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DG POST/Health Products Division

'Questions - Answers' for manufacturers of Class I devices concerning the application of Regulation 2017/745 on Medical Devices

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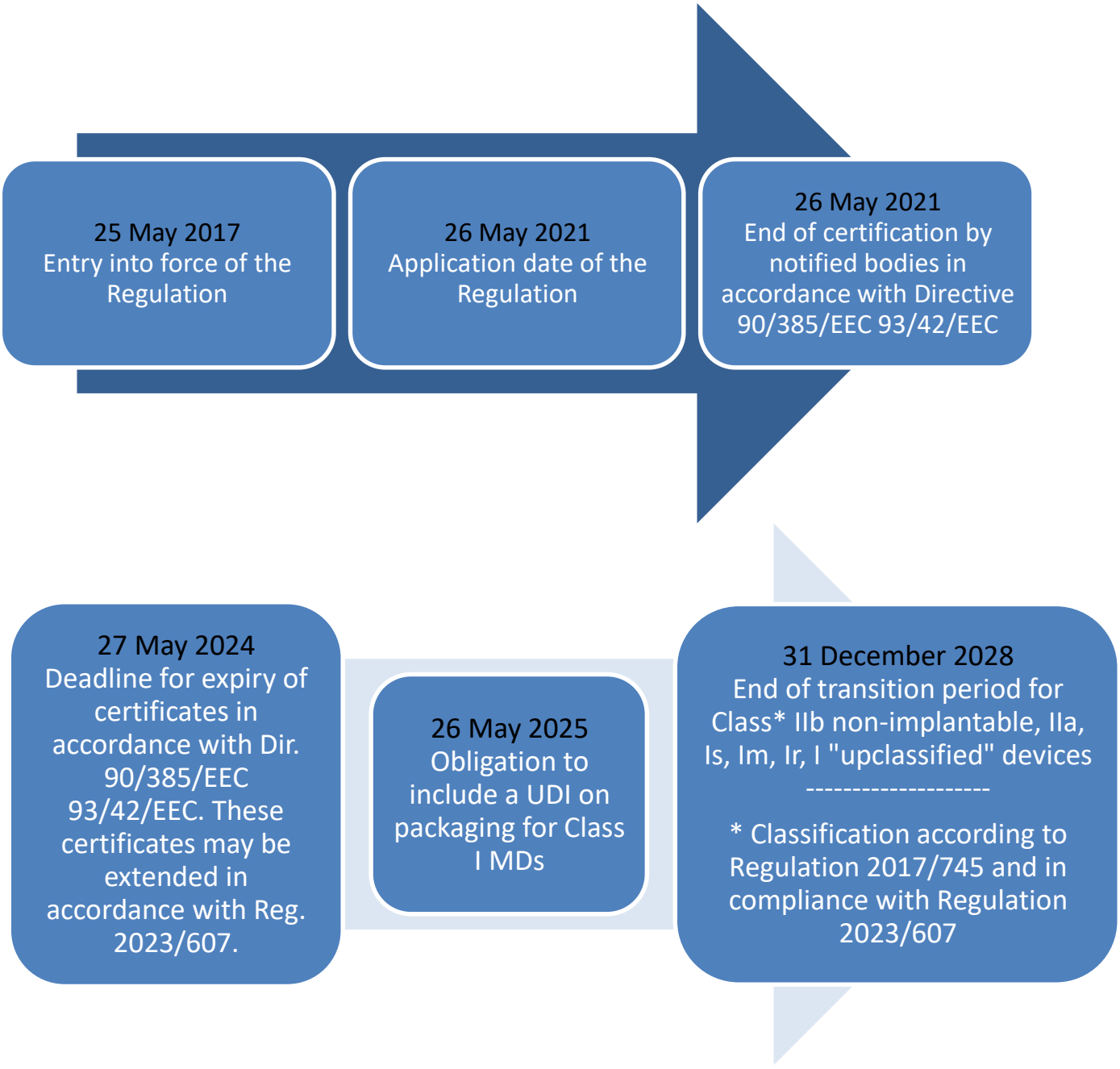
1. General information on Regulation 2017/745

Some key dates specific to Class I devices:



A transition period has been provided for Class I devices that already had a certificate under the Directives, as well as for those that did not have one under the Directives but require one under Regulation 2017/745.
Other Class I devices must have complied with Regulation 2017/745 since 26 May 2021.

The European Commission has published specific guidance for manufacturers of Class I devices. This document sets out the different steps involved in bringing a Class I device to market, as well as the manufacturer's main obligations.

2. Transition period

Legacy device[1] manufacturers benefit from a delay for the certification of their devices if they meet the following conditions[2]:

I	**Class**	**Is or Im**
	Certificates (in accordance with Dir. 93/42/EEC)	Issued after 25/05/2017
		Still valid on 05/26/2021
		Expired **before** 20/03/2023

These certificates are valid until the date indicated on the certificate. However, they may have a transition period until 31 December 2028 if they have not been withdrawn and one of the following conditions is met (Art. 120.2 of Regulation 2017/745):

1. Before the expiry date of the certificate, the manufacturer and a notified body have signed a written agreement for the conformity assessment of the device covered by the expired certificate or a device intended to replace this device;
2. A competent authority of a Member State has granted a derogation from the conformity assessment procedure in accordance with Article 59 of Regulation 2017/745 or has requested that the manufacturer, in accordance with Article 97(1) of Regulation 2017/745, implement the applicable conformity assessment procedure.

II	**Class**	**Is or Im**
	Certificates (in accordance with Dir. 93/42/EEC)	Issued after 25/05/2017
		Still valid on 05/26/2021
		Expires on **20/03/2023 or later**

These certificates remain valid after the end of the period indicated on the certificate and until 31 December 2028, provided they have not been withdrawn (Art. 120. 3bis of Regulation 2017/745).

III	**Class**	**I (without certificate under Dir. 93/42/EEC)**
	Certificates under Regulation 2017/745	a certificate is required under Regulation 2017/745

This category mainly includes Class Ir devices and those moving from Class I to a higher risk class (Art. 120.3b of Regulation 2017/745). These devices can be placed on the market or put into service until 31 December 2028.

If the device falls into one of the three categories above, it must also meet the following conditions to benefit from the transition period (Art. 120.3 d):

1. Those devices continue to comply with Directive 93/42/EEC;

[1] The term legacy device is used to describe medical devices, active implantable medical devices and in vitro diagnostic medical devices covered by valid certificates issued under Directive 93/42/EEC, Directive 90/385/EEC or Directive 98/79/EC and which will continue to be placed on the market or used after the date of application of Regulation (EU) 2017/745 or Regulation (EU) 2017/746 in accordance with Article 120 of the MDR and Article 110 of the IVDR.

[2] Based on Regulation 2023/607 and Art. 120 of Regulation 2017/745

2. there are no significant changes in the design and intended purpose[3];
3. the devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health;
4. No later than 26 May 2024, the manufacturer has put in place a quality management system (in accordance with Article 10(9) of Regulation 2017/745);
5. No later than 26 May 2024, the manufacturer or the authorised representative has lodged a formal application with a notified body for a conformity assessment of a device or a device intended to replace that device, and no later than 26 September 2024, the notified body and the manufacturer have signed a written agreement.

NB:

- Other Class I devices must have complied with Regulation 2017/745 since 26 May 2021.
- As soon as one of the above conditions is no longer met, the manufacturer can no longer benefit from the transition period. The device can then only be placed on the market if it complies with Regulation 2017/745.

[3] See MDCG 2020-3 guidance for significant changes

3. Registration as a Class I manufacturer

Currently, a Class I manufacturer is not required to register either in our online applications or in Eudamed. However, manufacturers and authorised representatives with registered offices in Belgium must notify the placing on the market of their Class I devices (see next question).

As Eudamed's "Actor" module is already accessible, manufacturers can register there on a voluntary basis. The legal obligation to register on Eudamed will become effective six months after Eudamed is fully functional. **The FAMHP strongly encourages manufacturers to register proactively**. In fact, Eudamed will be considered as the authentic source for the "actor" data of economic operators (manufacturers, authorised representatives and importers), and our database (the web portal) communicates with Eudamed in order to retrieve this data. This means that registration on Eudamed is considered as registration on our web portal.

This registration on Eudamed will also enable you to obtain your unique registration number (also known as **SRN** for *Single Registration Number*). This number is assigned to the following actors:

- EU manufacturers;
- manufacturers outside the EU (following the pre-validation of their authorised representative);
- authorised representatives;
- assemblers of systems and procedure packs;
- importers.

A company with different roles can have several SRNs.

All the actors listed above can register regardless of the devices they make available on the EU market (MDs in accordance with Dir. 93/42/EEC or 90/385/EEC or Regulation 2017/745).

Actors with "distributor" activity must always register via online applications for distributor activity. This does not prevent them from also registering in Eudamed for other activities. For further information, please see the 'Registration of distribution and import activities' page.

When you register in Eudamed, you will be asked to provide a number of details about your company. Please note the following points:

- **the VAT number**: we will use this number to match the data with the Crossroads Bank for Enterprises (CBE). This means that the data in Eudamed must match the data in the CBE.
- **the signed declaration** (declaration of responsibility for information security). The purpose of this document is to appoint a Local Actor Administrator (LAA) who will be responsible for the "administration" of the data in Eudamed. This declaration must be signed by a legal representative of the company.

The registration of players in Eudamed will be mandatory six months after the database is fully operational. If you have already registered, you will not need to repeat this operation.

You can find more information about actor registration in the webportal FAQ.

4. Registration of Class I devices

Any manufacturer whose registered office is in Belgium and which places Class I devices on the market in its own name is required to notify the FAMHP no later than the day on which the devices are placed on the market (Art. 10 of the Law of 18 March 1999).
This obligation also applies to authorised representatives with a registered office in Belgium.

The placing of Class I MDs on the market must be notified either via Eudamed or via a national notification form.

4.1 Via Eudamed

The FAMHP encourages Belgian manufacturers and non-European Union manufacturers who have an authorised representative located in Belgium to register their device(s) in Eudamed through the "Devices" module. This registration replaces the FAMHP notification. No acknowledgement of receipt will be sent in this case. If you still wish to receive an acknowledgement of receipt, please contact us by e-mail at notifications.meddev@fagg-afmps.be with the following details:

- The manufacturer's SRN
- The authorised representative's SRN (if applicable)
- The basic UDI-DI
- The device model
- The Number of the CE certificate and notified body for Class I sterile devices, with measuring function or reusable surgical instruments.

Please note that there is currently no legal obligation to register your devices in Eudamed. The registration of medical devices will be mandatory two years after Eudamed goes live. If the devices are already registered before the obligation, this operation need not be repeated.
The FAMHP online applications communicate with Eudamed and your data encoded in the European database will be considered as main data. This means that once you have registered in Eudamed, you will no longer need to reregister in our online applications.

4.2 By email/by post

If you do not want to register your Class I device via Eudamed, a notification must be made:

- via the placing on the market notification form (FR MDR form, NL MDR form, FR MDD form, NL MDD form),
- on the day the devices are placed on the market at the latest,
- separately for each device.

5. What is in 'Eudamed'?

Eudamed for ***Eu****ropean* ***Da****tabase on* ***Med****ical Devices*, is the European database on medical devices.

Below is a brief description of this future database:

- **Actors module:** dedicated to identifying economic operators. These actors will have to identify themselves before making their medical devices available on the market (Art. 30-31 MDR-2017/745). This module is available on a voluntary basis;
- **Devices module:** for registering different medical devices. The Unique Identifiers for medical devices (UDI) are also integrated (Art. 28-29 MDR-2017/745). This module is available on a voluntary basis;
- **Certificates module:** dedicated to the registration of notified bodies and certificates issued by them (Art. 57 MDR-2017/745). This module is available on a voluntary basis;
- **Clinical investigations module:** for the registration of clinical investigations (Art. 73-74 MDR-2017/745);
- **Vigilance module:** for all post-market vigilance and surveillance reports (Art. 92 MDR-2017/745).
- **Market surveillance module:** dedicated to the coordination of market surveillance actions between the different competent authorities (Art. 100 MDR-2017/745).

The different modules will be interconnected.

Most of the information in the Actors, Devices and Certificates modules will be publicly available. Information in the other modules will be limited to the public (Clinical Studies and Vigilance).

It is the responsibility of the competent authorities, notified bodies, manufacturers, importers and authorised representatives to enter and update the information contained in Eudamed.

6. Non-medical devices

Regulation 2017/745 provides for certain non-medical products to be considered as devices within the meaning of the Regulation (Annex XVI products). This means that these products must comply with medical device regulations.

The products concerned are:

1. **Contact lenses** or other items intended to be introduced into or onto the eye.
2. Products intended to be totally or partially introduced into the human body through surgically **invasive means** for the purpose of modifying the anatomy or fixation of body parts with the exception of tattooing products and piercings.
3. Substances, combinations of substances, or items intended to be used for **facial or other dermal or mucous membrane filling** by subcutaneous, submucous or intradermal injection or other introduction, excluding those for tattooing.
4. Equipment intended to be used to reduce, remove or destroy adipose tissue, such as equipment for **liposuction, lipolysis or lipoplasty**.
5. **High intensity electromagnetic radiation** (e.g. infra-red, visible light and ultra-violet) emitting equipment intended for use on the human body, including coherent and non-coherent sources, monochromatic and broad spectrum, such as lasers and intense pulsed light equipment, for skin resurfacing, tattoo or hair removal or other skin treatment.
6. Equipment intended for **brain stimulation** that apply electrical currents or magnetic or electromagnetic fields that penetrate the cranium to modify neuronal activity in the brain.

Like devices with a medical purpose, these products are divided into four risk classes (I, IIa, IIb and III). This means, among other things, that these devices must comply with the certification requirements linked to the risk class.

The requirements of the regulation have applied to these products since 23 June 2023. However, there are transition periods for devices placed on the market before 22 June 2023, which require certification by a notified body, as well as for those for which a clinical investigation is required to demonstrate conformity.

For devices requiring the intervention of a notified body but for which a transition period will run until 31 December 2029 for products for which a notified body is involved in the conformity assessment and the manufacturer decides to carry out a clinical investigation. However, certain conditions must be met, and are described in greater detail on the European Commission website.

Products for which a notified body is involved in conformity assessment and for which the manufacturer does not intend to carry out a clinical investigation during this period may (under certain conditions) benefit from a transition period until 31 December 2028.

7. What does the Regulation require a declaration of conformity to contain?

Annex IV of Regulation 2017/745 describes the structure of the declaration of conformity:

The EU Declaration of Conformity must contain all of the following information:

1. Name, registered trade name or registered trade mark and, if already issued, SRN as referred to in Article 31 of the manufacturer, and, if applicable, its authorised representative, and the address of their registered place of business where they can be contacted and their location be established;
2. A statement that the EU declaration of conformity is issued under the sole responsibility of the manufacturer;
3. The basic UDI-DI;
4. Product and trade name, product code, catalogue number or other unambiguous reference allowing identification and traceability of the device covered by the EU declaration of conformity, such as a photograph, where appropriate, as well as its intended purpose. Except for the product or trade name, the information allowing identification and traceability may be provided by the Basic UDI-DI referred to in point 3;
5. Risk class of the device;
6. A statement that the device that is covered by the present declaration is in conformity with this Regulation and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity;
7. References to any common specifications used and in relation to which conformity is declared;
8. Where applicable, the name and identification number of the notified body, a description of the conformity assessment procedure performed and identification of the certificate or certificates issued;
9. Where applicable, additional information;
10. Place and date of issue of the declaration, name and function of the person who signed it as well as an indication for, and on behalf of whom, that person signed, signature.

8. What is the single registration number and how do I get one?

The **Single Registration Number** (*SRN*) or *Actor ID* is a number assigned to: economic operators:

- EU manufacturers;
- manufacturers outside the EU (following the pre-validation of their authorised representative);
- authorised representatives;
- assemblers of systems and procedure packs;
- importers.

This number is assigned via registration in the Eudamed database (Actors module). A company performing different roles can have several SRNs.

Eudamed will only be fully functional in 2027. Nevertheless, the first modules, including the "Actor" module, are available.

All the companies carrying out the activities listed above can register regardless of the devices they make available on the market (MDs in accordance with Dir. 93/42 or 90/385 or Regulation 2017/745, in vitro diagnostic MDs in accordance with Dir. 98/79 or Regulation 2017/746).

There is currently no legal obligation to register in Eudamed. Eudamed is scheduled to go into full production by 2027. The obligation to be registered will become effective 6 months after the production start date. Nevertheless, if you register today, you won't need to do so when it becomes compulsory. Furthermore, the FAMHP national databases communicate with Eudamed. Once registered, the Eudamed data will become the actor's master data and the FAMHP online applications will search for updates directly in Eudamed. This means that it is no longer necessary to register as an actor in our databases.

Players with a "distributor" activity must always register in our online applications, as these actors will not be present in Eudamed.

The European Commission has published information about the actor module on its website.

When you register, you will be asked to provide a number of details about your company. Please note the following points:

- **the VAT number**: we will use this number to match the data with the Crossroads Bank for Enterprises (CBE). This means that the data in Eudamed must match the data in the CBE.
- **the signed declaration** (declaration of responsibility for information security). The purpose of this document is to appoint a Local Actor Administrator (LAA) who will be responsible for the "administration" of the data in Eudamed. This declaration must be signed by a legal representative of the company.

9. What is the unique device identifier (UDI)?

The UDI (or Unique Device Identifier) is a series of numeric and alphanumeric characters used to identify a device. The **UDI** is comprised of two parts: the UDI-DI and the UDI-PI.

- The **UDI-ID** is specific to the device. It contains information such as the manufacturer's name, risk class, trade name, etc. (see part B of Annex VI of the MDR).
- The **UDI-PI** (UDI production identifier) identifies the device at production unit level. It contains information such as serial number, lot number, software identification and manufacturing and/or expiry date (see Part C of Annex VI of the MDR (e.g. serial number, lot number, software identification, manufacturing and/or expiry date, etc.)).

Devices placed on the market under Regulation 2017/745 must apply the IUD rules (except for custom-made devices). Class I devices placed on the market in accordance with Regulation 2017/745 must obtain this number.

The UDI "carriers" (consisting of an Automatic Identification and Data Capture (AIDC) system and a human readable representation) must be placed on the device label and all higher levels of packaging. This obligation is staggered over time according to the risk class. For Class I devices, this provision applies from 26 May 2025.

There is an additional obligation for Class I reusable devices: from 26 May 2027, the IUD carrier must be affixed to the device itself. The Regulation specifies that: "[...] *The UDI carrier for reusable devices that require cleaning, disinfection, sterilisation or refurbishing between patient uses shall be permanent and readable after each process performed to make the device ready for the subsequent use throughout the intended lifetime of the device. The requirement of this Section shall not apply to devices in the following circumstances: a) any type of direct marking would interfere with the safety or performance of the device; b) the device cannot be directly marked because it is not technologically feasible*".

MD under Regulation 2017/745 (MDR)	Implantable and Class III MDs	Class IIa and IIb MDs	Class I MDs
UDI carriers are affixed to the device label	26 May 2021	26 May 2023	26 May 2025
Direct marking on reusable MDs	26 May 2023	26 May 2025	26 May 2027

Several IUD guidelines have been published on the Commission website. You can also consult the '*UDI Frequently Asked Questions and Answers*' document.

10. How to obtain a UDI

"Issuing entities" supply the UDIs. Four entities are recognised:

- GS1 AISBL
- Health Industry Business Communications Council (HIBCC);
- International Council for Commonality in Blood Banking Automation (ICCBBA);
- Informationsstelle für Arzneispezialitäten (IFA) GmbH;

To obtain the necessary information, please contact one of these issuing bodies directly. You can also find more information on the European Commission website.

11. What is the role of the "person responsible for regulatory compliance" (PRRC)?

Regulation 2017/745 (MDR) requires every manufacturer to appoint a person responsible for regulatory compliance (PCVRR).

This person must be part of the company. Nevertheless, micro and small enterprises can "outsource" this function. This person must then be permanently and continuously available.

"Micro and small enterprises" are defined as structures employing fewer than 50 people and whose annual turnover and/or annual balance sheet total does not exceed EUR 10 million (definition according to Commission Recommendation 2003/361/EC).

This person must meet certain requirements in terms of professional qualifications and experience (Art. 15 §1 of Regulation 2017/745):

"*Manufacturers shall have available within their organisation at least one person responsible for regulatory compliance who possesses the requisite expertise in the field of in vitro diagnostic medical devices. The requisite expertise shall be demonstrated by either of the following qualifications:*

a) ***a diploma, certificate or other evidence of formal qualification****, awarded on completion of a university degree or of a course of study recognised as equivalent by the Member State concerned, in law, medicine, pharmacy, engineering or another relevant scientific discipline, and at least one year of professional experience in regulatory affairs or in quality management systems relating to in vitro diagnostic medical devices;*

b) four years of ***professional experience*** *in regulatory affairs or in quality management systems relating to in vitro diagnostic medical devices.*

Without prejudice to national provisions regarding professional qualifications, manufacturers of custom-made devices may demonstrate the requisite expertise referred to in the first subparagraph by having at least two years of professional experience within a relevant field of manufacturing."

The PCVRR must perform regulatory tasks (Art. 15 §3 of Regulation 2017/745):

"*The person responsible for regulatory compliance shall at least be responsible for ensuring that:*

a) the conformity of the devices is appropriately checked, in accordance with the quality management system under which the devices are manufactured, before a device is released;

b) the conformity of the devices is appropriately checked, in accordance with the quality management system under which the devices are manufactured, before a device is released;

c) the post-market surveillance obligations are complied with

d) the reporting obligations

e) in the case of investigational devices, the statement referred to in Section 4.1 of Chapter II of Annex XV is issued".

In the case of authorised representatives, at least one person must be permanently and uninterruptedly available to ensure compliance with the regulations and have the requisite expertise in the field of medical device regulation in the Union.

These provisions are described in Article 15 of Regulation 2017/745.

A guideline has also been published on this subject to provide further clarification: "*MDCG 2019-7 Guidance on Article 15 of the Medical Devices Regulation (MDR) and in vitro Diagnostic Devices Regulation (IVDR) regarding a 'person responsible for regulatory compliance'(PRRC)*".

12. Where can I find the European guidance and other useful documents?

The European Commission publishes guidance on many subjects (UDI, Eudamed, nomenclature, notified bodies, etc.).
The European Commission also publishes more general information on the Regulation. CAMD (*Competent Authorities for Medical Devices*) publishes interpretative documents, such as a question-and-answer document on the transition period.

13. Glossary

AIMDD: *Active Implantable Medical Devices Directive* (Dir. 90/385/EEC transposed into Belgian law by R.D. of 15/07/1997)
RD: Royal Decree
MD: Medical Device
Eudamed: ***Eu****ropean* ***da****tabase on* ***me****dical devices*
Im: Class I device with a measuring function
Ir: Class I device that is a reusable surgical instrument - an instrument intended for surgical use in cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar procedures, without a connection to an active device and which is intended by the manufacturer to be reused after appropriate procedures such as cleaning, disinfection and sterilisation.
Is: Class I device placed on the market sterile
UDI: Unique Device Identifier
MDD: *Medical Devices Directive* (Dir. 93/42/EEC transposed into Belgian law by R.D. of 18/03/1999)
MDR: *Medical Devices Regulation* - Regulation 2017/745 on Medical Devices
NB: Notified Body
PRRC: *Person Responsible for Regulatory Compliance* The tasks of this person are defined in Art. 22 of Regulation 2017/745.
SRN: *Single Registration Number* for manufacturers, authorised representatives and importers (Art. 31 of Regulation 2017/745).
EU: European Union

Reviewed on 29/01/2024