

Medical Devices and *In Vitro* Diagnostic Medical Device Regulation

Legal requirements for distributors

EMDDA Webinar

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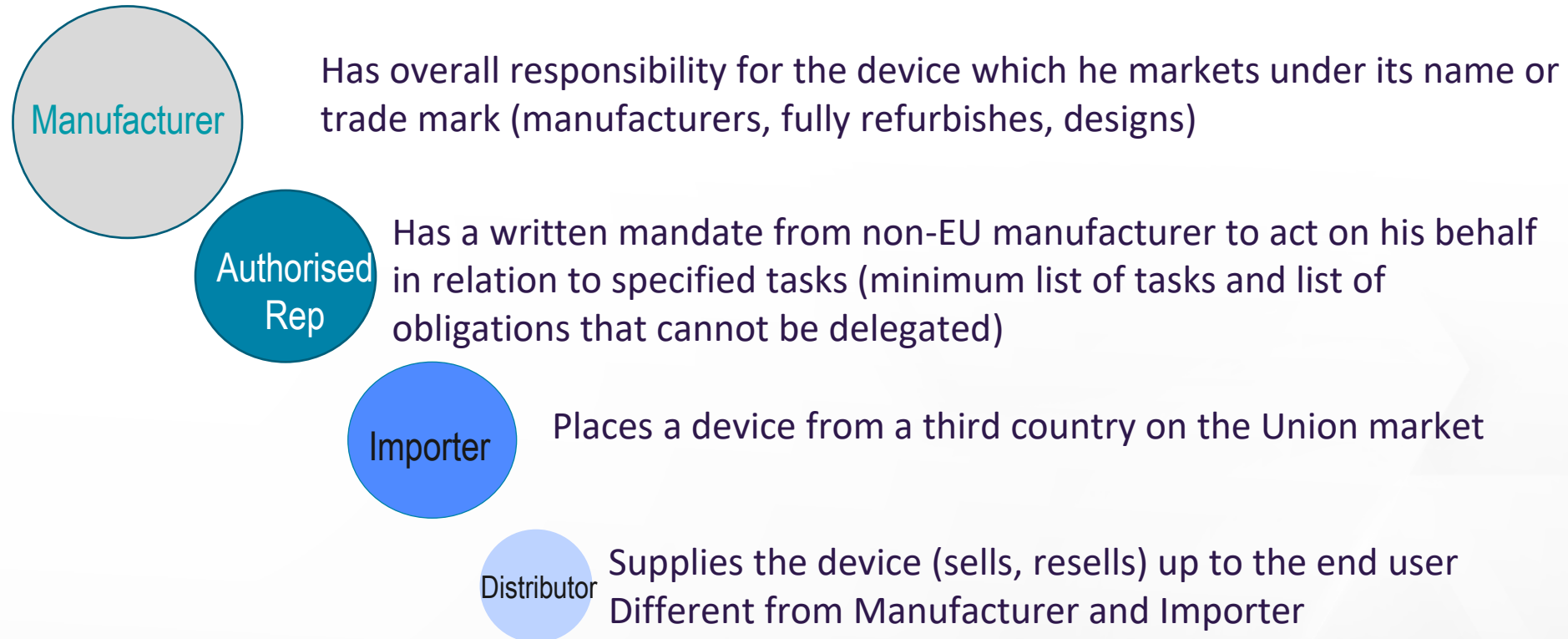
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Topics covered

1. Requirements arising from MDR/IVDR for medical device distributors
2. MDR and IVDR UDI and traceability requirements
3. Device information from EUDAMED and National registration requirements for distributors
4. Relevant documents for distributors

Economic Operators under MDR/IVDR

Economic Operators under MDR/IVDR



Documentation on/Information accompanying the device

Each actor in the supply chain checks the compliance of the previous one

Manufacturer

- Draw up technical doc, DoC and affixes CE mark
- UDI carrier on the device label and higher levels of packaging
- IFU in an official EU language
- Label correct

Authorised rep

- + Verify technical doc and conf. assessment
- + Keep a copy of the technical doc, DoC, certificate

Importer

- + Verify that a manufacturer is identified and AR is designated
- + Importer details on device label or on its packaging or in an accompanying doc

Distributor

Verify:

- CE mark and EU DoC
- Label and IFU
- UDI

Batch verification

Sampling

Market surveillance/Supply chain obligations

Cooperate with a competent authority, at its request, on any corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices

Inform competent authority about serious risk

Inform MNF/AR/IMP about non-conformity

Manufacturer

- Vigilance system
- **Vigilance reporting**
- Provide Notified Body with information on serious risk devices
- Implement FSCAs
- Inform NCA about serious risk

Authorised rep

Importer

Same as distributor

Distributor

- keep register of complaints, non-conforming devices complaint, recalls, withdrawals
- Provides free sample
- Provide doc demonstrating MD compliance to CA

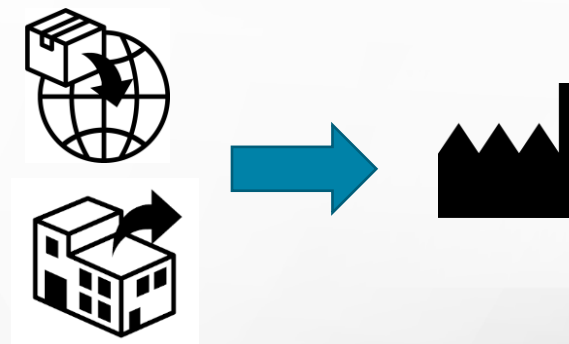
Implement corrective actions

Communicate complaints and incidents immediately

Article 16: Activities that turn Distributors or Importers into Manufacturers

You may become the manufacturer for MDR purposes if you:

1. Make a device available on the market under your own name, registered trade name/trade mark
2. Change the intended purpose of a device already placed on the market/put into service
3. Modify a device already placed on the market/put into service in such a way that compliance with the applicable requirements may be affected (e.g. breaking the sterile packaging)



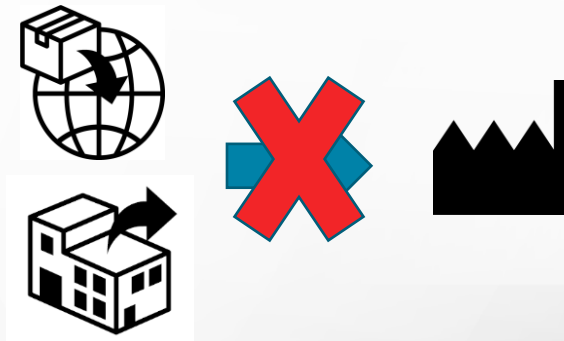
Article 16: Activities that **do not** turn Distributors or Importers into Manufacturers

1. translation of the information supplied by the manufacturer
2. changes to the outer packaging of a device, including a change of pack size (but sterile condition may not be affected)



Conditions (must):

- Quality Management System for the relevant activities
- Contact details on the product
- Inform Manufacturer and relevant Competent Authority 28 days in advance and upon request provide a sample or mock-up



Quality Management System

- Manufacturers always need a QMS, even if they only market 'simple Class I' devices
- Distributors or importers need a QMS, certified by a Notified Body, if they translate the IFU/label or repackage the device (Article 16)
- ISO 13485:2016 -- Quality management systems -- Requirements for regulatory purposes requires controls on providers of outsourced processes in the distribution chain.

UDI and traceability requirements under MDR / IVDR

MDR / IVDR UDI Requirements and traceability

The Unique Device Identification ('UDI') system described in the MDR/IVDR shall allow the identification and facilitate the traceability of devices, other than custom-made and investigational devices, and shall consist of...



Assign



Label



Register



Store

Manufacturers

Economic Operators and Health Institutions

Identification in the Supply Chain



Aa labelling requirement

- Unique Device Identification (UDI carriers) shall be placed on the label of devices and on all higher levels of packaging (≠shipping containers).

A tool for traceability

- Economic operators (manufacturer, authorised representative, importer, distributor, and system or procedure pack producers) **must store and keep**, preferably **by electronic means**, the UDI of the devices which they have supplied or with which they have been supplied, if those devices belong to
 - **class III implantable devices**,
 - the devices, categories or groups of devices determined by a future implementing act.
- Same obligation applies to Health institutions for class III implantable devices.
- For other devices, Member States shall encourage health institutions and healthcare professionals to do the same.

Eventually every device will have one – consider how/if you will use UDI for stock-taking?

Unique Device Identification on the label

- Devices certified under the AIMDD / MDD / IVDD (legacy devices may have but are not required to have a UDI-carrier on the label).
- Because a transition period is in place to include UDI on the labels of MDR/IVDR devices (see table), you may continue seeing MD devices being received without the UDI-carrier on the label.
- If not already present, UDI-carriers will be added to labels in phases up to 26 May 2025 (MDs), 26 May 2027 (IVDs) depending on the risk class of devices transitioning to MDR / IVDR.

Device as per Regulation (EU) 2017/745 (MDR)	Implantable devices and Class III devices	Class IIa and Class IIb devices	Class I devices
Placing UDI-carriers on the labels of devices MDR Article 123(3)(f), Article 27(4)	26 May 2021	26 May 2023	26 May 2025
Direct marking of the reusable devices MDR Article 123(3)(g), Article 27(4)	26 May 2023	26 May 2025	26 May 2027

Device as per Regulation (EU) 2017/746 (IVDR)	Class D IVDs	Class C and B IVDs	Class A IVDs
Placing UDI-carriers on the labels of devices IVDR Article 113(3)(e), Article 24(4)	26 May 2023	26 May 2025	26 May 2027

Examples of UDI-carrier formats put on the label

There are no technological but some practical limitations

Typical formats:

- Linear Barcode



- 2D/Matrix Barcode



- RFID



Human Readable Interpretation (HRI)

HRI is a legible interpretation of the data characters encoded in the UDI-carrier.

Automatic identification and data capture (AIDC):

Technology used to automatically capture data. AIDC technologies include bar codes, smart cards, biometrics and RFID.

Examples of where the HRI information should be located



What is a UDI ?

UDI = UDI-DI + UDI-PI

Unique Device Identification

Unique Device Identifier ('UDI')

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.

Device Identifier

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.

=

+

Production Identifier

UDI-PI

The UDI-PI is a numeric or alphanumeric code that identifies the unit of device production.

The different types of UDI-PIs include serial number, lot number, software identification and manufacturing or expiry date or both types of date.

MDR compliance for traceability requires keeping and storing the **FULL UDI** so that **both UDI-DI and UDI-PI are captured!**

Example of UDI-carrier put on the label

Example: GS1 Code 128, Linear Barcode, Application Identifier Code



Device Identifier (UDI-DI)

Format: GTIN-14

0 403 5479 11422 0



Production Identifiers (UDI-PI)

- Serial Number: (21)(+X..20)
- Lot Number: (10)(+X..20)
- Manuf. Date (YYMMDD): (11)(+N6)
- Expiry Date (YYMMDD): (17)(+N6)
- Software Version: (8012)(+X..20)

Device information from EUDAMED and National registration requirements for distributors

EUDAMED - Central database for Medical Devices

Economic Operators (manufacturer, authorised representative, importer & system / procedure pack producers) and Notified Bodies can enter data on a voluntary basis

150k MDR, 18k IVDR devices already registered

EUDAMED public

Dedicated European Commission's EUDAMED page



EN English

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Search

EUDAMED - European Database on Medical Devices

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Certificates ▾

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EUDAMED database

The creation of a European database on medical devices (EUDAMED) is one of the key aspects of the new rules on medical devices ([Regulation \(EU\) 2017/745](#)) and in vitro diagnostic medical devices ([Regulation \(EU\) 2017/746](#)).

EUDAMED will provide a living picture of the lifecycle of medical devices that are made available in the European Union (EU). It will integrate different electronic systems to collate and process information about medical devices and related companies (e.g. manufacturers). In doing so, EUDAMED aims to enhance overall transparency, including through better access to information for the public and healthcare professionals, and to enhance coordination between the different Member States in the EU.

EUDAMED will be composed of six modules related to: actor registration, unique device identification (UDI) and device registration, notified bodies and certificates, clinical investigations and performance studies, vigilance and market surveillance.

Search for



Economic Operators

Search for economic operators (manufacturers, system/procedure pack producers, authorised representatives, importers).



Devices, Systems, Procedure packs

Search for UDI-DI and device data including SS(C)P.



Certificates (Issued or Refused)

Search for certificates and refused certificates.

Transparency through EUDAMED

Actor, UDI/Device, Certificate
information transparently available

Information partially available

Public Site

Eudamed

European Databank on Medical Devices



Economic Operators
(Actor) Registration



UDI and Device
Registration



Notified Bodies and
Certificates



Clinical Investigations



Vigilance and Post-
Market Surveillance



Market Surveillance

Transparency through EUDAMED

EUDAMED Module	Public access	Information
Actor registration	Full	Economic Operators: Manufacturers, Authorised representatives, Procedure Pack Producers, Importers and Sponsors Full
Device and UDI registration	Full	Device information Full
Certificates and Notified bodies (<u>NANDO</u>)	Full	Summary of safety and (clinical) performance SS(C)P Class III and implantable MDs & Class C&D IVDs Full
Vigilance and Post-market surveillance	Partial	Manufacturer Incident Reporting (MIR) Partial Field safety corrective actions (FSCA) Partial Field safety notice (FSN) Full Periodic safety update report (PSUR) No Trend report No
Clinical Investigations / Performance Studies	Partial	Application form and accompanying documents (TBC) Partial Clinical Investigation report/Performance Study report (TBC) Partial + its summary Full Serious Adverse Event report Partial PMCF/PMPF notification Partial
Market surveillance (authorities only)	Partial	Summary of the results (of the reviews and assessments) of market surveillance activities Full

Data elements available at EUDAMED

MDR

Device

Basic UDI-DI & UDI-DI attributes

Basic UDI-DI set of data in UDI database

Principle: Each UDI-DI inherits the attributes of its linked Basic UDI-DI and devices DI

Basic UDI-DI

- Applicable legislation (MDR) (*)
- 2. Basic UDI-DI value (*)
- 2b Basic UDI-DI Issuing entity (*);
- 6. Manufacturer SRN (*)
- 5. Name and address of manufacturer
- 7. Name and address and SRN of AR
- 9. Risk class (*)
- Implantable (Y/N) (*)
- For IIB implantable: Suture, staple, dental filling, dental brace, tooth crown, screw, wedge, plate, wire, pin, clip, connector (Y/N)
- Measuring function (Y/N) (*)
- Reusable surgical instrument (Y/N) (*)
- Active device (Y/N) (*)
- Intended to administer/remove a medicinal substance (Y/N) (*)
- 11. A. Name and/or, if applicable, device model that identifies the device(s) with this BASIC UDI-DI in the technical documentation and/or certificate or declaration of conformity (Name and/or model shall be provided)

Version April 2019

UDI-DIs

- 0. UDI-DI value (*)
- 0b. UDI-DI Issuing Entity (*)
- Secondary DI (value and issuing entity)
- 11.B. Reference, Article or Catalogue number (*)
- Device with Direct marking (Y/N) (*)
- Direct marking UDI-DI value (*)
- Direct marking UDI-DI issuing entity (*)
- 1. Quantity of device(s) (*)
- 3. Type of UDI-PI (*)
- 4. Unit of use UDI-DI (*)
- 12. Clinical size (*)
- 14. Storage/handling conditions
- 10-15. Name(s)/Trade name(s) (including languages)
- 13. Additional product description
- 22. URL for additional information
- 16. Labelled as single use (Y/N) (*)
- 17. Maximum number of reuse (*)
- 18. Device labelled as sterile (Y/N) (*)
- 19. Need for sterilisation (Y/N) (*)
- 20. Containing latex (Y/N) (*)
- 21. CMR/Endocrine disruptor
- 23. Critical warnings or contra-indications
- 8. Medical device nomenclature (CND) code (1)
- 24. Status
- 25. (A.2.6) Reprocessed single-use (Y/N) (*)
- 26. (A.2.12) Annex XVI (*)
- 27. (A.2.13) In the case of devices designed and manufactured by another legal or natural person as referred in Article 10(15), the name, address and contact details of that Natural/legal person

UDI-DIs (container package DI)

- 0. UDI-DI value (*)
- 0b. Issuing entity (*)
- 1. Quantity per package (*)
- 24. Status

(1) Nomenclature decision:
<https://ec.europa.eu/docroom/documents/34264>

- (*) may not be changed
- Mandatory
 - Mandatory if applicable
 - Optional

MDR

Other Device Data

Other Device Data attributes

Basic UDI-DI

- A.2.2 Certificate IDs (NB, type .. Link);
- A.2.14 SSCP;
- A.2.11 Clinical Investigations IDs (..link);
- A.2.9 Presence of Human tissues/Cells (Y/N) (*);
- A.2.10 Presence of Animal tissues/Cells (Y/N) (*);
- A.2.7 Presence of medicinal product substance (Y/N) (*);
- A.2.8 Presence of medicinal product substance derived from human blood or human plasma (Y/N) (*);
- Special device types: Software (Y/N), contact lenses (Y/N) ... (max one choice) (*);
- System which is a device in itself (Y/N) (*);
- Procedure pack which is a device in itself (Y/N) (*);

- Provided by NB or for certificate ID under Art 29(3) provided by manufacturer and confirmed by NB

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UDI-DIs

- A.2.7 Medicinal product Substance(s);
- A.2.8 Medicinal product Substance(s) derived from human blood or human plasma;
- A.2.3 Member State of the Placing on the EU Market of the Device (*);
- A.2.4 Member State(s) where the Device is made available in the Country;

- (*) may not be changed
- Mandatory
 - Mandatory if applicable
 - Optional

Source: https://ec.europa.eu/health/system/files/2020-09/md_budi_mdr_en_0.pdf

National databases for distributors

Distributors are not required to be registered in EUDAMED, Member States have the right to establish a national database (*see MDR Article 30.2. / IVDR 27.2*).

- The central EUDAMED database will be filled with reliable actor and device registration data which will eventually become the source of truth.
- Beneficial to avoid the duplication of existing reliable data in local national distributor databases, any additional info requested from distributors to be complementary to EUDAMED and kept to the minimum.

Registration of DISTR required in a national database

- No: 13
- Yes: 14

EU countries that require distributor registration in national database:

Belgium, Bulgaria, Croatia, Czech Republic, Denmark, Finland, France, Hungary, Ireland, Malta, Portugal, Slovenia, Spain, Sweden

Relevant documents for distributors

MDCG guidance relevant for Importers/Distributors

- [MDCG 2021-27](#) Questions and Answers on Articles 13 & 14 (General obligations of importers and distributors) of MDR and IVDR
- [MDCG 2021-26](#) Q&A on repackaging & relabelling activities under Article 16 of MDR and IVDR
- [MDCG 2021-23](#) Guidance for notified bodies, distributors and importers on certification activities in accordance with Article 16(4) of MDR and IVDR
- [MDCG 2021-13 Rev. 1](#) Questions and answers on obligations and related rules for the registration in EUDAMED of actors other than manufacturers, authorised representatives and importers subject to the obligations of Article 31 MDR and Article 28 IVDR
- [MDCG 2021-25](#) Regulation (EU) 2017/745 - application of MDR requirements to 'legacy devices' and to devices placed on the market prior to 26 May 2021 in accordance with Directives 90/385/EEC or 93/42/EEC

[Full list of MDCG guidance documents](#)

[Upcoming MDCG guidance documents](#)

- European Commission Factsheet for [Authorised Representatives, Importers and Distributors of MDs and IVDs](#)
- [The European Commission 'Blue Guide' on the implementation of EU product rules](#)

[DG SANTE's website on the Medical Devices - New regulations](#)