraindications;	
1105.			- an identification of the general safety and performance requirements as described in Annex I section I and Annex I section II.6 that require support from	

Row	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
			relevant scientific validity and analytical and clinical performance data;	
1106.			- a specification of methods (2.3), including the appropriate statistical tools, used for the examination of the analytical and clinical performance of the device and of the limitations of the device and information provided by it;	
1107.			- a description of the state of the art, including an identification of existing relevant standards, CS, guidance or best practices documents;	
1108.			- an indication and specification of parameters to be used to determine the acceptability of the benefit/risk ratio for the intended purpose(s) and for the analytical and clinical performance of the device according to the state of the art in medicine;	
1109.			- for software qualified as a device, an identification and specification of reference databases and other sources of data used as the basis for its decision making;	
1110.			- an outline of the different development phases including the sequence and means of determination of the scientific validity, the analytical and clinical performance, including an indication of	

Row	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
			milestones and a description of potential acceptance criteria;	
1111.			- the post-market performance follow-up (PMPF) planning according to Part B of this Annex**,**	
1112.			Where any of the above mentioned elements are not deemed appropriate in the Performance Evaluation Plan due to the specific device characteristics a justification shall be provided in the plan.	
1113.				
1114.	**1.2.1. Analytical performance**	**1.2.1. Analytical performance**		
1115.	1.2.1.1 The analytical performance characteristics are described in point (a) of Section 6(1) of Annex I.	1.2.1.1 The analytical performance characteristics are described in point (a) of Section 6(1) of Annex I.		
1116.	1.2.1.2 As a general rule, the analytical performance shall always be demonstrated on the basis of analytical performance studies.	1.2.1.2 As a general rule, the analytical performance shall always be demonstrated on the basis of analytical performance studies.		
1117.	1.2.1.3 For novel devices, it may not be possible to demonstrate trueness since suitable higher order reference materials or a suitable comparative method may not be available. If there are no comparative methods, different approaches may be used (e.g. comparison to some other well-	1.2.1.3 For novel devices, it may not be possible to demonstrate trueness since suitable higher order reference materials or a suitable comparative method may not be available. If there are no comparative methods, different approaches may be used (e.g. comparison to some other well-		

Row	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
	documented method, comparison to the composite reference method). In the absence of such approaches, a clinical performance study comparing test performance to the current clinical standard practice would be needed.	documented method, comparison to the composite reference method). In the absence of such approaches, a clinical performance study comparing test performance to the current clinical standard practice would be needed.		
1118.	1.2.1.4 The analytical performance data shall be summarised as part of the clinical evidence report.	1.2.1.4 The analytical performance full dataset shall accompany the clinical evidence report and may be summarised as part of it.		
1119.	1.2.2. Clinical performance	1.2.4. Clinical performance		
1120.	1.2.2.1 The clinical performance characteristics are described in point (b) of Section 6(1) of Annex I.	1.2.2.1 The clinical performance characteristics are described in point (b) of Section 6(1) of Annex I.		
1121.	1.2.2.2 Clinical performance data may not be required for established and standardised devices and for devices classified as class A according to the rules set out in Annex VII.	1.2.2.2 Clinical performance data may not be required for established and standardised devices and for devices classified as class A according to the rules set out in Annex VII.		
1122.	1.2.2.3 Clinical performance of a device shall be demonstrated based on one or a combination of the following sources	1.2.2.3 Clinical performance of a device shall be demonstrated based on one or a combination of the following sources		
1123.	- clinical performance studies;	- clinical performance studies;		
1124.	- literature;	- literature;		
1125.	- experience gained by routine diagnostic	- experience gained by routine diagnostic		

Row	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
	testing.	testing.		
1126.	1.2.2.4 Clinical performance studies shall be performed unless it is duly justified to rely on other sources of clinical performance data.	1.2.2.4 Clinical performance studies shall be performed unless it is duly justified to rely on other sources of clinical performance data.		
1127.	1.2.2.5 Clinical performance data shall be summarised as part of the clinical evidence report.	1.2.2.5 Clinical performance full dataset shall accompany the clinical evidence report and may be summarised as part of it.		
1128.	1.2.2.6 When the clinical performance evaluation includes a clinical performance study, the level of detail of the clinical performance study report referred to in Section 2.3.3 of this Annex will vary based on the risk class of the device determined according to the rules set out in Annex VII:	1.2.2.6 When the clinical performance evaluation includes a clinical performance study, the level of detail of the clinical performance study report referred to in Section 2.3.3 of this Annex will vary based on the risk class of the device determined according to the rules set out in Annex VII:		
1129.	- For devices classified as class B according to the rules set out in Annex VII, the clinical performance study report may be limited to a summary of the study protocol, results and conclusion;	- For devices classified as class B according to the rules set out in Annex VII, the clinical performance study report may be limited to a summary of the study protocol, results and conclusion;		
1130.	- For devices classified as class C according to the rules set out in Annex VII, the clinical performance study report shall include the method of data analysis, the study conclusion and the relevant details of the study protocol;	- For devices classified as class C according to the rules set out in Annex VII, the clinical performance study report shall include the method of data analysis, the study conclusion and the relevant details of the study protocol and the full dataset;		

Row	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
1131.	- For devices classified as class D according to the rules set out in Annex VII, the clinical performance study report shall include the method of data analysis, the study conclusion, the relevant details of the study protocol and the individual data points.	- For devices classified as class D according to the rules set out in Annex VII, the clinical performance study report shall include the method of data analysis, the study conclusion, the relevant details of the study protocol and the full dataset.		
1132.			1.3. Demonstration of the scientific validity and the analytical and clinical performance:	
1133.			As a general methodological principle the manufacturer shall:	
1134.			- identify through systematic scientific literature review the available data relevant to the device and its intended purpose and identify any remaining unaddressed issues or gaps in the data;	
1135.			- appraise available data by evaluating their suitability for establishing the safety and performance of the device;	
1136.			- generate any new or additional data needed to address outstanding issues.	
1137.			1.3.1. Demonstration of the scientific validity	
1138.			The manufacturer shall demonstrate the scientific validity based on one or a	

Row	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
			combination of the following sources: - relevant information on the scientific validity of devices measuring the same analyte or marker; - scientific (peer-reviewed) literature; - consensus expert opinions/positions from relevant professional associations; - results from proof of concept studies; - results from clinical performance studies. The scientific validity of the analyte or marker shall be demonstrated and documented in the scientific validity report.	
1139.			1.3.2. Demonstration of the analytical performance	
1140.			The manufacturer shall demonstrate the analytical performance of the device according to all the parameters described in point (a) of Section 6(1) of Annex I, unless any omission can be justified as not applicable. As a general rule, the analytical performance shall always be demonstrated on the basis of analytical performance studies.	
1141.			For novel markers, it may not be possible to demonstrate trueness since certified reference materials or reference measurement procedures may not be available. If there are no comparative	

Row	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
			methods, different approaches may be used if demonstrated to be appropriate (e.g. comparison to some other well-documented methods, comparison to the composite reference method). In the absence of such approaches, a clinical performance study comparing performance of the novel device to the current clinical standard practice is required.	
1142.			Analytical performance shall be demonstrated and documented in the analytical performance report.	
1143.			1.3.3. Demonstration of the clinical performance	
1144.			The manufacturer shall demonstrate the clinical performance of the device according to all the parameters described in point (b) of Section 6(1) of Annex I, unless any omission be justified as not applicable.	
1145.			Demonstration of the clinical performance of a device shall be based on one or a combination of the following sources: - clinical performance studies; - scientific peer-reviewed literature; - published experience gained by routine diagnostic testing**.**	
1146.			Clinical performance studies shall be	

Row	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
			performed unless it is duly justified to rely on other sources of clinical performance data.	
1147.			Clinical performance shall be demonstrated and documented in the clinical performance report.	
1148.			1.4. Clinical evidence and performance evaluation report	
1149.			1.4.1. The manufacturer shall assess all relevant scientific validity, analytical and clinical performance data to verify the conformity of his device with the general safety and performance requirements in Annex I.	
1150.			The amount and quality of that data shall allow the manufacturer to make a qualified assessment whether the device will achieve the intended clinical benefit(s) and safety, when used as intended by the manufacturer.	
1151.			The data and conclusions drawn from this assessment shall constitute the clinical evidence for the device.	
1152.			The clinical evidence shall scientifically demonstrate that the intended clinical benefit(s) and safety will be achieved according to the state of the art in	

Row	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
			medicine.	
1153.			1.4.2. Performance evaluation report	
1154.			The clinical evidence shall be documented in a performance evaluation report. This report shall include the scientific validity report, the analytical performance report, the clinical performance report and an assessment of these reports allowing demonstration of the clinical evidence.	
1155.			The performance evaluation report shall in particular include:	
1156.			- the justification for the approach taken to gather the clinical evidence;	
1157.			- the literature search methodology and the literature search protocol and literature search report of a literature review;	
1158.			- the technology on which the device is based, the intended purpose of the device and any claims made about the device's performance or safety;	
1159.			- the nature and extent of the scientific validity and the analytical and clinical performance data that has been evaluated;	

Row	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
1160.			- the clinical evidence as the acceptable performances against the state of the art in medicine;	
1161.			- any new conclusions derived from post-market performance follow-up reports according to Part B of this Annex	
1162.			1.4.3. The clinical evidence and its assessment in the performance evaluation report shall be updated throughout the life cycle of the device concerned with data obtained from the implementation of the manufacturer's post-market performance follow-up plan in accordance with part B of this Annex**,** as part of the performance evaluation and the post- market surveillance plan referred to in Article 8(5). The Performance Evaluation Report shall be part of the technical documentation.	
1163.	**2. CLINICAL PERFORMANCE STUDIES**	**2. CLINICAL PERFORMANCE STUDIES**	**2. CLINICAL PERFORMANCE STUDIES**	
1164.	**2.1. Purpose of clinical performance studies**	**2.1. Purpose of clinical performance studies**	**2.1. Purpose of clinical performance studies**	
1165.	The purpose of clinical performance studies is to establish or confirm aspects of device performance which cannot be determined by analytical performance studies, literature and/or previous experience gained by routine diagnostic	The purpose of clinical performance studies is to establish or confirm aspects of device performance which cannot be determined by analytical performance studies, literature and/or previous experience gained by routine diagnostic	The purpose of clinical performance studies is to establish or confirm aspects of device performance which cannot be determined by analytical performance studies, literature and/or previous experience gained by routine diagnostic	No change

Row	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
	testing. This information is used to demonstrate compliance with the relevant general safety and performance requirements with respect to clinical performance. When clinical performance studies are conducted, the data obtained shall be used in the performance evaluation process and be part of the clinical evidence for the device	testing. This information is used to demonstrate compliance with the relevant general safety and performance requirements with respect to clinical performance. When clinical performance studies are conducted, the data obtained shall be used in the performance evaluation process and be part of the clinical evidence for the device	testing. This information is used to demonstrate compliance with the relevant general safety and performance requirements with respect to clinical performance. When clinical performance studies are conducted, the data obtained shall be used in the performance evaluation process and be part of the clinical evidence for the device.	
1166.	**2.2. Ethical considerations for clinical performance studies**	**2.2. Ethical considerations for clinical performance studies**	**2.2. Ethical considerations for clinical performance studies**	
1167.	Every step in the clinical performance study, from first consideration of the need and justification of the study to the publication of the results, shall be carried out in accordance with recognised ethical principles, as for example 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, Finland, in 1964 and last amended by the 59th World Medical Association General Assembly in Seoul, Korea, in 2008.	Every step in the clinical performance study, from first consideration of the need and justification of the study to the publication of the results, shall be carried out in accordance with recognised ethical principles, as for example 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, Finland, in 1964 and last amended by the 59th World Medical Association General Assembly in Seoul, Korea, in 2008.	Every step in the clinical performance study, from first consideration of the need and justification of the study to the publication of the results, shall be carried out in accordance with recognised ethical principles.	
1168.		Conformity with the above principles shall be granted after an examination by the Ethics Committee concerned.		
1169.	**2.3. Methods for clinical performance studies**	**2.3. Methods for clinical performance studies**	**2.3. Methods for clinical performance studies**	

Row	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
1170.	2.3.1. Clinical performance study design type	2.3.1. Clinical performance study design type	2.3.1. Clinical performance study design type	
1171.	Clinical performance studies shall be designed in such a way as to maximize the relevance of the data while minimising potential biases.	Clinical performance studies shall be designed in such a way as to maximize the relevance of the data while minimising potential biases.	Clinical performance studies shall be designed in such a way as to maximize the relevance of the data while minimising potential bias.	
1172.	The design of the study shall provide the data necessary to address the clinical performance of the device.	The design of the study shall provide the data necessary to address the clinical performance of the device.		
1173.	2.3.2. Clinical performance study protocol	2.3.2. Clinical performance study protocol	2.3.2. Clinical performance study plan	
1174.	Clinical performance studies shall be performed on the basis of an appropriate 'clinical performance study protocol'.	Clinical performance studies shall be performed on the basis of an appropriate 'clinical performance study protocol'.	Clinical performance studies shall be performed on the basis of a 'clinical performance study plan'.	
1175.	The clinical performance study protocol shall set out how the study is intended to be conducted.	The clinical performance study protocol shall set out how the study is intended to be conducted.	The clinical performance study plan (CPSP) shall define the rationale, objectives, design and proposed analysis, methodology, monitoring, conduct and record-keeping of the clinical performance study.	
1176.	It shall contain information about the study design	It shall contain information about the study design	It shall contain in particular the information as laid down below. If part of this information is submitted in a separate document, it shall be referenced in the CPSP.	
1177.	such as the purpose, objectives, study population, description of test method(s)	such as the purpose, objectives, study population, description of test method(s)	(a) Identification of the clinical performance study and the CPSP.	

Row	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
1178.	and interpretation of results, site training and monitoring, specimen type, specimen collection, preparation, handling and storage, inclusion and exclusion criteria, limitations, warning and precautions, data collection/management, data analysis, required materials, number of study sites and if applicable, clinical endpoints/outcomes, and requirements for patient follow-up.	and interpretation of results, site training and monitoring, specimen type, specimen collection, preparation, handling and storage, inclusion and exclusion criteria, limitations, warning and precautions, data collection/management, data analysis, required materials, number of study sites and if applicable, clinical endpoints/outcomes, and requirements for patient follow-up.	(b) Identification of the sponsor – name, address of the registered place of business and contact details of the sponsor and, if applicable, the name, address of the registered place of business and contact details of his contact person/ legal representative pursuant to Article 48 paragraph 3 established in the Union.	
1179.	In addition, the clinical performance study protocol shall identify the key factors which may impact the completeness and significance of results, such as intended participant follow-up procedures, decision algorithms, discrepancy resolution process, masking/blinding, approaches to statistical analyses, and methods for recording endpoints/outcomes and, where appropriate, communication of test results.	In addition, the clinical performance study protocol shall identify the key factors which may impact the completeness and significance of results, such as intended participant follow-up procedures, decision algorithms, discrepancy resolution process, masking/blinding, approaches to statistical analyses, and methods for recording endpoints/outcomes and, where appropriate, communication of test results.	(c) Information on investigator(s) (i.e. principal, coordinating, other; qualifications; contact details) and investigation site(s) (number, qualification(s), contact details) and, in the case of devices for self-testing, the location and number of lay persons involved. The roles, responsibilities and qualifications of the investigators shall be specified in the CPSP	
1180.			(d) The starting date and scheduled duration for the clinical performance study.	
1181.			(e) Identification and description of the device, its intended purpose, the analyte(s) or marker(s), the metrological traceability, and the manufacturer	
1182.			(f) Information about the type of specimens under investigation, .	
1183.			(g) Overall synopsis of the clinical	

Row	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
			performance study, its design type (eg observational, interventional) together with the objectives and hypotheses of the study, reference to the current state of the art in diagnosis and/or medicine	
1184.			(h) A description of the expected benefits/risks of the device and of the clinical performance study in the context of the state of the art in clinical practice, the medical procedures involved and patient management.	
1185.			(i) The instructions for use of the device or test protocol, the necessary training and experience of the user, the appropriate calibration procedures and means of control, the indication of any other devices, medical devices, medicinal product or other articles to be in- or excluded and the specifications on any comparator or comparative method used as reference,	
1186.			(j) Description of and justification for the design of the clinical performance study, its scientific robustness and validity, including the statistical design, and details of measures to be taken to minimise bias (e.g. randomisation) and management of potential confounding factors.	
1187.			(k) The analytical performance according to point a) of Section 6(1) of Annex I with	

Row	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
			justification for any omission.	
1188.			(l) Parameters of clinical performance according to point b) of Section 6(1) of Annex I to be determined, with justification for any omission; specified clinical outcomes/endpoints (primary/secondary) used with a justification and the potential implications for individual health and/or public health management decisions	
1189.			(m) Information on the performance study population: specifications of the subjects, selection criteria, size of performance study population, representativity to target population and, if applicable, information on vulnerable subjects involved (e.g. children, immuno-compromised, elderly, pregnant women);	
1190.			(n) Information on use of data out of left over specimens banks, genetic or tissue banks, patient or disease registries etc with description of reliability and representativity and statistical analysis approach; assurance of relevant method for determining the true clinical status of patient specimens.	
1191.			(o) Monitoring plan;	
1192.			(p) Data management;	

Row	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
1193.			(q) Decision algorithms;	
1194.			(r) Policy regarding any amendments (incl. those according to Article 53) to or deviations from the CPSP, with a clear prohibition of use of waivers from the CPSP	
1195.			(s) Accountability regarding the device, in particular control of access to the device, follow-up in relation to the device used in the clinical performance study and the return of unused, expired or malfunctioning devices.	
1196.			(t) Statement of compliance with the recognised ethical principles for medical research involving humans and the principles of good clinical practice in the field of clinical performance studies as well as with the applicable regulatory requirements.	
1197.			(u) Description of the informed consent process, including a copy of the patient information sheet and consent forms.	
1198.			(v) Procedures for safety recording and reporting, including definitions of recordable and reportable events, and procedures and timelines for reporting.	
1199.			(w) Criteria and procedures for suspension or early termination of the	

Row	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
			clinical performance study,	
1200.			(x) Criteria and procedures for follow up of subjects following completion of a performance study, procedures for follow up of subjects in the case of suspension or early termination, procedures for follow up of subjects who have withdrawn their consent and procedures for subjects lost to follow up. Procedures for communication of test results outside the study, including communication of test results to the performance study subjects.	
1201.			(y) Policy as regards the establishment of the clinical performance study report and publication of results in accordance with the legal requirements and the ethical principles referred to in Section 1 of Chapter I.	
1202.			(z) List of the technical and functional features of the device indicating those that are covered by the performance study.	
1203.			(aa) Bibliography.	
1204.			Where any of the above-mentioned elements are not deemed appropriate for inclusion in the CPSP due to the specific study design chosen (e.g. use of left-over samples versus interventional clinical	

Row	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
			performance studies), a justification shall be provided.	
1205.	2.3.3. Clinical performance study report	2.3.3. Clinical performance study report	2.3.3. Clinical performance study report	
1206.	A 'clinical performance study report', signed by a medical practitioner or any other authorised person responsible, shall contain documented information on the clinical performance study protocol, results and conclusions of the clinical performance study, including negative findings. The results and conclusions shall be transparent, free of bias and clinically relevant. The report shall contain sufficient information to enable it to be understood by an independent party without reference to other documents. The report shall also include as appropriate any protocol amendments or deviations, and data exclusions with the appropriate rationale.	A 'clinical performance study report', signed by a medical practitioner or any other authorised person responsible, shall contain documented information on the clinical performance study protocol, results and conclusions of the clinical performance study, including negative findings. The results and conclusions shall be transparent, free of bias and clinically relevant. The report shall contain sufficient information to enable it to be understood by an independent party without reference to other documents. The report shall also include as appropriate any protocol amendments or deviations, and data exclusions with the appropriate rationale.	A 'clinical performance study report', signed by a medical practitioner or any other authorised person responsible, shall contain documented information on the clinical performance study plan, results and conclusions of the clinical performance study, including negative findings. The results and conclusions shall be transparent, free of bias and clinically relevant. The report shall contain sufficient information to enable it to be understood by an independent party without reference to other documents. The report shall also include as appropriate any protocol amendments or deviations, and data exclusions with the appropriate rationale.	
1207.		The report shall be accompanied by the clinical evidence report as described in point 3.1 and be accessible through the electronic system referred to in Article 51.		
1208.	**3. CLINICAL EVIDENCE REPORT**	**3. CLINICAL EVIDENCE REPORT**		
1209.	3.1 The clinical evidence report shall contain the scientific validity data, the analytical performance data and, where applicable, the clinical performance data.	3.1 The clinical evidence report shall contain the scientific validity data, the analytical performance data and, where applicable, the clinical performance data.		

Row	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
	If the analytical performance data is determined to be sufficient to declare conformity with the general safety and performance requirements set out to in Annex I without the need for clinical performance data, a rationale should be documented and included in the clinical evidence report.	If the analytical performance data is determined to be sufficient to declare conformity with the general safety and performance requirements set out to in Annex I without the need for clinical performance data, a rationale should be documented and included in the clinical evidence report.		
1210.	3.2 The clinical evidence report shall in particular outline:	3.2 The clinical evidence report shall in particular outline:		
1211.	- the justification for the approach taken to gather the clinical evidence;	- the justification for the approach taken to gather the clinical evidence;		
1212.	- the technology on which the device is based, the intended purpose of the device and any claims made about the device's clinical performance or safety;	- the technology on which the device is based, the intended purpose of the device and any claims made about the device's clinical performance or safety;		
1213.	- the nature and extent of the scientific validity and the performance data that has been evaluated;	- the nature and extent of the scientific validity and the performance data that has been evaluated;		
1214.	- how the referenced information demonstrate the clinical performance and safety of the device in question;	- how the referenced information demonstrate the clinical performance and safety of the device in question;		
1215.	- the literature search methodology, if a literature review is the approach taken to gathering clinical evidence.	- the literature search methodology, if a literature review is the approach taken to gathering clinical evidence.		
1216.	3.3 The clinical evidence and its	3.3 The clinical evidence data and its		

Row	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
	documentation shall be updated throughout the life cycle of the device concerned with data obtained from the implementation of the manufacturer's post-market surveillance plan referred to in Article 8(5) which shall include a plan for the device post-market follow-up in accordance with Part B of this Annex.	documentation shall be updated throughout the life cycle of the device concerned with data obtained from the implementation of the manufacturer's post-market surveillance plan referred to in Article 8(5) which shall include a plan for the device post-market follow-up in accordance with Part B of this Annex.		
1217.		The clinical evidence data and its subsequent updates through post-market follow-up shall be accessible through the electronic systems referred to in Articles 51 and 60.		
1218.	**Part B: Post-market follow-up**	**Part B: Post-market follow-up**	**Part B: Post-market performance follow-up**	
1219.	1. Manufacturers shall put in place procedures to enable them to collect and evaluate information relating to the scientific validity, as well as the analytical and clinical performance of their devices on the basis of data obtained from post-market follow-up.	1. Manufacturers shall put in place procedures to enable them to collect and evaluate information relating to the scientific validity, as well as the analytical and clinical performance of their devices on the basis of data obtained from post-market follow-up.	Post-market performance follow-up (PMPF) is a continuous process to update the performance evaluation referred to in Article 47 and Part A of this Annex and shall be part of the manufacturer's post-market surveillance plan.	
1220.			To this end, the manufacturer shall proactively collect and evaluate performance and relevant scientific data from the use of a device which bear the CE marking, placed on the market or put into service within its intended purpose as referred to in the relevant conformity assessment procedure, with the aim of confirming the safety, performance and	

Row	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
			scientific validity throughout the expected lifetime of the device, the continued acceptability of the benefit/risk ratio and to detect emerging risks on the basis of factual evidence.	
1221.	2. Where such information becomes available to the manufacturer, an appropriate risk assessment shall be conducted and the clinical evidence report shall be amended accordingly.	2. Where such information becomes available to the manufacturer, an appropriate risk assessment shall be conducted and the clinical evidence report shall be amended accordingly.		
1222.			2a. The PMPF shall be performed pursuant to a documented method laid down in a PMPF plan.	
1223.			2a.1. The PMPF plan shall specify the methods and procedures to proactively collect and evaluate safety, performance and scientific data with the aim of	
1224.			(a) confirming the safety and performance of the device throughout its expected lifetime,	
1225.			(b) identifying previously unknown risks or limits to performance and contraindications,	
1226.			(c) identifying and analysing emergent risks on the basis of factual evidence,	
1227.			(d) assuring the continued acceptability of the clinical evidence and of the	

Row	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
			benefit/risk ratio referred to in Sections 1 and 5 of Annex I, and	
1228.			(e) identifying possible systematic misuse or off-label use of the device with a view to verify the correctness of its intended purpose.	
1229.			2a.2. The PMPF plan shall include at least:	
1230.			(a) the general methods and procedures of the PMPF to be applied, such as gathering of clinical experience gained, feedback from users, screening of scientific literature and of other sources of performance or scientific data;	
1231.			(b) the specific methods and procedures of PMPF to be applied (e.g. ring trials and other quality assurance activities, epidemiological studies, evaluation of suitable patient or disease registers, genetic data banks or post-market clinical performance studies);	
1232.			(c) a rationale for the appropriateness of the methods and procedures referred to in points (a) and (b);	
1233.			(d) a reference to the relevant parts of the performance evaluation report referred to in Section 1.5 of Part A of this Annex and to the risk management referred to in	

Row	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
			Section 2 of Annex I;	
1234.			(e) the specific objectives to be addressed by the PMPF;	
1235.			(f) an evaluation of the performance data related to equivalent or similar devices, and the current state of the art;	
1236.			(g) reference to relevant CS, standards and guidance on PMPF;	
1237.			(h) a detailed and adequately justified time schedule for PMPF activities (e.g. analysis of PMPF data and reporting) to be undertaken by the manufacturer.	
1238.	3. Where changes to devices are necessary, the conclusion of the post market follow-up shall be taken into account for the clinical evidence referred to in Part A of this Annex and for the risk assessment referred to in Section 2 of Annex I. If necessary, the clinical evidence or risk management shall be updated and/or corrective actions be implemented.	3. Where changes to devices are necessary, the conclusion of the post market follow-up shall be taken into account for the clinical evidence referred to in Part A of this Annex and for the risk assessment referred to in Section 2 of Annex I. If necessary, the clinical evidence or risk management shall be updated and/or corrective actions be implemented.	4a. The conclusions of the PMPF evaluation report shall be taken into account for the performance evaluation referred to in Article 47 and Part A of this Annex and in the risk management referred to in Section 2 of Annex I. If through the PMPF the need for preventive and/or corrective measures has been identified, the manufacturer shall implement them.	
1239.			3a. The manufacturer shall analyse the findings of the PMPF and document the results in a PMPF evaluation report that shall update the Performance Evaluation Report and be part of the technical documentation.	

Row	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
1240.	4. Any new intended purpose of a device shall be supported by an updated clinical evidence report.	4. Any new intended purpose of a device shall be supported by an updated clinical evidence report.		
1241.			5. If PMPF is not deemed appropriate for a specific device then a justification shall be provided and document within the performance evaluation report.	
1242.	<u>**ANNEX XIII**</u> **INTERVENTIONAL CLINICAL PERFORMANCE STUDIES AND OTHER CLINICAL PERFORMANCE STUDIES INVOLVING RISKS FOR THE SUBJECTS OF THE STUDIES**	<u>**ANNEX XIII**</u> **INTERVENTIONAL CLINICAL PERFORMANCE STUDIES AND OTHER CLINICAL PERFORMANCE STUDIES INVOLVING RISKS FOR THE SUBJECTS OF THE STUDIES**	<u>**ANNEX XIII**</u> **INTERVENTIONAL CLINICAL PERFORMANCE STUDIES AND OTHER CLINICAL PERFORMANCE STUDIES INVOLVING RISKS FOR THE SUBJECTS OF THE STUDIES**	**See specific documents on Clinical Evidence**
1243.	**I. Documentation regarding the application for interventional clinical performance studies and other clinical performance studies involving risks for the subjects of the studies**	**I. Documentation regarding the application for interventional clinical performance studies and other clinical performance studies involving risks for the subjects of the studies**	**I. Documentation regarding the application for interventional clinical performance studies and other performance studies involving risks for the subjects of the studies**	
1244.	For 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 of the studies the sponsor shall draw up and submit the application in accordance with Article 49 accompanied by the documentation as laid down below:	For 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 of the studies the sponsor shall draw up and submit the application in accordance with Article 49 accompanied by the documentation as laid down below:	For devices for intended to be used in the context of interventional clinical performance studies or other performance studies involving risks for the subjects of the studies the sponsor shall draw up and submit the application in accordance with Article 49 accompanied by the documentation as laid down below:	
1245.	**1. Application form**	**1. Application form**	**1. Application form**	

Row	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
1246.	The application form shall be duly filled out containing the following information:	The application form shall be duly filled out containing the following information:	The application form shall be duly filled out containing the following information:	
1247.	1.1. Name, address and contact details of the sponsor and, if applicable, name, address and contact details of his contact person established in the Union.	1.1. Name, address and contact details of the sponsor and, if applicable, name, address and contact details of his contact person established in the Union.	1.1. Name, address and contact details of the sponsor and, if applicable, name, address and contact details of his contact person or legal representative according to Article 48 paragraph 3 established in the Union.	
1248.	1.2. If different from the above, name, address and contact details of the manufacturer of the device intended for performance evaluation and, if applicable, of his authorised representative.	1.2. If different from the above, name, address and contact details of the manufacturer of the device intended for performance evaluation and, if applicable, of his authorised representative.	1.2. If different from the above, name, address and contact details of the manufacturer of the device intended for performance evaluation and, if applicable, of his authorised representative.	No change
1249.	1.3. Title of the clinical performance study.	1.3. Title of the clinical performance study.	1.3. Title of the performance study.	
1250.	1.4. Single identification number in accordance with Article 49(1).	1.4. Single identification number in accordance with Article 49(1).	1.4. Single identification number in accordance with Article 49(1).	
1251.	1.5. Status of the clinical performance study (e.g. first submission, resubmission, significant amendment).	1.5. Status of the clinical performance study (e.g. first submission, resubmission, significant amendment).	1.5. Status of the performance study (i.e. first submission, resubmission, significant amendment);	
1252.			1.5a. Details/reference to the performance study plan (e.g. including details of the design phase of the performance study).	
1253.	1.6. If resubmission with regard to same	1.6. If resubmission with regard to same	1.6. If resubmission with regard to same	

Row	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
	device, previous date(s) and reference number(s) of earlier submission(s) or in the case of significant amendment, reference to the original submission.	device, previous date(s) and reference number(s) of earlier submission(s) or in the case of significant amendment, reference to the original submission.	device, previous date(s) and reference number(s) of earlier submission(s) or in the case of significant amendment, reference to the original submission. The sponsor shall identify all of the changes from the previous submission together with a rationale for those changes, in particular, whether any changes have been made to address outcomes of previous competent authority or ethics committee reviews.	
1254.	1.7. If parallel submission for a clinical trial on a medicinal product in accordance with Regulation (EU) No [Ref. of future Regulation on clinical trials], reference to the official registration number of the clinical trial.	1.7. If parallel submission for a clinical trial on a medicinal product in accordance with Regulation (EU) No [Ref. of future Regulation on clinical trials], reference to the official registration number of the clinical trial.	1.7. If parallel submission for a clinical trial on a medicinal product in accordance with Regulation (EU) No 536/2014, reference to the official registration number of the clinical trial.	
1255.	1.8. Identification of the Member States, EFTA countries, Turkey and third countries in which the clinical performance study shall be conducted as part of a multicentre/ multinational study at the time of application.	1.8. Identification of the Member States, EFTA countries, Turkey and third countries in which the clinical performance study shall be conducted as part of a multicentre/ multinational study at the time of application.	1.8. Identification of the Member States, EFTA countries, Turkey and third countries in which the clinical performance study shall be conducted as part of a multicentre/ multinational study at the time of application.	No change
1256.	1.9. Brief description of the device for performance evaluation (e.g. name, GMDN code or internationally recognised nomenclature code, intended purpose, risk class and applicable classification rule according to Annex VII).	1.9. Brief description of the device for performance evaluation (e.g. name, GMDN code or internationally recognised nomenclature code, intended purpose, risk class and applicable classification rule according to Annex VII).	1.9. Brief description of the device for performance evaluation**,** its classification and other information necessary for the identification of the device and device type.	
1257.	1.10 Summary of the clinical performance	1.10 Summary of the clinical performance	1.10. Summary of the performance study	

Row	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
	study protocol.	study protocol.	plan.	
1258.	1.11. If applicable, information regarding a comparator.	1.11. If applicable, information regarding a comparator.	1.11. If applicable, information regarding a comparator device, its classification and other information necessary for the identification of the comparator device.	
1259.			1.11a. Evidence from the sponsor that the clinical investigator and the investigational site are capable of conducting the clinical performance study in accordance with the performance study plan.	
1260.			1.12. Details of the anticipated start date and duration of the performance study.	
1261.			1.13. Details to identify the notified body, if the sponsor is using one at the point of application for performance study.	
1262.			1.13a. Confirmation that the sponsor is aware that the competent authority may contact the ethics committee assessing the application.	
1263.			1.14. The statement referred to in Section 4.1 of this Annex .	
1264.		**1.a Incapacitated subjects and minors**		
1265.		1. Incapacitated subjects		

Row	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
1266.		In the case of incapacitated subjects who have not given, or who have not refused to give, informed consent before the onset of their incapacity, interventional clinical performance studies and other clinical performance studies involving risks for the subjects of the studies may be conducted only where, in addition to the general conditions, all of the following conditions are met:		
1267.		- the informed consent of the legal representative has been obtained; consent shall represent the subject's presumed will and may be revoked at any time, without detriment to the subject;		
1268.		- the informed consent of the legal representative has been obtained; consent shall represent the subject's presumed will and may be revoked at any time, without detriment to the subject;		
1269.		- the explicit wish of an incapacitated subject, who is capable of forming an opinion and assessing this information, to refuse participation in, or to be withdrawn from, the clinical performance study at any time without giving a reason and with no liability or prejudice whatsoever being incurred by the subject or their legal representative as result shall be followed by the investigator;		

Row	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
1270.		- no incentives or financial inducements are given except compensation for participation in the clinical performance study;		
1271.		- such research is essential to validate data obtained in a clinical performance study on persons able to give informed consent or by other research methods;		
1272.		- such research relates directly to a medical condition from which the person suffers;		
1273.		- the clinical performance study has been designed to minimise pain, discomfort, fear and any other foreseeable risks in relation to the disease and the developmental stage and both the risk threshold and the degree of distress are specially defined and constantly observed;		
1274.		- the research is necessary to promote the health of the population concerned by the clinical performance study and cannot instead be performed on capacitated subjects;		
1275.		- there are ground for expecting that participation in the clinical performance study will produce a benefit for the incapacitated subject outweighing the risks or will produce only a minimal risk;		

Row	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
1276.		- an ethics committee, with expertise regarding the relevant disease and the patient population concerned, or that has taken advice on clinical, ethical and psychosocial questions in the field of the relevant disease and patient population concerned, has endorsed the protocol;		
1277.		The test subject shall as far as possible take part in the consent procedure.		
1278.		2. Minors		
1279.		An interventional clinical performance study and other clinical performance studies involving risks for the minor may be conducted only where, in addition to the general conditions, all of the following conditions are met:		
1280.		- the written informed consent of the legal representative has been obtained, whereby consent shall represent the minor's presumed will;		
1281.		- the informed and express consent of the minor has been obtained, where the minor is able to give consent according to national law;		
1282.		- the minor has received all relevant information in a way adapted to his or her age and maturity, from a medical doctor (either the investigator or member of the		

Row	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
		study team) trained or experience in working with children, regarding the study, the risks and benefits;		
1283.		- without prejudice to second indent, the explicit wish of a minor who is capable of forming an opinion and assessing this information to refuse participation in, or to be withdrawn from, the clinical performance study at any time, is dult taken into consideration by the investigator;		
1284.		- no incentives or financial inducements are given except payment for participation in the clinical performance study;		
1285.		- such research either relates directly to a medical condition from which the minor concerned suffers or is of such a nature that it can only be carried out on minors;		
1286.		- the clinical performance study has been designed to minimise pain, discomfort, fear and any other foreseeable risk in relation to the disease and developmental stage, and both the risk threshold and the degree of distress are specially defined and constantly observed;		
1287.		- there are grounds to expect that some direct benefit for the category of patients		

Row	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
		concerned by the study may be obtained from the clinical performance study;		
1288.		- the corresponding scientific guidelines of the Agency have been followed;		
1289.		- the interests of the patient shall always prevail over those of science and society; - the clinical performance study does not replicate other studies based on the same hypothesis and age-appropriate technology is used;		
1290.		- the clinical performance study does not replicate other studies based on the same hypothesis and age-appropriate technology is used;		
1291.		The minor shall take part in the consent procedure in a manner adapted to his or her age and maturity. Minors who are able to give consent according to national law shall also give their informed and express consent to participate in the study.		
1292.		If during a clinical performance study the minor reaches the age of majority as defined in the national law of the Member State concerned, his/her express informed consent shall be obtained before the study may continue.		
1293.	**2. Investigator's Brochure**	**2. Investigator's Brochure**	**2. Investigator's Brochure**	

Row	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
1294.	The investigator's brochure (IB) shall contain the information on the device for performance evaluation that is relevant for the study and available at the time of application. It shall be clearly identified and contain in particular the following information:	The investigator's brochure (IB) shall contain the information on the device for performance evaluation that is relevant for the study and available at the time of application. It shall be clearly identified and contain in particular the following information:	The investigator's brochure (IB) shall contain the information on the device for performance evaluation that is relevant for the study and available at the time of application. Any updates to the brochure or other relevant information that is newly available shall be brought to the attention of the investigators in a timely manner. It The IB shall be clearly identified and contain in particular the following information:	
1295.	2.1. Identification and description of the device, including information on the intended purpose, the risk classification and applicable classification rule according to Annex VII, design and manufacturing of the device and reference to previous and similar generations of the device.	2.1. Identification and description of the device, including information on the intended purpose, the risk classification and applicable classification rule according to Annex VII, design and manufacturing of the device and reference to previous and similar generations of the device.	2.1. Identification and description of the device, including information on the intended purpose, the risk classification and applicable classification rule according to Annex VII, design and manufacturing of the device and reference to previous and similar generations of the device.	No change
1296.	2.2. Manufacturer's instructions for installation, and use, including storage and handling requirements, as well as the label and instructions for use to the extent that this information is available.	2.2. Manufacturer's instructions for installation, and use, including storage and handling requirements, as well as the label and instructions for use to the extent that this information is available.	2.2. Manufacturer's instructions for installation, maintenance, maintaining hygiene standards and use, including storage and handling requirements, as well as the label and instructions for use to the extent that this information is available. In addition, information relating to any relevant training required.	
1297.	2.3. Pre-clinical testing and experimental data.	2.3. Pre-clinical testing and experimental data.	2.3. Analytical performance	

Row	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
1298.	2.4. Existing clinical data, in particular the following:	2.4. Existing clinical data, in particular the following:	2.4. Existing clinical data, in particular the following:	
1299.	- relevant scientific literature available relating to the safety, performance, design characteristics and intended purpose of the device and/or of equivalent or similar devices;	- relevant scientific literature available relating to the safety, performance, design characteristics and intended purpose of the device and/or of equivalent or similar devices;	- relevant peer reviewed scientific literature and consensus expert opinions/positions from relevant professional associations available relating to the safety, performance, clinical benefits to patients design characteristics, scientific validity, clinical performance and intended purpose of the device and/or of equivalent or similar devices;	
1300.	- other relevant clinical data available relating to the safety, performance, design characteristics and intended purpose of equivalent or similar devices of the same manufacturer, including length of time on the market and a review of performance and safety related issues and any corrective actions taken.	- other relevant clinical data available relating to the safety, performance, design characteristics and intended purpose of equivalent or similar devices of the same manufacturer, including length of time on the market and a review of performance and safety related issues and any corrective actions taken.	- other relevant clinical data available relating to the safety, scientific validity, clinical performance, clinical benefits to patients design characteristics and intended purpose of similar devices including details of their similarities and differences.	
1301.	2.5. Summary of the risk/benefit analysis and the risk management, including information regarding known or foreseeable risks and warnings.	2.5. Summary of the risk/benefit analysis and the risk management, including information regarding known or foreseeable risks and warnings.	2.5. Summary of the risk/benefit analysis and the risk management, including information regarding known or foreseeable risks and warnings.	No change
1302.	2.6. In the case of devices that include tissues, cells and substances of human, animal or microbial origins detailed information on the tissues, cells and substances, and on the compliance with the relevant general safety and	2.6. In the case of devices that include tissues, cells and substances of human, animal or microbial origins detailed information on the tissues, cells and substances, and on the compliance with the relevant general safety and	2.6. In the case of devices that include tissues, cells and substances of human, animal or microbial origins detailed information on the tissues, cells and substances, and on the compliance with the relevant general safety and	No change

Row	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
	performance requirements and the specific risk management in relation to the tissues, cells and substances.	performance requirements and the specific risk management in relation to the tissues, cells and substances.	performance requirements and the specific risk management in relation to the tissues, cells and substances.	
1303.	2.7. Reference to harmonised or other internationally recognised standards complied with in full or in part.	2.7. Reference to harmonised or other internationally recognised standards complied with in full or in part.	2.7. Reference to harmonised or other internationally recognised standards complied with in full or in part.	
1304.			A list detailing how the relevant general safety and performance requirements set out in Annex I are fulfilled, including the standards and Common Specifications applied, in full or in part, as well as a description of the solutions for fulfilling the relevant general safety and performance requirements, in so far as these standards and CS have not or only been partly fulfilled or are lacking.	
1305.			2.7a. A detailed description of the clinical procedures and diagnostic tests used in the course of the performance study and in particular information on any deviation from normal clinical practice.	
1306.	2.8. A clause that any updates to the IB or any other relevant information that is newly available shall be brought to the attention of the investigators.	2.8. A clause that any updates to the IB or any other relevant information that is newly available shall be brought to the attention of the investigators.		
1307.	**3. Clinical performance study protocol**, as referred to in Section 2.3.2 of Annex XII.	**3. Clinical performance study protocol**, as referred to in Section 2.3.2 of Annex XII.	**3. Clinical performance study plan**' as referred to in Section 2.3.2. of Annex XII.	

Row	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
1308.	**4. Other information**	**4. Other information**	**4. Other information**	
1309.	4.1. A signed statement by the natural or legal person responsible for the manufacture of the device for performance evaluation that the device in question conforms to the general safety and performance requirements apart from the aspects covered by the clinical performance study and that, with regard to these aspects, every precaution has been taken to protect the health and safety of the subject. This statement may be supported by an attestation issued by a notified body.	4.1. A signed statement by the natural or legal person responsible for the manufacture of the device for performance evaluation that the device in question conforms to the general safety and performance requirements apart from the aspects covered by the clinical performance study and that, with regard to these aspects, every precaution has been taken to protect the health and safety of the subject. This statement may be supported by an attestation issued by a notified body.	4.1. A signed statement by the natural or legal person responsible for the manufacture of the device for performance evaluation that the device in question conforms to the general safety and performance requirements apart from the aspects covered by the clinical performance study and that, with regard to these aspects, every precaution has been taken to protect the health and safety of the subject.	
1310.	4.2. Where applicable according to national law, a copy of the opinion(s) of the ethics committee(s) concerned as soon as available.	4.2. Where applicable according to national law, a copy of the opinion(s) of the ethics committee(s) concerned as soon as available.	4.2. Where applicable according to national law, a copy of the opinion(s) of the ethics committee(s) concerned. When according to national law the opinion(s) of the ethics committee(s) is not required at the time of the submission of the notification, copy of the opinion(s) of ethics committee(s) shall be submitted as soon as available.	
1311.	4.3. Proof of insurance cover or indemnification of subjects in case of injury, according to the national law	4.3. Proof of insurance cover or indemnification of subjects in case of injury, according to the national law	4.3. Proof of insurance cover or indemnification of subjects in case of injury, according to Article 48c and the corresponding national legislation.	
1312.	4.4. Documents and procedures to be used to obtain informed consent.	4.4. Documents and procedures to be used to obtain informed consent.	4.4. Documents to be used to obtain informed consent, including the patient information sheet and the informed	

Row	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
			consent document.	
1313.	4.5 Description of the arrangements to comply with the applicable rules on the protection and confidentiality of personal data, in particular:	4.5 Description of the arrangements to comply with the applicable rules on the protection and confidentiality of personal data, in particular:	4.5 Description of the arrangements to comply with the applicable rules on the protection and confidentiality of personal data, in particular:	No change
1314.	- organisational and technical arrangements that will be implemented to avoid unauthorised access, disclosure, dissemination, alteration or loss of information and personal data processed;	- organisational and technical arrangements that will be implemented to avoid unauthorised access, disclosure, dissemination, alteration or loss of information and personal data processed;	- organisational and technical arrangements that will be implemented to avoid unauthorised access, disclosure, dissemination, alteration or loss of information and personal data processed;	No change
1315.	- a description of measures that will be implemented to ensure confidentiality of records and personal data of subjects concerned in clinical performance studies;	- a description of measures that will be implemented to ensure confidentiality of records and personal data of subjects concerned in clinical performance studies;	- a description of measures that will be implemented to ensure confidentiality of records and personal data of subjects concerned in clinical performance studies;	No change
1316.	- a description of measures that will be implemented in case of data security breach in order to mitigate the possible adverse effects.	- a description of measures that will be implemented in case of data security breach in order to mitigate the possible adverse effects.	- a description of measures that will be implemented in case of data security breach in order to mitigate the possible adverse effects.	No change
1317.			4.6. Full details of the available technical documentation, for example detailed risk analysis/management documentation or specific test reports shall be submitted to the competent authority reviewing an application upon request.	
1318.		**Ia.**		

Row	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
1319.		1. Incapacitated subjects		
1320.		In the case of incapacitated subjects who have not given, or who have not refused to give, informed consent before the onset of performance studies and other clinical performance studies involving risks for the subjects of the studies may be conducted only where, in addition to the general conditions, all of the following conditions are met:		
1321.		– the informed consent of the legal representative has been obtained; consent shall represent the subject's presumed will and may be revoked at any time, without detriment to the subject;		
1322.		– the incapacitated subject has received adequate information in relation to his or her capacity for understanding regarding the study and its risks and benefits from the investigator or his/her representative, in accordance with the national law of the Member State concerned;		
1323.		– the explicit wish of an incapacitated subject who is capable of forming an opinion and assessing this information to refuse participation in, or to be withdrawn from, the clinical performance study at any time without giving a reason and with no liability or prejudice whatsoever being incurred by the subject or their legal		

Row	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
		representative as a result shall be followed by the investigator;		
1324.		– no incentives or financial inducements are given except compensation for participation in the clinical performance study;		
1325.		– such research is essential to validate data obtained in a clinical performance study on persons able to give informed consent or by other research methods;		
1326.		– such research relates directly to medical condition from which the person concerned suffers;		
1327.		– such research relates directly to medical condition from which the person concerned suffers;		
1328.		- the research is necessary to promote the health of the population concerned by the clinical performance study and cannot instead be performed on capacitated subject;		
1329.		– there are grounds for expecting that participation in the clinical performance study will produce a benefit to the incapacitated subject outweighing the risks or will produce only a minimal risk;		

Row	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
1330.		– an ethics committee, with expertise regarding the relevant disease and the patient population concerned, or that has taken advice on clinical, ethical and psychosocial questions in the field of the relevant disease and patient population concerned, has endorsed the protocol;		
1331.		The test subject shall as far as possible take part in the consent procedure.		
1332.		2. Minors		
1333.		An interventional clinical performance study and other clinical performance studies involving risks for the minor may be conducted only where, in addition to the general conditions, all of the following conditions are met:		
1334.		– the written informed consent of the legal representative or representatives has been obtained, whereby consent shall represent the minor's presumed will;		
1335.		- the informed and express consent of the minor has been obtained, where they are able to give consent according to national law,		
1336.		– the minor has received all relevant information in a way adapted to his or her age and maturity, from a medical doctor (either the investigator or member of the		

Row	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
		study team) trained or experienced in working with children, regarding the study, the risks and the benefits;		
1337.		– without prejudice to second indent, the explicit wish of a minor who is capable of forming an opinion and assessing this information to refuse participation in, or to be withdrawn from, the clinical performance study at any time, is duly taken into consideration by the investigator;		
1338.		– no incentives or financial inducements are given except compensation for participation in the clinical performance study		
1339.		– such research either relates directly to a medical condition from which the minor concerned suffers or is of such a nature that it can only be carried out on minors;		
1340.		– the clinical performance study has been designed to minimise pain, discomfort, fear and any other foreseeable risk in relation to the disease and developmental stage, and both the risk threshold and the degree of distress are specially defined and constantly observed;		
1341.		– there are grounds to expect that some direct benefit for the category of patients		

Row	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
		concerned by the study may be obtained from the clinical performance study;		
1342.		– the corresponding scientific guidelines of the Agency have been followed;		
1343.		- the interest of the patient shall always prevail over those of science and society;		
1344.		- the clinical performance study does not replicate other studies based on the same hypothesis and age-appropriate technology are used;		
1345.		– an ethics committee, with paediatric expertise or after taking advice in clinical, ethical and psychosocial problems in the field of paediatrics, has endorsed the protocol.		
1346.		The minor shall take part in the consent procedure in a manner adapted to his or her age and maturity. Minors who are able to give consent according to national law shall also give their informed and express consent to participate in the study.		
1347.		The minor shall take part in the consent procedure in a manner adapted to his or her age and maturity. Minors who are able to give consent according to national law shall also give their informed and express consent to participate in the		

Row	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
		study.		
1348.	**II. Other sponsor's obligations**	**II. Other sponsor's obligations**	**II. Other sponsor's obligations**	
1349.	1. The sponsor shall undertake to keep available for the competent national authorities any documentation necessary to provide evidence for the documentation referred to in Chapter I of this Annex. If the sponsor is not the natural or legal person responsible for the manufacture of the device intended for performance evaluation, this obligation may be fulfilled by that person on behalf of the sponsor.	1. The sponsor shall undertake to keep available for the competent national authorities any documentation necessary to provide evidence for the documentation referred to in Chapter I of this Annex. If the sponsor is not the natural or legal person responsible for the manufacture of the device intended for performance evaluation, this obligation may be fulfilled by that person on behalf of the sponsor.	1. The sponsor shall undertake to keep available for the competent national authorities any documentation necessary to provide evidence for the documentation referred to in Chapter I of this Annex. If the sponsor is not the natural or legal person responsible for the manufacture of the device intended for performance evaluation, this obligation may be fulfilled by that person on behalf of the sponsor.	No change
1350.	2. The reportable events shall be provided by the investigator(s) in timely conditions.	2. The reportable events shall be provided by the investigator(s) in timely conditions.	2. The sponsor shall have an agreement in place to ensure that the serious adverse events are reported by the investigator(s) to the sponsor in a timely manner.	
1351.	3. The documentation mentioned in this Annex shall be kept for a period of time of at least five years after the clinical performance study with the device in question has ended, or, when the device is subsequently placed on the market, at least five years after the last device has been placed on the market.	3. The documentation mentioned in this Annex shall be kept for a period of time of at least five years after the clinical performance study with the device in question has ended, or, when the device is subsequently placed on the market, at least five years after the last device has been placed on the market.	3. The documentation mentioned in this Annex shall be kept for a period of time of at least five years after the clinical performance study with the device in question has ended, or, when the device is subsequently placed on the market, at least five years after the last device has been placed on the market.	No change
1352.	Each Member State shall make provision that this documentation is kept at the disposal of the competent authorities for	Each Member State shall make provision that this documentation is kept at the disposal of the competent authorities for	Each Member State shall make provision that this documentation is kept at the disposal of the competent authorities for	No change

Row	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
	the period indicated in the preceding paragraph in case the sponsor, or his contact person, established within its territory goes bankrupt or ceases its activity prior to the end of this period.	the period indicated in the preceding paragraph in case the sponsor, or his contact person, established within its territory goes bankrupt or ceases its activity prior to the end of this period.	the period indicated in the preceding paragraph in case the sponsor, or his contact person, established within its territory goes bankrupt or ceases its activity prior to the end of this period.	
1353.			4. The sponsor shall appoint a monitor that is independent from the investigation site to ensure that the clinical performance study is conducted in accordance with the Clinical Investigation Plan, the principles of Good Clinical Practice and this Regulation.	
1354.			5. The sponsor shall establish follow-up measures for the investigation subjects.	