MERCATOR

MDR

we are ready

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AMENDMENT OF THE LAW CONCERNING MEDICAL DEVICES

Since 26 May 2021, a new legislative act – Medical Device Regulation 2017/745 – took effect in all EU member states. Mercator Medical S.A. is proud to inform you that both our products and our quality management, market surveillance and product registration systems are in compliance with the applicable law within the relevant periods.

What do you need to know?

MDD (old)

MEDICAL DEVICES DIRECTIVE

20 articles · 60 pages · 12 annexes

The Directive is binding to every Member State to which it is addressed regarding the result to be achieved, but it leaves the national authorities free to choose the preferred form and means.

MDR (new)

MEDICAL DEVICES REGULATION

123 articles · 369 pages · 17 annexes

The Regulation has a general scope. It is binding in its entirety and directly applicable in all Member States. It does not leave any room for interpretation.

Why does the Regulation supersede the Directive?

A directive and a regulation are different types of law.

A **directive** indicates an objective to be achieved by all EU member states in a particular area, but it does not formulate specific steps to be taken by the individual member states to achieve the objective. Specific provisions designed to implement the objectives of the directive are formulated in internal laws (e.g. acts).

The directive affects the legislations of the individual member states indirectly, i.e., the legislators are obliged to prepare legislative acts to achieve the objectives of the directive. The implementation of the requirements of the directive in the legal order of the member states is required but the legislators are free in how they choose to implement them. As a legislative act of the European Union, the directive creates an outline of how the particular area should be regulated.

A **regulation** is binding to all member states of the European Union. The provisions of the regulation apply directly as of the time it becomes effective.

A regulation is the most important legislative act in the European Union. A regulation has the widest scope because it directly binds all member states. The purpose of issuing regulations is to unify the law in all member states of the European Union.

Requirements of the MDR – schedule

Class I (non-sterile)
Since 26 May 2021, class I devices (non-sterile) have to conform to the MDR when first placed on the market.

Class I (sterile)
Transitional period: products of class I (sterile) may be sold with an existing certificate of conformity to the MDD* **until 26 May 2024.**
* Depending on the expiry date of the MDD certificate.

Classes II & III
Transitional period: Products of classes II and III may be sold with an existing certificate of conformity to the MDD* **until 26 May 2024.**
* Depending on the expiry date of the MDD certificate.

Classes I & Is & II & III
End of the transitional period
As of May 2025, irrespective of class, medical devices certified, registered and labelled according to the MDD cannot longer be sold or distributed.

MDR definitions of economic operators in the supply chain:

Manufacturer
means a natural or legal person who manufactures or fully refurbished a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark

Authorised representative
means any natural or legal person established within the Union who has received and accepted a written mandate from a manufacturer, located outside the Union, to act on the manufacturer's behalf in relation to specified tasks with regard to the latter's obligations under this Regulation

Importer
means any natural or legal person established within the Union that places a device from a third country on the Union market

Distributor
means any natural or legal person in the supply chain, other than the manufacturer or the importer, that makes a device available on the market, up until the point of putting into service

	manufacturer	authorised representative	importer	distributor
Normative graphical symbol		EC REP		
Registration in the EUDAMED database	✓	✓	✓	⊗
Issuing the UDI code	✓	⊗	⊗	⊗
Preparation of the technical documentation for the device	✓	⊗	⊗	⊗
Conformity of the device	✓	✓	✓	✓
Conformity after handling, storage and distribution	✓	⊗	✓	✓
Non-conformity management	✓	✓	✓	✓
Observation and reporting, including device recall	✓	✓	✓	✓
Correct labelling of the device	✓	✓	✓	✓
Management of complaints and reports	✓	✓	✓	✓
Post-market surveillance	✓	✓	✓	✓
Person responsible for regulatory compliance	✓	✓	⊗	⊗
Sufficient financial coverage in case of legal liability	✓	✓	⊗	⊗

⊗ No authorisation under the MDR · ✓ New obligation under the MDR
✓ Prior obligation under the MDD that continues to be effective

What is EUDAMED?

EUDAMED is a European database on medical devices whose aim is to reinforce market surveillance by providing the relevant authorities with quick access to information about the manufacturers and authorised representatives, devices and certificates and to vigilance data for the purpose of exchanging data concerning clinical trials and contribute to the uniform application of the indicated directives, including, inter alia, the requirements concerning registration.

What information can be found in the EUDAMED database?

- Basic UDI-DI codes,
- UDI-DI codes,
- registration of economic operators (excluding distributors),
- specific data of the devices, including certificates, clinical trials and performance tests, post-market surveillance, vigilance and market surveillance.

The information included in the EUDAMED database will be sent by everyone and will be available to everyone (including the general public) on levels depending on the access rights of such persons and the information they are obliged to submit.

The database will facilitate access to regulatory documents using UDI codes and enable access to certificates covering the particular devices.

The EUDAMED database will also be used by the manufacturers to report incidents, and EU/EEA market surveillance authorities will use it as a platform for cooperation and exchange of information.

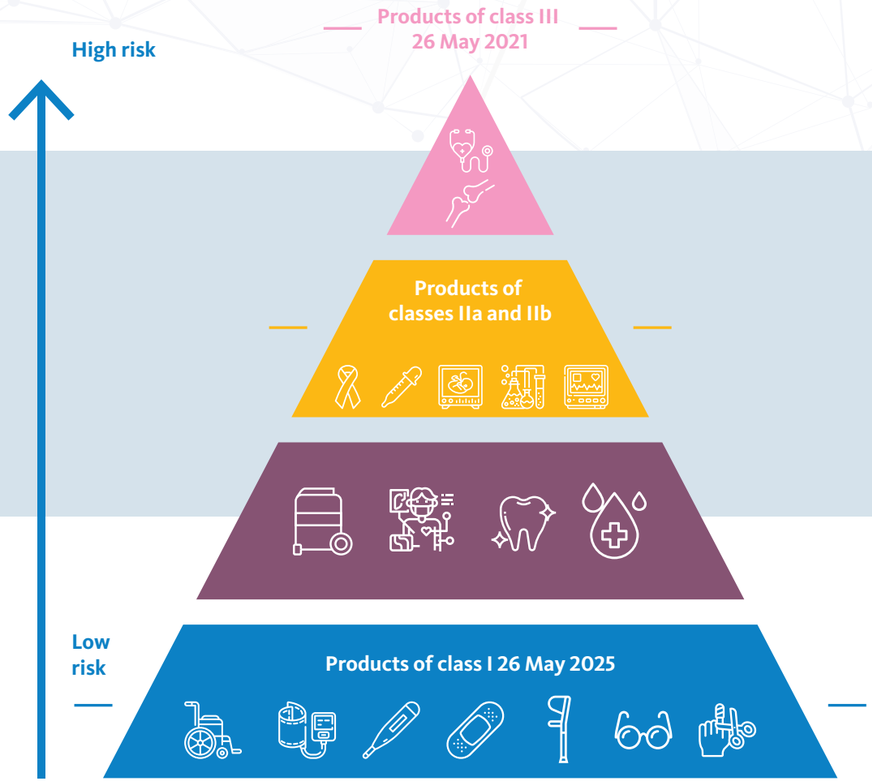
Traceability of the supply chain and unique device identification (UDI) codes

UDI (Unique Device Identification) – unique device identification codes are a completely new element of the regulation. Thanks to the UDI codes, all stakeholders will have access to basic information about the devices via the European database on medical devices (EUDAMED).

UDI is not just a code, it is an entire UDI system, including the following:

- **creating the UDI code** containing the UDI device identifier (UDI-DI) specific to the manufacturer and device and UDI production identifier (UDI-PI) identifying the unit of device production
- **placing the UDI carrier on the label of the device** or on the packaging or, in the case of reusable devices, on the device itself (direct marking)
- **retention of the UDI code** by economic operators, health institutions and healthcare professionals,
- **creating an electronic database** of Unique Medical Device Identification (UDI database), which is a part of the EUDAMED database (European Database on Medical Devices).

UDI codes must be placed on the label of the devices depending on their class within the following time limits:



Source: Eucomed

The code is placed on each level of medical device packaging:

UDI-DI is specific to the device manufacturer, and it is the identifier of the device. UDI-DI is the "access key" to information kept in the UDI database. UDI-DI is unique at each level of device packaging.

UDI-PI identifies the unit of device production, including, in particular, the lot number, manufacturing date or expiry date or both types of date.

The Basic UDI-DI code used for the registration of the Medical Device, indicated in the documents, is NOT placed directly on the device.

In the EU, the manufacturer also assigns the **Basic UDI-DI** code to their devices together with the UDI. The Basic UDI-DI is not yet required by other jurisdictions. The Basic UDI-DI code is the primary identifier of a device model – it is a key element that enables the association of different modules of the European Database on Medical Devices (EUDAMED). It is the main key for records in the UDI database and is referenced in relevant certificates and EU declarations of conformity. It is used for the registration of medical devices, and it is assigned independently of the packaging/label, is not shown on any trade unit, and is **different from the UDI-DI identifier of trade units in the supply chain**. Every Basic UDI-DI code identifies the device, but according to the MDCG 2018-1 guidelines: it is an identification number not intended for a specific product but for a **group of products** with the same:

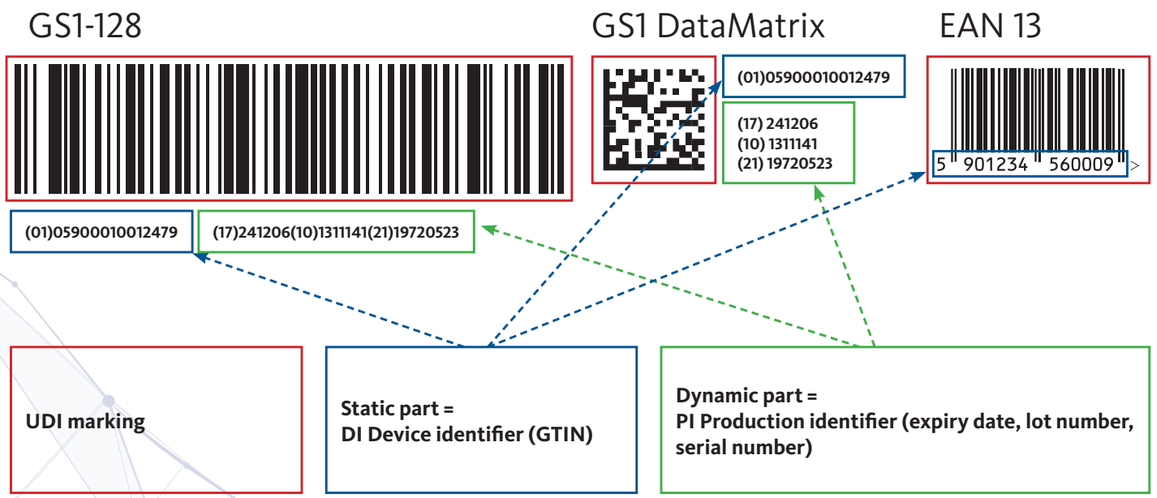
- intended use,
- risk class,
- important design and production features.

It is intended primarily for documentary purposes, and it is not physically present on any packaging of the device (it will not be shown in any data carrier, e.g. barcode).

The UDI carrier (Automatic identification and data capture (AIDC) and human-readable interpretation (HRI)) should be placed on the label or on the device itself and on all higher levels of packaging. UDI carriers include, inter alia, ID/linear bar code, 2D/Matrix bar code, RFID.

According to the **GS1** guidelines, the carrier of the UDI code may, for instance, be the GS1-128 code, which contains the static part in the form of the GTIN (DI – device identifier), where the GTIN consists of digits that represent successively: the national prefix (59 for Poland), company prefix, product symbol and check digit, and the dynamic part (PI – production identifier), including information such as the expiry date, lot number and serial number.

Other examples of a UDI code carrier include a 2D code: **GS1 DataMatrix**, containing the GTIN – device identifier (DI) – and production identifier (PI), or the EAN-13 code alone, containing the GTIN with the device identifier (DI).

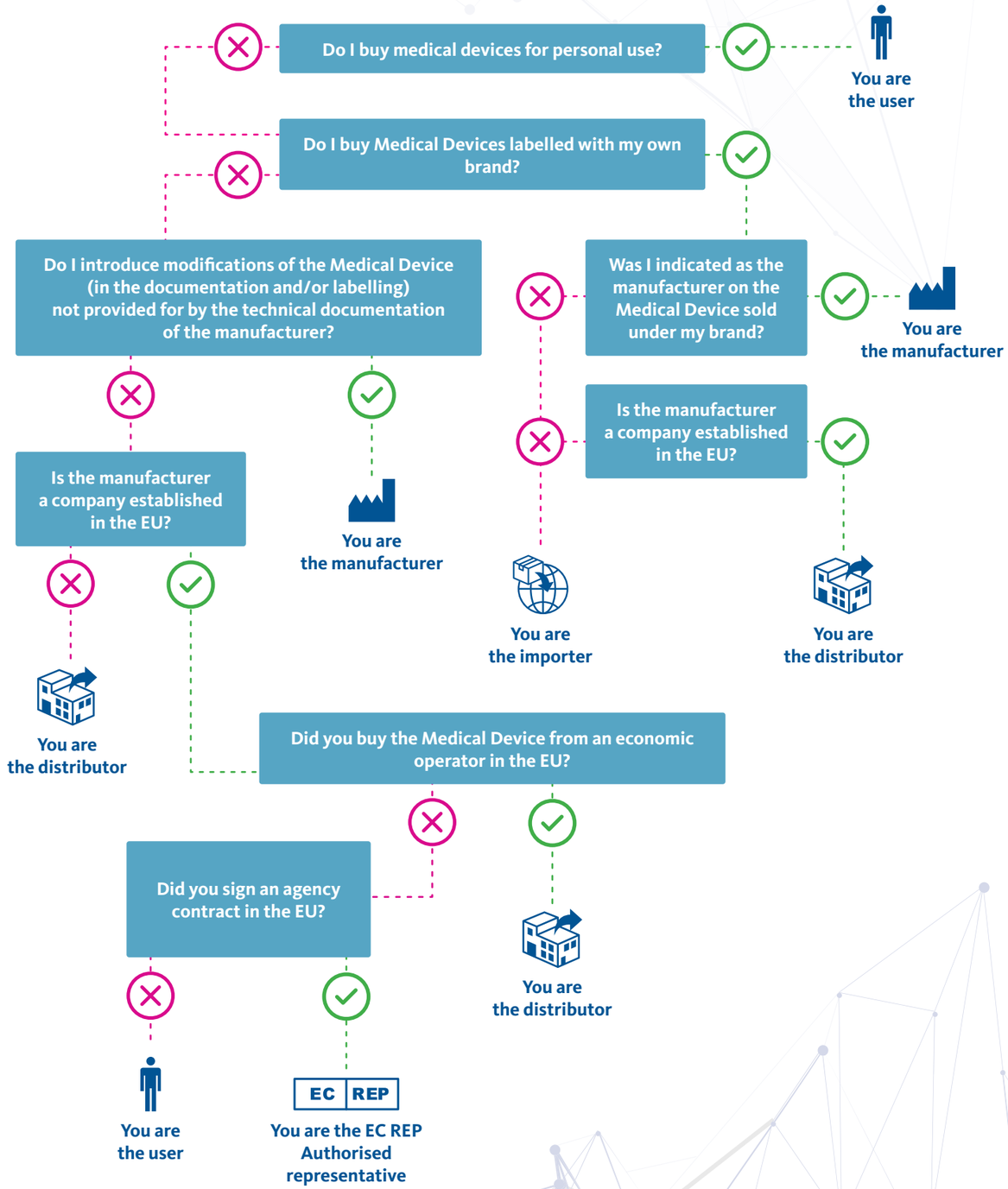


In the event of space constraints on the unit-of-use packaging, the UDI carrier may be placed on the next higher packaging level. Higher packaging levels have their own unique UDI code. Please note that transport packaging is exempt from the requirements.

Source: https://coleman.pl/blog/unikalna-identyfikacja-wyrobow-medycznych-dowiedz-sie-wiecej/

Who are you according to the amended provisions concerning Medical Devices?

Determine your role in the entire Medical Device supply chain and check the obligations arising from the new law, i.e. Medical Devices Regulation 2017/745.



Any questions? Want to know more?
Contact us now!
Find out how you can benefit from working with us. Our experts will be happy to answer all your questions.

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