European Commission

Unique Device Identification (UDI) System

under the EU Medical Device Regulations 2017/745 and 2017/746

MEDICAL DEVICES CHANGE OF LEGISLATION

What you need to know!

Introduction to the new UDI system and the obligations of operators

The existing regulatory framework on medical devices dates back to the 1990s and consists of three Directives. Two new Regulations (Regulation (EU) 745/2017 on medical devices and Regulation (EU) 746/2017 on *In Vitro* diagnostic medical devices) were adopted in April 2017 and entered into force on 25 May 2017. The general application dates of the two Regulations are 25 May 2020 for medical devices and 25 May 2022 for *In Vitro* diagnostic medical devices, though different timelines apply for certain specific provisions.

These Regulations introduce an EU identification system for medical devices based on a Unique Device Identifier (UDI).

The UDI system will facilitate easier traceability of medical devices, significantly enhance the effectiveness of the post-market safety-related activities for devices and allow for better monitoring by competent authorities. It will also help to reduce medical errors and to fight against falsified devices. The use of the UDI system finally should also improve purchasing and waste disposal policies and stock-management by health institutions and other economic operators.

The new system will be applied to all medical devices except custom-made and performance study/investigational devices and is substantially based on internationally recognised principles, notably by using definitions that are compatible with those used by major trade partners.[1,2]

1 IMDRF/UDI WG/N7FINAL:2013 *http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-udi-guidance-140901.pdf*
2 IMDRF/UDI WG/N48 FINAL: 2019 *Unique Device Identification system (UDI system) Application Guide - DOCX (12.5Mb)*

Article 27 of Regulation (EU) 2017/745 ('MDR') and Article 24 of Regulation (EU) 2017/746 ('IVDR') lay down that the UDI system shall consist of:

a. the production of a UDI that comprises a UDI device identifier ('UDI-DI') specific to a manufacturer and a device, providing access to the information, and a UDI production identifier ('UDI-PI') that identifies the unit of device production and if applicable the packaged devices, as specified in Part C of Annex VI;

b. the placing of the UDI carrier on the label of the device or on its packaging or in case of reusable devices on the device itself (direct marking);

c. the storage of the UDI by economic operators, health institutions and healthcare professionals, in accordance with the conditions laid down in paragraphs 8 and 9, respectively, of the Articles;

d. the establishment of an electronic database for Unique Device Identification (the 'UDI database'), which is part of the Eudamed database, in accordance with Article 28 of MDR and Article 25 of IVDR.

In accordance with the new rules, any manufacturer shall thus assign a unique UDI to a device and to all higher levels of packaging before placing that device on the market except custom-made medical devices and performance study/investigational devices. The UDI carrier shall be placed on the label of the device and on all higher levels of packaging and in case of reusable devices on the device itself (direct marking). The manufacturer shall also ensure that the information – related to the device in question - referred to in Part B and Part A, Section 2, of Annex VI of the relevant Regulation, is correctly submitted to the European Database on Medical Devices (Eudamed) as required by Article 27(3) of MDR and Article 24(3) of IVDR. The manufacturer shall also maintain unique UDIs for its devices.

NOTE: Timelines related to those obligations are indicated under question 6 of this document.

Within the EU, the manufacturer shall assign to their devices, together with a UDI, also a Basic UDI-DI, which is not yet required by other jurisdictions. The Basic UDI-DI is the main key in Eudamed and relevant documentation (e.g. certificates, declaration of conformity, technical documentation and summary of safety and clinical performance) and will also be the access key for device-related information entered in the database.

UDI issuing entities designated by the European Commission operate a system for the assignment of UDI in the EU.[3]

Frequently Asked Questions and Answers

1. What is the 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 medical device on the market. The UDI is comprised of the UDI-DI and UDI-PI. The unique identifier may include information on the lot or serial number and be able to be applied anywhere in the world.

The production of a UDI comprises the following:

- A UDI device identifier ('UDI-DI') specific to a device, providing access to the information laid down in Part B of Annex VI.
- A UDI production identifier ('UDI-PI') that identifies the unit of device production and if applicable the packaged devices, as specified in Part C of Annex VI.

2. What is the Basic UDI-DI?

The Basic UDI-DI is the main access key for device-related information in the Eudamed database and it is referenced in relevant documentation [e.g. certificates (including certificate of free sale), EU declaration of conformity, technical documentation and summary of safety and (clinical) performance)].

It is intended to identify and connect devices with the same intended purpose, risk class and essential design and manufacturing characteristics.

It is independent/separate from the packaging/labelling of the device and it does not appear on any trade item.

Any Basic UDI-DI shall identify the devices (group) covered by that Basic UDI-DI in a unique manner.

Additional information on Basic UDI-DI is available at *https://ec.europa.eu/docsroom/documents/35382*.

3. Which products are subject to the UDI system?

The UDI system should apply to all devices, except custom-made and performance study/investigational devices.

3 Issuing entities have been designated on 6 June 2019 via the Commission Implementing Decision (EU) 2019/939.

4. Who is responsible for placing the UDI carrier on the device itself, on the label and on the package of a device?

The manufacturer is responsible for complying with all UDI related requirements. This includes the assignment of the UDI (and Basic UDI-DI), the UDI (and Basic UDI-DI) registration in the Eudamed database and the placement of the UDI carrier on the label of the device or on its packaging or, in case of reusable devices, on the device itself (direct marking).

4.1 What happens in the case of Article 16 of the MDR and IVDR? Which obligations do economic operators have regarding UDI when assuming obligation incumbent on manufacturers per Article 16 of the MDR and IVDR?

Any distributor, importer or other natural or legal person that assumes the obligations incumbent on manufacturers in accordance with Article 16(1), assumes all the relevant responsibilities related to UDI, including UDI labelling.

The distributor or importer carrying out the operations described in Article 16(2) (providing translation or repackaging of devices) shall ensure that:

- the activities are performed by means and under conditions that in no way compromise the readability of the UDI carrier and its information identifying the actual device.
- the specific procedures are part of the distributor's or importer's quality management system.

A dedicated guideline with additional information on this aspect is available at *https://ec.europa.eu/docsroom/documents/31927*.

5. What is the procedure for systems and procedure packs to undergo a UDI registration?

Systems and procedure packs shall undergo a UDI registration, as described in Article 29(2) of MDR.

Before placing on the market a system or procedure pack pursuant to Article 22(1) and (3), that is not a custom-made device, the system or procedure pack producer shall assign to the system or procedure pack, in compliance with the rules of the issuing entity, a Basic UDI-DI and shall provide it to the Eudamed database together with the other relevant core data elements listed in the document *https://ec.europa.eu/docsroom/documents/31925*.

Further information on rules applicable to systems and procedure packs is available at *https://ec.europa.eu/docsroom/documents/31924*.

6. What is the mandatory deadline for a device to comply with the UDI requirements?

The obligation for UDI assignment applies as from the date of application of the two new Regulations, i.e. 26 May 2020 for medical devices and 26 May 2022 for *In Vitro* diagnostic medical devices.

The obligation for submission of UDI data in the Eudamed database applies mandatorily as from 26 November 2021 for medical devices and 26 November 2023 for *In Vitro* diagnostic medical devices (provided that registration of devices in Eudamed is fully functional before the date of application, otherwise 24 months after the availability of Eudamed functionality). However, manufacturers will be in a position to voluntarily comply with registration obligations as from 26 May 2020 for medical devices and 26 May 2022 for *In Vitro* diagnostic medical devices.

It shall be noted that, provided that Eudamed is fully functional, at any time after 26 May 2020 for medical devices and 26 May 2022 for *In Vitro* diagnostic medical devices, the full registration of devices (Article 29 of MDR and Article 26 of IVDR) remains a pre-condition for the possible registration of their relevant serious incident in Eudamed.

More information on this subject is available at *https://ec.europa.eu/docsroom/documents/34921*.

The obligation for placing the UDI carrier applies according to the following timelines:

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

NOTE: Devices which are compliant with the Regulations may be placed on the market ahead of the general application date of 26 May 2020 (MDR) and 26 May 2022 (IVDR). For more information on this aspect, please consult the answers provided to questions 5 and 6 in the following documents https://www.camd-europe.eu/wp-content/uploads/2018/05/FAQ_MDR_ 180117_V1.0-1.pdf and https://www.camd-europe.eu/wp-content/uploads/2018/05/FAQ_IVDR_180117_V1.0-1.pdf.

7. Are devices, which are compliant with the Medical Device Directives (MDD and AIMDD) and placed on the market after the application date of the Regulations (legacy devices), continue to be subject to UDI requirements?

In order to facilitate the transition to the new system, the new Regulations give manufacturers the possibility to place products on the market after the general application dates of the new Regulations (and until 26 May 2024 at the latest) by virtue of valid Directive certificates.[4]

These legacy devices are not subject to UDI obligations but they should be registered in the Eudamed database. Timelines for registration as described under question 6 also apply to these products. More information on the operational aspects of the registration of legacy devices is available at *https://ec.europa.eu/docsroom/documents/34922*.

8. What is the role of the UDI issuing entities? Who designates them?

The issuing entities operate a system for the assignment of UDIs.

Following a call for applications launched at the end of 2018, the Commission has designated the following entities:

a. GS1 AISBL

b. Health Industry Business Communications Council (HIBCC)

c. International Council for Commonality in Blood Banking Automation (ICCBBA)

d. Informationsstelle für Arzneispezialitäten (IFA) GmbH

For more information, please refer to the relevant implementing act designating the entities: Commission Implementing Decision (EU) 2019/939 of 6 June 2019 designating issuing entities designated to operate a system for the assignment of Unique Device Identifiers (UDIs) in the field of medical devices. This is available at *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*.

9. How should a UDI appear on the label or package of a device?

The UDI Carrier [Automated Identification for Data Capture (AIDC) and human readable interpretation (HRI) representation of the UDI] shall be on the label or on the device itself and on all higher levels of device packaging.

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.

Higher levels of packaging shall have their own unique UDI. Please note that shipping containers shall be exempted from the requirement.

The UDI must appear in a plain-text version/human readable information (HRI) and in a form that uses AIDC technology. AIDC means any technology that conveys the unique device identifier or the device identifier of a device in a form that can be entered into an electronic patient record or another computer system via an automated process. The HRI consists of legible characters that can easily be read by people.

If there are significant constraints limiting the use of both AIDC and HRI on the label, only the AIDC format shall be required to appear on the label.

For devices intended to be used outside healthcare facilities, such as devices for home care, the HRI shall, however, appear on the label even if this results in there being no space for the AIDC.

For other specific requirements related to the UDI carrier, please consult Section 4 of Annex VI Part C of the two Regulations.

For single-use devices of classes I and IIa medical devices and class A and class B IVD medical devices packaged and labelled individually, the UDI carrier shall not be required to appear on the packaging but it shall appear on a higher level of packaging, e.g. a carton containing several (individually packaged) devices. However, when the healthcare provider is not expected to have access, in cases such as in home healthcare settings, to the higher level of device packaging, the UDI shall be placed on the packaging (of the individual device).

For devices exclusively intended for retail point of sale, the UDI-PIs in AIDC shall not be required to appear on the point of sale packaging.

If the UDI carrier is readily readable or, in the case of AIDC, scannable, through the device's packaging, the placing of the UDI carrier on the packaging shall not be required.

4 For additional information on the general conditions for legacy devices to be placed on the market after the general application dates of the new Regulations, see the FAQs papers published by the CAMD Transitional Task-force (*https://www.camd-europe.eu/regulatory/available-now-mdr-ivdr-transitional-faqs*).

10. Are there any requirements for the PI (Production Identifier) information?

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.

The different types of UDI-PIs include serial number, lot number, software identification and manufacturing date and/or expiry date. The UDI-PI characteristics such as the lot or serial number shall be defined by the manufacturer. However:

- For active implantable devices, the UDI-PI shall include at least the serial number; for other implantable devices, the serial number or lot number.
- A configurable device UDI-PI shall be assigned to each individual configurable device.

It is important to note that no UDI-PI information can be included in the UDI database.

11. What changes in the medical device would require a new UDI-DI?

A new UDI-DI shall be required whenever there is a change that could lead to misidentification of the device and/or ambiguity in its traceability. In particular, a new UDI-DI shall be required in the case of any change of the following elements: name or trade name, device version or model, labelled as single use, packaged sterile, need for sterilisation before use, quantity of devices provided in a package, critical warnings or contra-indications and CMR/Endocrine disruptors.

A UDI-DI shall be associated with one and only one Basic UDI-DI.

Additional information on this aspect is available at *https://ec.europa.eu/docsroom/documents/35382?locale=en*.

12. What are the obligations of economic operators and health institutions in relation to UDI?

According to the two medical devices Regulations, manufacturers shall be responsible for the UDI assignment and placement of the UDI carrier, the initial submission and updates of the identifying information and other device data elements in the Eudamed database. Manufacturers shall update the relevant database record within 30 days of a change being made to an element, which does not require a new UDI-DI.

Distributors and importers shall verify that, where applicable, a UDI has been assigned by the manufacturer.

All economic operators and health institutions shall 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. Please note that the Commission may decide to adopt implementing acts to expand the scope of devices for which economic operators shall store and keep the UDI.

13. Is the software subject to UDI rules?

The UDI shall be assigned at the system level of the software.

Only software that is commercially available on its own and software that constitutes a device in itself shall be subject to that requirement.

The software identification shall be considered the manufacturing control mechanism and shall be displayed in the UDI-PI.

UDI requirements for software are laid down in Annex VI Part C of the two medical device Regulations.

A dedicated guideline with additional information on this aspect is available at *https://ec.europa.eu/docsroom/documents/31926*.

ET-02-16-953-EN-N

14. Direct marking of reusable devices. Are there exemptions?

Devices that are reusable shall bear a UDI carrier on the device itself.

The UDI carrier for reusable devices that require 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 UDI carrier shall be readable during normal use and throughout the intended lifetime of the (reusable) device.

The requirements shall not apply to the device in case of the following circumstances:

- any type of direct marking would interfere with the safety or performance of the device;
- the device cannot be directly marked because it is not technologically feasible.

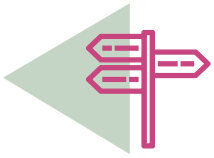
15. Is there an adjudication process for ad-hoc exemptions foreseen for medical devices?

An adjudication process to allow for ad-hoc exemptions is not envisaged in the EU. All devices are therefore subject in principle to UDI requirements, with the only exceptions explicitly stated in the Regulation.

However, the UDI Expert Group will analyse requests for adaptation of UDI requirements to certain specific device types and recommend the Medical Device Coordination Group (MDCG) to issue dedicated guidelines, where necessary.

16. What are the UDI and device data sets to be provided in Eudamed?

Two dedicated guidelines containing information on this aspect, concerning the MDR and IVDR, are available at *https://ec.europa.eu/growth/sectors/medical-devices/new-regulations/guidance_en*.



Guidance

Further Guidance on UDI is available at *https://ec.europa.eu/growth/sectors/medical-devices/guidance_en*.

***NOTE:** The Commission intends to expand this document on a regular basis based on the assessment of most frequently asked questions and/or of other specific needs.*

01/08/2019

Funded under the Third EU Health Programme

https://ec.europa.eu/growth/sectors/medical-devices_en

ISBN:XXXXX DOI: XXXXX