European Commission

Frequently Asked Questions

Unique Device Identification (UDI) Helpdesk

1. Are there any restrictions under MDR and IVDR in using different issuing entities for the assignment of the Basic UDI-DI and the UDI-DI?

No restriction is foreseen in MDR and IVDR for using different issuing entities to assign the Basic UDI-DI and the UDI-DI to a device.

As regards the registration of the device in EUDAMED, the Basic UDI-DI information is linked to the UDI-DI information identified on the first packaging level. The current existing data dictionary for the data elements allows for the Basic UDI-DI to have a different issuing entity than the UDI-DI.

2. Will devices placed on the market packaged in different quantities require a different Basic UDI-DI? E.g., Syringe XYZ in 30 units and Syringe XYZ in 50 units?

In case the same medical device (with the same indented purpose and same design characteristics) is packaged in different quantities, the Basic UDI-DI remains the same as it serves to connect devices with 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.

For more details, please review the "*UDI/DEVICES USER GUIDE*" and "*Guidance on Basic UDI-DI and changes to UDI-DI*", provided on the following website:

https://ec.europa.eu/health/system/files/2021-11/md_eudamed_udi-devices-user-guide_en_0.pdf

https://ec.europa.eu/health/system/files/2021-04/md_mdcg_2018-1_guidance_udi-di_en_0.pdf

3. If a device is sold exclusively at retail point of sale, are the UDI PI information to be provided in the AIDC format?

The UDI-PI information is not required to appear on the label in AIDC format on the point of sales packaging if the device is **exclusively** sold at retail point of sale. The MDR 2017/745 excludes the UDI PI information from AIDC format on the point of sales packaging level, however, the exception is not applicable for the HRI, which needs to be identified on the point of sales packaging. The mentioned exception is defined for the sales packaging level only, so the primary packaging level must be in compliance with UDI requirements as defined in MDR (UDI-DI and UDI-PI in both AIDC and HRI format.)

Reference: Annex VI, part C, section 4.4:

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.

4. What is the difference between the Unit of Use DI and 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. The UDI-DI shall be unique at each level of device packaging.

This mandatory, fixed portion of a UDI identifies a manufacturer's specific product and package configuration.

The Unit of Use DI (UoU DI) is an **identifier** (following the UDI rules of the chosen issuing entity) assigned to an individual medical device when a UDI is not labeled on the individual device at the level of its unit of use. Its purpose is to provide a UDI-DI to identify a device used on a patient when a UDI-DI does not appear on the label of the device.

For example: If the lowest base packaging level with a identified UDI, has a device count greater than 1, a Unit of Use DI (UoU DI) shall be assigned.

If the device is not directly marked and the base quantity of the device is greater than one, the Unit of Use DI shall be provided within EUDAMED.

The Issuing entity for the Unit of Use DI Code is the same as the UDI-DI.

The same Unit of Use DI can be used for several Devices.

According to Annex VI, part C, section 1, the Unit of Use-DI is defined as follows:

> *The Unit of Use DI serves to associate the use of a device with a patient in instances in which a UDI is not placed on the individual device at the level of its unit of use, for example in the event of several units of the same device being packaged together.*

https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0745

Please refer for further details to:

"Appendixes E-I of IMDRF N48 under the EU regulatory framework for medical devices" (May 2021; MDCG 2021-10)

https://ec.europa.eu/health/system/files/2021-06/md_2021-10_en_0.pdf

5. What are the rules and exceptions for UDI carrier direct marking on medical devices?

According to Annex VI, part C, section 4.10, the rules and exemption for the UDI carrier are defined as follows:

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

The UDI carrier is the means of conveying the UDI by using AIDC and, if applicable, the HRI. The UDI carrier (AIDC and HRI representation of the UDI) shall be placed on the label or on the device itself and on all higher levels of device packaging.

It is noted that single use devices are not covered by this requirement.

6. What are the rules for UDI Carrier assignment for software medical devices?

The UDI information for SW medical device must be provided in addition to the regulatory required information for the SW medical device in question.

The assignment criteria for the UDI carrier are defined in Annex VI, part C, section 6.5 as follows:

> **6.5.1** *The UDI shall be assigned at the system level of the software. Only software which is commercially available on its own and software which constitutes a device in itself shall be subject to that requirement.*
>
> *The software identification shall be considered to be the manufacturing control mechanism and shall be displayed in the UDI-PI.*
>
> **6.5.2** *A new UDI-DI shall be required whenever there is a modification that changes:*
>
> **a.** *the original performance;*
> **b.** *the safety or the intended use of the software*;
> **c.** interpretation of data.

Such modifications include new or modified algorithms, database structures, operating platform, architecture or new user interfaces or new channels for interoperability.

6.5.3 *Minor software revisions shall require a new UDI-PI and not a new UDI-DI.*

Minor software revisions are generally associated with bug fixes, usability enhancements that are not for safety purposes, security patches or operating efficiency.

Minor software revisions shall be identified by a manufacturer-specific form of identification.

6.5.4 *UDI placement criteria for software*

- **a.** *where the software is delivered on a physical medium, e.g. CD or DVD, each packaging level shall bear the human readable and AIDC representation of the complete UDI. The UDI that is applied to the physical medium containing the software and its packaging shall be identical to the UDI assigned to the system level software;*
- **b.** *the UDI shall be provided on a readily accessible screen for the user in an easily-readable plain-text format, such as an 'about' file, or included on the start-up screen;*
- **c.** *software lacking a user interface such as middleware for image conversion, shall be capable of transmitting the UDI through an application programming interface (API);*
- **d.** *only the human readable portion of the UDI shall be required in electronic displays of the software. The marking of UDI using AIDC shall not be required in the electronic displays, such as 'about' menu, splash screen etc.;*
- **e.** *the human readable format of the UDI for the software shall include the Application Identifiers (AI) for the standard used by the issuing entities, so as to assist the user in identifying the UDI and determining which standard is being used to create the UDI.*

For more details, please refer to the MDCG 2018-5 document: https://ec.europa.eu/health/sites/default/files/md_sector/docs/md_mdcg_2018_5_software_en.pdf

Additionally, the following document "*Appendixes E-I of IMDRF N48 under the EU regulatory framework for medical devices*" (May 2021; MDCG 2021-10) may assist also: https://ec.europa.eu/health/system/files/2021-06/md_2021-10_en_0.pdf

7. What is the EMDN and how to get access to it?

The EMDN has primarily a regulatory purpose to support MDR and IVDR requirements. It also plays a key role in MDR/IVDR device documentation and technical documentation, sampling of technical documentation conducted by notified bodies, post-market surveillance, vigilance and post-market data analysis, etc.

It is intended to support all actors in their activities under the MDR/IVDR and provides key device descriptions to patients as regards their own devices and all other devices available on the market and registered in EUDAMED.

It also aims at supporting the functioning of the European database on medical devices (EUDAMED). Among its various uses, it will be utilized by manufacturers for the registration of medical devices in EUDAMED, where it will be associated to each Unique Device Identifier – Device Identifier (UDI-DI).

The EMDN is fully available in the EUDAMED public site:

https://ec.europa.eu/tools/eudamed/#/screen/home

The EMDN can also be accessed and downloaded in pdf and excel format following this link: https://webgate.ec.europa.eu/dyna2/emdn/.

This platform is also a submission platform for any linguistic, syntax, translation feedback users and the wider healthcare community may wish to provide.

More information can be found in the EMDN Q&A endorsed by the MDCG:

https://ec.europa.eu/health/sites/default/files/md_topics-interest/docs/md_q-a_emdn_en.pdf

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