MedTech Europe
from diagnosis to cure

Medical Devices and *In Vitro* Diagnostic Medical Device Regulation

Legal requirements for distributors

EMDDA Webinar
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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

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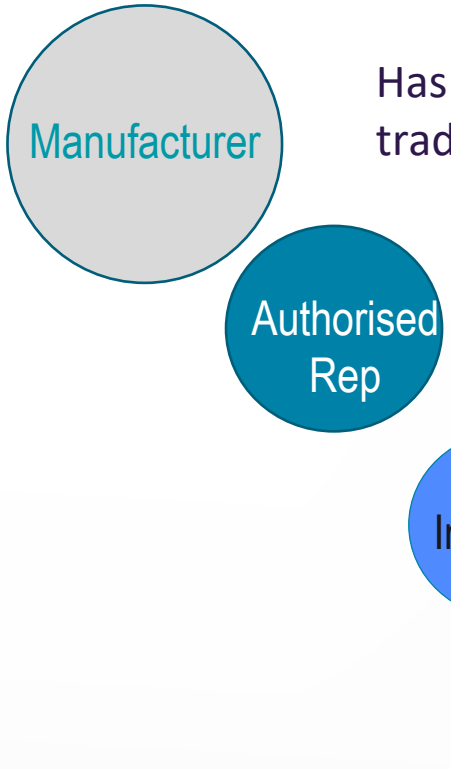


Has overall responsibility for the device which he markets under its name or trade mark (manufacturers, fully refurbishes, designs)

Has a written mandate from non-EU manufacturer to act on his behalf in relation to specified tasks (minimum list of tasks and list of obligations that cannot be delegated)

Places a device from a third country on the Union market

Supplies the device (sells, resells) up to the end user
Different from Manufacturer and Importer

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 seroius 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

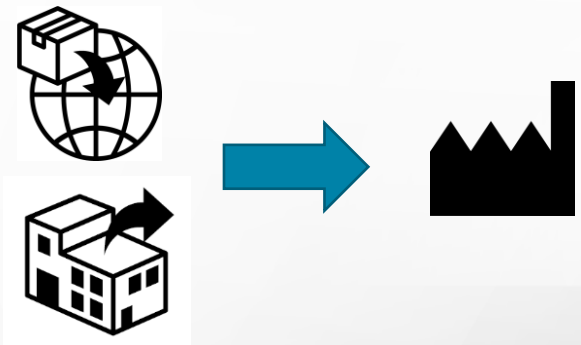
Implement corrective actions

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)

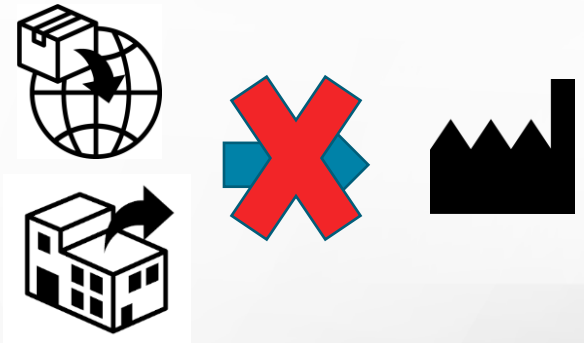


Article 16: Activities that do not turn Distributors or Importers into Manufacturers

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

+A123BJC5D6E71G

- RFID

Automatic identification and data capture (AIDC):

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

Human Readable Interpretation (HRI)

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

Examples of where the HRI information should be located

(01)1234567891234
(21)908765422

(01)1234567891234
(21)908765422

(01)1234567891234(21)908765422

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!**

Sources: 2017/745 MDR/IVDR, Annex VI, Part C, 1. Definitions
Compare to: IMDRF/UDI WG/N7FINAL:2013, Section 5: Definitions

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

Global Company Prefix GCP

GS1-DE (400-440)

Product Manufacturer

Check-Digit

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

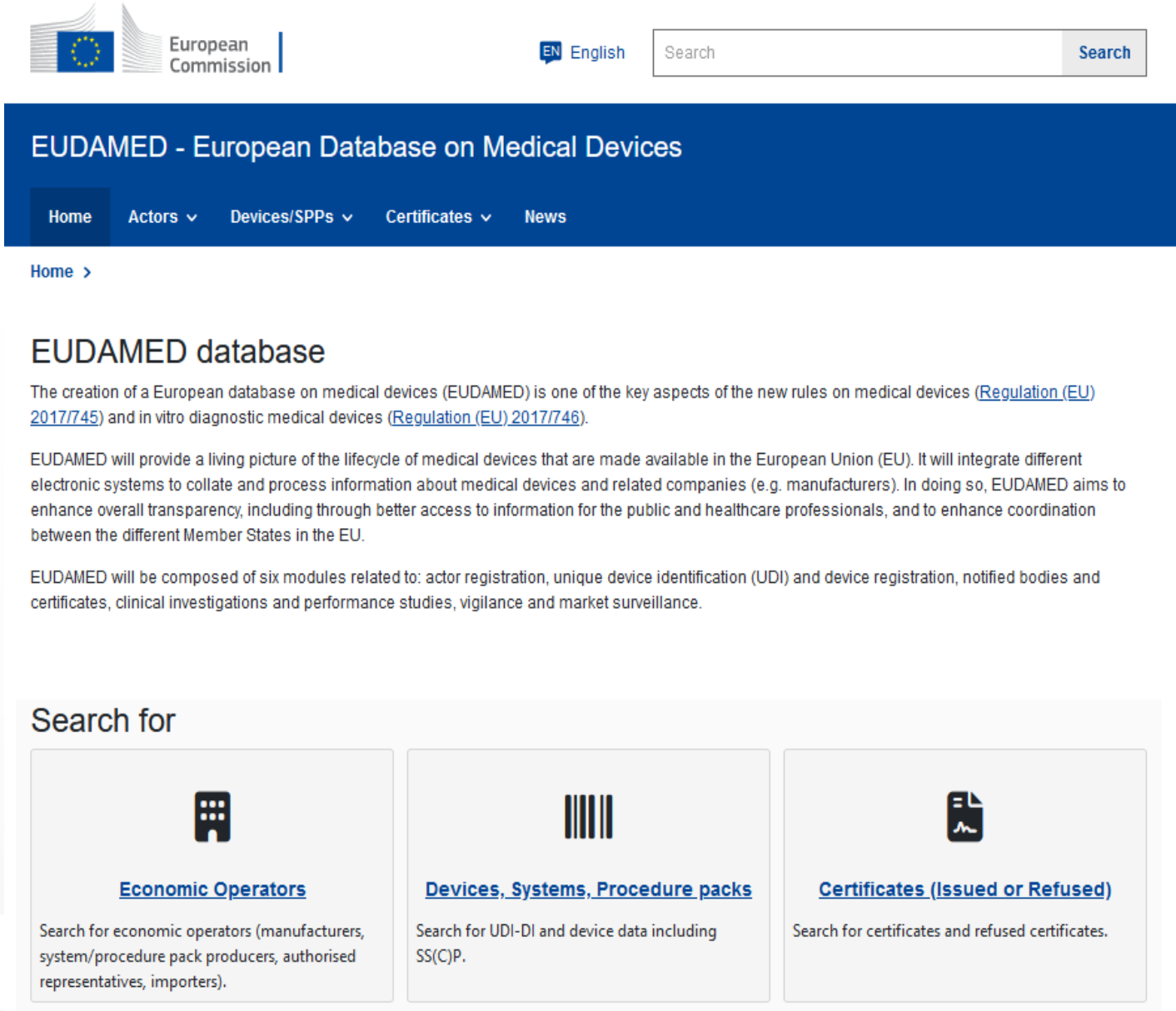
EUDAMED - Central database for Medical Devices

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

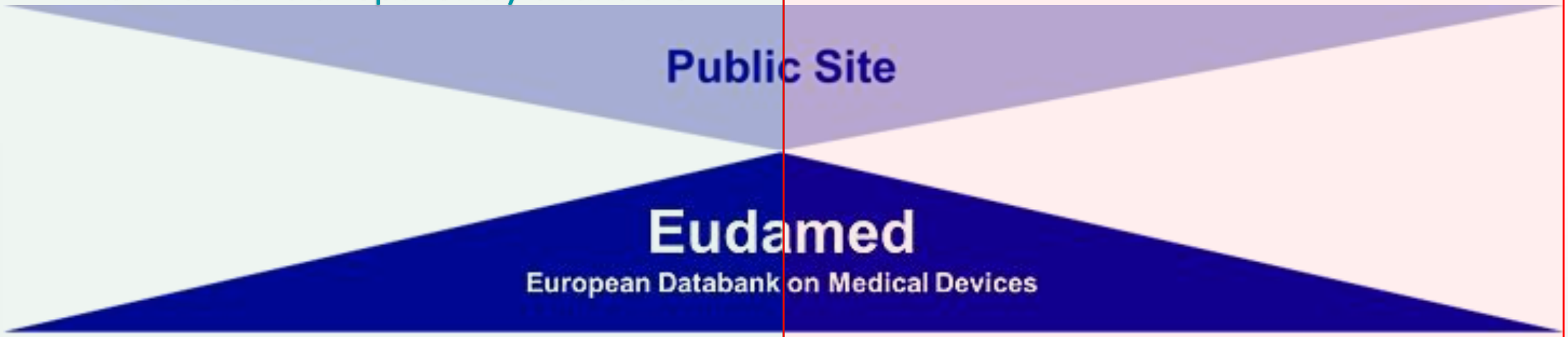
Dedicated European Commission's EUDAMED page



Transparency through EUDAMED

Actor, UDI/Device, Certificate information transparently available

Information partially available



Economic Operators (Actor) Registration

UDI and Device Registration

Notified Bodies and Certificates

Clinical Investigations

Vigilance and Post-Market Surveillance

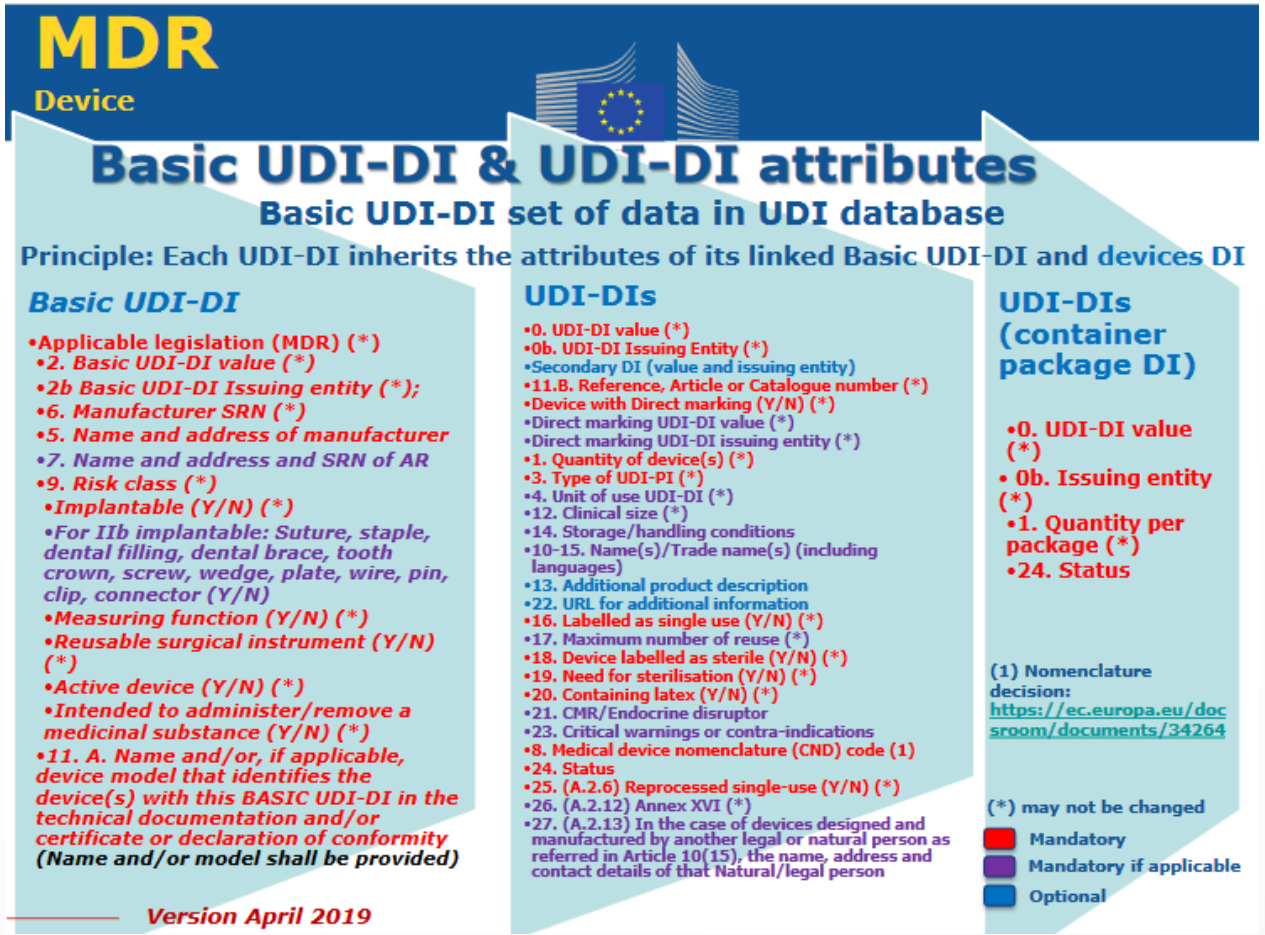
Market Surveillance

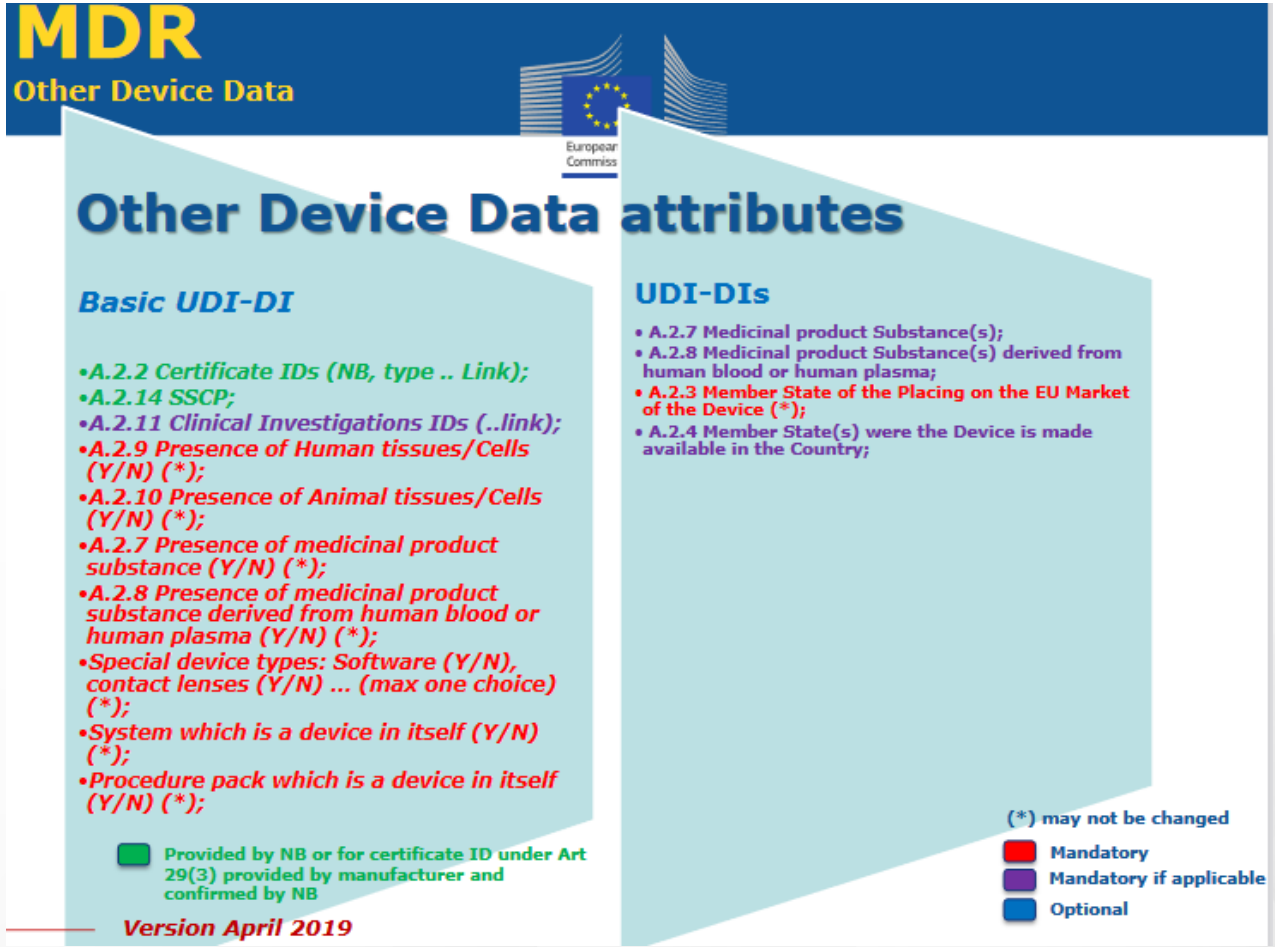
Transparency through EUDAMED

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 (NANDO)	**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**

See: Fact sheet on MDR requirements for Transparency and Public Information, EUDAMED Functional Specification (v7.2)

Data elements available at EUDAMED





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