European Commission

Frequently Asked Questions

Unique Device Identification (UDI) Helpdesk

Issuing entities

Which are the designated issuing entities?

According to Commission Implementing Decision (EU) 2019/939 of 6 June 2019 the following issuing entities are designated to operate a system for assigning UDIs pursuant to Regulation (EU) 2017/745 (MDR) and Regulation (EU) 2017/746 (IVDR). The issuing entities are:

(a) GS1 AISBL

(b) Health Industry Business Communications Council (HIBCC)

(c) ICCBBA

(d) Informationsstelle für Arzneispezialitäten — IFA GmbH

The Commission Implementing Decision (EU) 2019/939 can be found here:

https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2019.149.01.0073.01.ENG&toc=OJ:L:2019:149:TOC

Basic UDI-DI

How to get a Basic UDI-DI?

A Basic UDI-DI should be assigned in compliance with the rules of the chosen issuing entity.

What is a Basic UDI-DI and how does it relate to a UDI (UDI-DI + UDI-PI)?

A Basic UDI-DI is a primary identifier for medical devices having the same intended purpose, the same risk class and the same essential design.

A Basic-UDI-DI is also a general access key for EUDAMED, identifying all data entries for the devices covered by that Basic UDI-DI.

The Basic UDI-DI does not appear on any medical device labeling and is therefore independent of any packaging levels.

The Basic UDI-DI should be identified on the:

- EU-DoC;
- Technical documentation;
- Certificates issued by notified bodies;
- Summary of safety and clinical performance (SSCP);
- Free Sales Certificates (FSC);
- Manufacturer Incident Report (MIR).

Can one Basic UDI-DI be linked with more than one UDI-DI?

Medical devices with the same intended purpose, risk class, essential design etc, are grouped under a single and unique Basic UDI-DI.

As such, a medical device that has been assigned a UDI-DI can be linked to only one Basic UDI-DI. There is, therefore, a one-to-one relationship of 1 UDI-DI per 1 Basic UDI-DI.

On the other hand, one Basic UDI-DI can be linked to multiple UDI-DIs. Therefore, there is a relationship of 1 Basic UDI-DI to N UDI-DIs.

Further information is available in the following MDCG 2018-1 rev. 4 document:

https://ec.europa.eu/health/sites/default/files/md_sector/docs/md_mdcg_2018-1_guidance_udi-di_en.pdf

UDI (UDI-DI and UDI-PI)

Where to get a UDI?

The assignment of a UDI to a specific medical device and accessory falls within the responsibilities of the legal manufacturer. The UDI should be created in line with the rules defined by the chosen issuing entity.

Systems and procedure packs according to Article 22 MDR and Kits according to IVDR (Annex VI, Part C, section 3.7) must also be assigned and bear their own UDI.

Technical files and DoC

What are technical files and the Declaration of Conformity and why are they needed?

The technical file is a set of documents providing objective evidence that the applicable MDR or IVDR requirements have been fulfilled for a specific device or group of devices. The technical documentation should include the elements set out in Annexes II and III of the MDR or IVDR.

For devices, other than Class I (MDR) and Class A (IVDR) devices, the technical documentation is part of the assessments conducted by the notified body of the legal manufacturer.

Upon request by a competent authority, the manufacturer should provide the technical documentation in its entirety, or a summary thereof.

With the Declaration of Conformity (DoC), the legal manufacturer declares under its sole responsibility that all medical devices covered by the signed DoC are compliant with the corresponding applicable requirements of the MDR or IVDR.

The minimum content of the DoC is provided in Annex IV of both regulations (MDR / IVDR).

Legacy devices

What are legacy devices?

Legacy devices are devices that, in accordance with Article 120(3) MDR and Article 110(3) IVDR, are placed on the market after the respective dates of application of the MDR or IVDR and until 26 May 2024, or until the relevant certificate becomes void, if certain conditions are fulfilled.

- devices that are class I devices under Directive 93/42/EEC, for which a declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure under the MDR requires the involvement of a notified body;
- devices covered by a valid certificate issued in accordance with Directives 90/385/EEC or 93/42/EEC prior to 26 May 2021;
- devices covered by a valid certificate issued in accordance with Directive 98/79/EC prior to 26 May 2022.

Legacy devices follow the requirements of MDD 93/42/EEC but, according to article 120(3) MDR 2017/745, some requirements of the MDR are also applicable to legacy devices. In particular: requirements relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and registration of devices. However, UDI obligations do not apply to legacy devices.

Do legacy devices need to be registered in EUDAMED?

According to MDCG-2019-05, legacy devices are to be registered in EUDAMED without a Basic UDI-DI and UDI-DI.

For registration in EUDAMED, EUDAMED will assign a EUDAMED DI and a EUDAMED ID to the device instead of the Basic UDI-DI and UDI-DI respectively. This will allow the system to work and to keep the EUDAMED design as close as possible to the MDR design. The EUDAMED DI and EUDAMED ID will be unique for a given legacy device.

The registration deadlines for these devices are those referred to in Article 123(3)(e): 18 months after the date of application provided that EUDAMED is fully functional on time, or 24 months after publication of notice referred to in Article 34(3).

In the event of a serious incident or field safety corrective action to be reported during the 18/24 months referred to in the paragraph above, if the legacy devices have not already been registered in EUDAMED, they must be registered when the serious incident/ field safety corrective action is reported.

Here the link to the MDCG 2019-05 document:

https://ec.europa.eu/health/sites/default/files/md_sector/docs/md_mdcg_2019_5_legacy_devices_registration_eudamed_en.pdf

EUDAMED

How to access eudamed? How to register a medical device?

The UDI/Device registration module is expected to be released for voluntary use in September 2021, after which registration of devices will be possible. To register devices in EUDAMED, it is necessary to first register as an Actor in the Actor registration module, which has been available since December 2020.

Further information will be provided as soon as possible.

Reusable devices and direct marking

What to do in the event of space constraints?

The requirements of MDR Annex VI, Part C, section 4.1 and 4.2 should be taken into consideration:

The UDI carrier (AIDC and HRI representation of the UDI) should be placed on the label or on the device itself and on all higher levels of device packaging. Higher levels do not include shipping containers.

The MDR (Annex VI, Part C, section 4.10) defines the exemptions for the direct marking of reusable medical devices. These are mentioned below.

The direct marking requirement 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.

In cases where, due to space constraints, the UDI information cannot be placed on the device itself, the manufacturer should explain this in the technical documentation.

In the event of significant space constraints on the unit of use packaging, the UDI carrier may be placed on the next higher packaging level.

As a result, the next higher packaging level to provide the required space for the UDI carrier must contain this information.

Systems and procedure packs and configurable devices

How to assign a UDI to procedure pack / configurable device components if they are medical devices in their own right or are implantable devices?

REQUIREMENTS FOR SYSTEMS / PROCEDURE PACKS:

According to Annex VI, Part C, section 6.3.2 of the MDR:

Device contents of systems or procedure packs shall bear a UDI carrier on their packaging or on the device itself.

Exemptions:

(a) individual single-use disposable devices, the uses of which are generally known to the persons by whom they are intended to be used, which are contained within a system or procedure pack, and which are not intended for individual use outside the context of the system or procedure pack, shall not be required to bear their own UDI carrier;

(b) devices that are exempted from bearing a UDI carrier on the relevant level of packaging shall not be required to bear a UDI carrier when included within a system or procedure pack.

REQUIREMENTS FOR CONFIGURABLE DEVICES:

According to Annex VI, Part C, section 6.4 of the MDR:

A UDI shall be assigned to the configurable device in its entirety and shall be called the configurable device UDI.

Each component that is considered a device and is commercially available on its own shall be assigned a separate UDI.

SPECIFIC REQUIREMENTS FOR IMPLANTABLE DEVICES, ACCORDING TO ANNEX VI, PART C, SECTION 6.1:

Implantable devices shall, at their lowest level of packaging ('unit packs'), be identified or marked with a UDI (UDI-DI + UDI-PI) using AIDC (automatic identification and data capture);

The UDI-PI shall have at least the following characteristics:

(a) the serial number for active implantable devices;

(b) the serial number or lot number for other implantable devices.

The UDI of the implantable device shall be identifiable prior to implantation.

If a medical device is in a pack with only non-medical devices (e.g. medicine, plastics, reagents etc.), does the UDI need to be assigned to the pack or to the medical device only?

If the "procedure pack" is covered by article 22 of the MDR, the "procedure pack" must be identified with a UDI (UDI-DI + UDI-PI). The medical device contained in the "procedure pack" must also be identified with the UDI information, if no exemptions are applicable as defined in Annex VI, Part C, section 6.3.2 of the MDR.

UDI-PI

How to create the UDI-PI?

The UDI-PI is created to provide information about the production control mechanism defined by the manufacturer for a specific device.

According to Annex VI, Part C, section 1 of the MDR (2017/745) the UDI-PI includes:

- serial number;
- lot number;
- software identification;
- manufacturing or expiry date, or both.

The manufacturer is responsible for defining the correct UDI-PI information applicable for traceability and control of manufacturing procedures. Annex VI, Part C provides more details regarding the UDI-PI information to be provided for special devices, such as active implantable devices or software-standalone devices.

If the lot number and the serial number appear on the label, do both numbers need to be part of the UDI-PI or just one or the other?

According to Annex VI, Part C, section 3.5 of the MDR, the minimum requirements for displaying the PI information are as follows:

If a lot number, serial number, software identification or expiry date appears on the label, it 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.

Result: If both serial number and lot number are provided on the label, both shall also be provided in the UDI-PI.

Rational: The manufacturer has decided to use both numbers on the label for traceability and control of production, since this is required for that specific device. Including both pieces of information in the UDI-PI helps with traceability on the market, making it possible to scan the device within the logistics chain.

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https://ec.europa.eu/health/md_newregulations/overview_en