MDCG 2022-7 – Questions and Answers on the Unique Device Identification system under Regulation (EU) 2017/745 and Regulation (EU) 2017/746

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Introduction

This document presents questions and answers on the Unique Device Identification system (UDI system) established under Regulation (EU) 2017/745 on medical devices[1] (MDR) and Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices[2] (IVDR). The questions covered by the document aim to provide further detail to operators on the application and practical implementation of the UDI requirements.

Note: This document is non-exhaustive and should be read in conjunction with the MDR/IVDR. Of additional relevance are the UDI FAQ[3] 'Introduction to the new UDI system and the obligations of operators', MDCG guidance[4] and other documents covering the UDI requirements[5].

Questions & Answers

A. UDI-DI

1. Where the number of items in a device package changes, is a new UDI-DI assignment required?

A new UDI-DI assignment is required whenever there is a change that could lead to misidentification of the device and/or ambiguity in its traceability.[6] In particular, a new UDI-DI (created in compliance with the rules of the designated issuing entities[7]), is required in the case of any change of the following elements[8]:

- name or trade name,
- device version or model,
- labelled as single use,
- packaged sterile,
- need for sterilization before use,
- quantity of devices provided in a package,
- critical warnings or contra-indications (e.g. Containing latex or DEHP), CMR/Endocrine disruptors[9].

For example, where the number of devices in a package changes e.g. from 5 to 10, a new UDI-DI assignment to the package would be required. This is because a change in pack quantity would lead to a misidentification of the device in this case and may

[1] Regulation (EU) 2017/745 on medical devices.
[2] Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices.
[3] See the 'UDI FAQ'.
[4] *Please see the MDCG guidance documents under the 'UDI Unique Device Identifier (UDI)' section of Commission's* website
[5] *For more information, please also refer to the 'Questions & Answers for applicants, marketing authorisation holders of medicinal products and notified bodies with respect to the implementation of the Medical Devices and In Vitro Diagnostic Medical Devices Regulations ((EU) 2017/745 and (EU) 2017/746)' document.*
[6] For further information, see Section 3.9, Part C, Annex VI to MDR/IVDR.
[7] Please, for more information refer to Articles 27 (2) and (3) MDR and 24 (2) and (3) IVDR. Find here the link to Commission Implementing Decision (EU) 2019/939 designating issuing entities to operate a system for the assignment of UDIs.
[8] Annex VI, Part C, Section 3.9 MDR/IVDR. In particular, see letter (f).
[9] Guidance on Basic UDI-DI and changes to UDI-DI - MDCG 2018-1

cause traceability issues where incidents occur. See: (Article 27(4) MDR/Article 24(4) IVDR).

2. **Are the UDI-DIs of single-use reprocessed devices the same as the original devices?**

   If reprocessing of single-use devices is permitted by national law, paragraph (2) of Article 17 provides that any natural or legal person who reprocesses a single-use device to make it suitable for further use, shall be considered the manufacturer of the reprocessed device and shall assume the obligations incumbent on manufacturers, including the ones referred to in Chapter III of the MDR. Namely, these include UDI assignment (e.g. Basic UDI-DI and UDI), UDI placement on the device label and all higher levels of packaging and UDI Eudamed registration obligations.

   Consequently, when a single-use device is reprocessed in accordance with paragraph (2) of Article 17, given that the person responsible for the reprocessing assumes the obligations laid down Chapter III MDR, they shall assign to the reprocessed device a new Basic UDI-DI and UDI. The person responsible for the reprocessing should keep the UDI of the original product as part of the technical documentation and the organisation's quality management system (QMS) to ensure traceability.

   However, in case the single-use device is reprocessed in accordance with paragraph (3) of Article 17 (i.e. reprocessed and used within a health institution), a new UDI is not required and Commission Implementing Regulation (EU) 2020/1207 applies, in combination with other possible requirements in national rules on reprocessing of single-use devices.

3. **Under Article 25 (1) in conjunction with Article 27 (8) MDR, and Article 22 (1) in conjunction with Article 24 (8) IVDR, are economic operators required to maintain registry of all UDIs of the devices which they have supplied or with which they have been supplied?**

   According to Article 25 (1) MDR and 22 (1) IVDR, distributors and importers[10] shall cooperate with manufacturers and authorised representatives to achieve an appropriate level of traceability. Moreover, distributors and importers have an obligation to contribute to the maintenance of an adequate level of traceability of medical devices along the supply chain. Articles 27 (8) MDR and 24 (8) IVDR provide that economic operators shall also store and keep the UDI of the devices which they have supplied or with which they have been supplied, if those devices are class III implantable devices (for MDR devices) or if those devices belong to devices, categories or groups of devices determined by a measure referred to in Article 27 (11) (a) MDR or Article 24 (11) (a) IVDR. Whilst solutions to implement full traceability should be put in place, the "storing" of all UDIs (other than those mentioned in Articles 27(8) MDR and 24 (8) IVDR), is not required. However, storing of UDIs may be a useful tool to ensure traceability.

[10] Please, for further information refer to MDCG 2021-27 - "Questions and Answers on Articles 13 & 14 of Regulation (EU) 2017/745 and Regulation (EU) 2017/746".

4. **Do the following described changes to substance-based medical devices require the assignment of a new UDI-DI?**
   i. **Formula quantity changes (e.g. from 100 to 120ml) but nothing else changes.**
   ii. **Additional claim but the product remains the same otherwise and looks exactly the same.**

Any changes that may lead to the misidentification of the device or ambiguity in its traceability require the assignment of a new UDI-DI (Annex VI, Part C, Section 3.9). Although these described changes are not specifically listed in section 3.9, they may pose a risk for device traceability if the same UDI-DI is used. According to MDR provisions on the general obligations of the manufacturer, and as outlined in MDCG guidance 2021-19[11] the manufacturer

- should maintain a system for the management of modifications to the devices, whereby verification of the UDI assignments made in accordance with Article 27(3) MDR to all relevant devices is done, and
- should ensure consistency and validity of information provided in accordance with Article 29 MDR.

As regards these specific examples, a new UDI-DI would be required, when a change in formulation or an extension of claims (e.g. additional medical purpose) is introduced.

B. Basic UDI-DI

1. **How should the Basic UDI-DI be assigned? How should the 'grouping' for design or manufacturing characteristics be determined?**

The Basic UDI-DI is the main key in the database and relevant documentation (e.g. product certificate, declaration of conformity, technical documentation and summary of safety and clinical performance (SSCP)) to connect devices with same intended purpose, risk class and essential design and manufacturing characteristics.

According to the MDR provisions on UDI and on the basis of the MDCG UDI Guidance document[12], the decision on how to assign the Basic UDI-DI to devices should be taken by the manufacturer. Indeed the manufacturer has the relevant technical knowledge about their devices and can evaluate which assignment solution would be the most appropriate based on their internal processes.
For devices that require a product certificate from a notified body it is recommended that the manufacturer aligns with the respective notified body regarding groupings to be established under the Basic UDI-DI. This is to facilitate effective handling with

[11] Guidance note on integration of the UDI within an organisation's quality management system - MDCG 2021-19
[12] Guidance on Basic UDI-DI and changes to UDI-DI - MDCG 2018-1

respect to product certificates and supporting regulatory documentation (e.g. SSCP and PSUR) which reference the Basic UDI-DI(s) of the device(s) covered by that product certificate.

2. **Where the same device model is sold under the brand name of the manufacturer and also by a distributor under its name, registered trade name or registered trademark, can the Basic UDI-DI assigned to the manufacturer's device also be used by the distributor?**

   Any distributor, importer or other natural or legal person making available on the market a device under its name, registered trade name or registered trademark, assumes the obligations incumbent on manufacturers in accordance with Article 16(1) MDR/IVDR including all the relevant responsibilities related to UDI. This involves Basic UDI-DI and UDI assignment and placing the UDI-carrier on the label where required.

   Therefore, in the above case, the distributor, assuming the obligations of the manufacturer will have to assign a new Basic UDI-DI to devices sold under its name, registered trade name or registered trademark. This means that the distributor (importer or other natural or legal person, as applicable) must also apply for registration as Manufacturers, receive a Single Registration Number (SRN), apply for the appropriate conformity assessment procedure and provide UDI/Device registration among other obligations related to Eudamed.[13]

   However, in accordance with the exception set out in Article 16(1)(a), the manufacturer and 'distributor' may enter into an agreement whereby the manufacturer is identified as such on the label and is responsible for meeting the requirements of the MDR, including those related to UDI assignment, registration and labelling. Under this exception, devices made available under a distributor's name, registered trade name or registered trademark, should retain the Basic UDI-DI assigned by the manufacturer, provided that the manufacturer is identified as such on the label.

   Note: Article 16(1)(a) sets out that this exception applies for importers and distributors who enter in such agreements with the manufacturer.

3. **A device consists of an installation, where patient facing modules are linked at a distance with a physician facing module that has most of the controls and displays needed for operating the device. The components use an external network for communication. Both components can only be used together and are only sold in this combination. These devices cannot function without the other and they are effectively operating as a single device. Can both components be covered by the same Basic UDI-DI?**

   In this example, given the components can only be used together and sold in this combination, they could be assigned the same Basic UDI-DI.

[13] Please, also see Guidance on 'Clarifications of UDI related responsibilities in relation to Article 16 of the Medical Device Regulation (EU) 2017/745 and the In-Vitro Diagnostic Medical Device Regulation (EU) 2017/746' - MDCG 2018-6

4. **Should Declarations of Conformity (DoC) reference Basic UDI-DIs including the check digit?**

   The check digit is an integral part of the Basic UDI-DI[14]. The complete Basic UDI-DI (including the check digit) and related information have to be provided to Eudamed. As the Basic UDI-DI is the main key to access related information in Eudamed, the check digit should appear on the DoC. Without the check digit, the Basic UDI-DI would be incomplete.

5. **Can a Declaration of Conformity (DoC) reference more than one Basic UDI-DI? Can one Basic UDI-DI be referenced in more than one DoC?**

   The DoC may reference more than one Basic UDI-DI, in accordance with Annex IV, paragraph (“the Basic UDI-DI”). In addition, the same Basic UDI-DI can be referenced in more than one DoC.

C. UDI Labelling

1. **Where does the UDI carrier need to be placed on the label?**

   In accordance with Annex VI, Part C, Section 4.1, the UDI Carrier (Automatic identification and data capture (AIDC) and Human Readable Interpretation (HRI) representation of the UDI) shall be placed on the label or on the device itself and on all higher levels of device packaging.

   However, in accordance with Annex VI, Part C, Section 4.2, in the event of there being significant space constraints on the unit of use packaging, the UDI carrier may be placed on the next higher packaging level.

   In addition, in accordance with Annex VI, Part C, Section 4.3, for single-use devices of classes I and IIa 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 to the higher level of device packaging, in cases such as in home healthcare settings, the UDI shall be placed on the packaging of the individual device.

   There are also other exemptions that could apply should the devices be part of a system or procedure pack and a certain class of devices (see Annex VI, Part C, Sections 4.3 and 6.3)

[14] See also ‘MDCG guiding principles for issuing entities rules on Basic UDI-DI’ – MDCG 2019-1

2. **Are the EU and US UDI requirements the same with respect to UDI labelling? Where a product is sold in the US and is compliant with the FDA UDI labelling requirements, can the same UDI product labelling be used when a placing a product on the market in the EU?**

   The EU and US UDI systems were established through collaborative work at International Medical Device Regulators Forum (IMDRF) level[15]. As such, whilst the two UDI systems are largely aligned, some differences also exist based on jurisdictional regulatory requirements. For example, the Basic UDI-DI is an additional EU requirement, not present in the US UDI system.

   In addition, the EU designated four issuing entities under Commission Implementing Decision (EU) 2019/939[16] to operate the system for UDI assignment in the EU, only 3 of which operate in the US market.

   As such, on a case-by-case analysis, where devices intended to be placed on both the EU and US market have been assigned UDIs in accordance with rules of an issuing entity operating in both jurisdictions, then the UDI product labelling could be the same. However, where a change in UDI-DI is triggered in accordance with the rules of that jurisdiction, the product label should be adapted accordingly.

   For further practical information and examples on how issuing entities standards should be applied for regulatory compliant UDI assignment and labelling of products in the EU and the US market respectively, the issuing entities may be contacted. For the EU, information is also available on the Commission's website.[17]

D. UDI Rules for Systems and procedure packs (SPPs) and configurable devices

1. **Should a system or procedure pack[18] be assigned its own UDI? Or can the UDI assigned to the devices in the system or procedure pack be used?**

   Systems and procedure packs shall be assigned and bear their own UDI (Annex VI, Part C, Section 3.7). The natural or legal person responsible for placing on the market a system or procedure pack shall therefore identify it with its own UDI, including both UDI-DI and UDI-PI (Annex VI, Part C, Section 6.3.1).

[15] Please see documents on the IMDRF website, noting in particular N48 - Unique Device Identification system (UDI system) Application Guide and N53 - Use of UDI Data Elements across different IMDRF Jurisdictions.
[16] Please see 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
[17] Commission medical devices website
[18] Please, for further information also see IMDRF Unique Device Identification system (UDI system) Application Guide - Appendix G, as endorsed at EU level in MDCG 2021-10 - 'The status of Appendixes E-I of IMDRF N48 under the EU regulatory framework for medical devices'.

In line with the above, the UDI assigned to the specific devices in the system or procedure pack cannot be used to identify nor be reflected on the UDI labelling of the system or procedure pack itself.

2. Where should the UDI carrier be placed on systems and procedure packs?

According to Article 22 (5) MDR, the system or procedure pack shall be accompanied by the information referred to in Annex I, section 23.2, letter (h), namely the information on the label, which include the UDI carrier.

MDR Annex VI, Part C, Section 6.3.3 (a) clarifies that as a general rule, the UDI carrier for a system or procedure pack shall be affixed to the outside of the packaging. Part (b) of the same section further specifies that 'the UDI carrier shall be readable, or, in the case of AIDC, scannable, whether placed on the outside of the packaging of the system or procedure pack or inside transparent packaging'.

In the case of devices in a system not packaged together, before placing the system on the market, the natural or legal person responsible should assign (identify) the system with a UDI, and ensure that the UDI carrier is affixed so that users may have access to it, including when the system is installed/is used or operating.

Regarding the devices contained in the system or procedure pack however, they should, as a general rule, bear their own UDI carrier, either on their packaging or on the device itself (Annex VI, Part C, Section 6.3.2). Exemptions to this rule are outlined in subparagraphs (a) and (b) of Annex VI, Part C, Section 6.3.2 and further information/clarification is also provided in Section 3.2. of MDCG 2018-3 Rev.1.

Note: the UDI rules under section 6.3 of Annex VI, Part C MDR pertain to systems and procedure packs referred to in Article 22 (1) and (3) MDR.

Finally, according to Article 22(4) MDR, in case the system or procedure pack incorporates devices which do not bear a CE marking (and do not have their own UDI assigned), the system or procedure pack shall be treated as a device in itself and the natural or legal person responsible for it assumes the obligations of a manufacturers, which include those on UDI and Basic UDI-DI assignment and placing the UDI-carrier on the label.

3. Wat is the difference between a Configurable device and a Configuration?

A **configurable device** is a device that consists of several components which can be assembled by the manufacturer in multiple configurations. Those individual components may be devices in themselves.

Example of configurable devices include:

- computed tomography (CT) systems, ultrasound systems, anaesthesia systems, physiological Monitoring systems, radiology information systems (RIS).

A configuration is a combination of items of equipment, as specified by the manufacturer, that operate together as a device to achieve an intended purpose. The combination of items may be modified, adjusted or customized to meet specific needs. Configurations include inter alia:

- gantries, tubes, tables, consoles and other items of equipment that can be configured/combined to deliver an intended function in computed tomography.
- ventilators, breathing circuits, vaporizers combined to deliver an intended function in anaesthesia.

4. Is a Configuration a combination of parts that are not devices in themselves?

According to the definition set out in Annex VI, part C, Section 1, a configuration is a combination of items of equipment that operate together as a device to achieve an intended purpose. The combination of items may be modified, adjusted or customised to meet specific needs. The configuration in itself is qualified as a medical device. However, as the definition refers to items of equipment, it does not exclude that these individual items of equipment may be qualified as medical devices in their own right (See definition of medical device Article 2(1) MDR – 'instruments, apparatus, appliance, material or other article'… 'alone or in combination').

5. Is a Configurable device always a combination of devices, each of which is a device in its own right?

No, not always. A configurable device can consist of several components, some of which may be considered a device in their own right.

6. What are the UDI requirements applicable to a Configurable device?

In accordance with Annex VI, Part C, Section 6.4 a UDI shall be assigned to the configurable device in its entirety and shall be called the configurable device UDI[19]. The configurable device UDI-DI shall be assigned to groups of configurations, not per configuration within the group. (A group of configurations is defined as the collection of possible configurations for a given device as described in the technical documentation).

A configurable device UDI-PI shall be assigned to each individual configurable device.

The carrier of the configurable device UDI shall be placed on the assembly that is most unlikely to be exchanged during the lifetime of the system and shall be identified as the

[19] Please, for further information on configurable devices, also see IMDRF Unique Device Identification system (UDI system) Application Guide - Appendix H, as endorsed at EU level in MDCG 2021-10 - 'The status of Appendixes E-I of IMDRF N48 under the EU regulatory framework for medical devices'.

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

Moreover, in accordance with Article 29 (1) MDR, the configurable device shall be assigned a Basic UDI-DI as it is considered a device in its own right.

E. Retail point of sale, promotional packs and marketing related samples

1. **Should devices being used for marketing purposes be assigned and bear a UDI?**

   Where such devices fall under the provisions of 'devices for special purposes' set out in Article 21 (3) MDR or Article 19 (3) IVDR, and are presented at trade fairs, exhibitions, demonstrations or similar events, these devices do not need to comply with UDI requirements. This is provided a visible sign clearly indicates that such devices are intended for presentation or demonstration purposes only and cannot be made available until they have been brought into compliance with the Regulation. These devices may not be put into service or placed on the market.

   However, where such devices being used for marketing purposes are devices which claim compliance with the Regulations, and are distributed as free samples to consumers (e.g. distribution of free condoms) the UDI requirements apply.

2. **What is intended by `point of sale packaging` referred to in MDR Annex VI, Part C, Section 4.4, for products exclusively intended for retail point of sale?**

   The 'point of sale packaging' referred to in MDR Annex VI, Part C, Section 4.4**,** is specific to devices exclusively sold in the retail context, and is considered the final packaging in which a device is sold to a customer. It is intended as the level at which the device reaches the end user in the retail context.

3. **What is understood by the "unit of use" in relation to products exclusively intended for retail point of sale?**

   The Unit of Use DI (UoU) is defined in Annex VI, Part C, of Regulation 2017/745: it serves to associate the use of a device with a patient in instances in which a UDI is not labelled 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.

   Whilst the Unit of Use DI (UoU) is applicable in a healthcare or hospital setting, for products made exclusively available at a retail point of sale associating the use of device with a patient is not necessarily relevant nor required and therefore a UoU-DI is not applicable.

Further examples of the UoU DI in practice can be found in the IMDRF N48 UDI Application guide[20].

F. Kits

1. What is a kit and what are the UDI requirements applicable?

Article 2 (11) IVDR, defines a 'kit' as set of components that are packaged together and intended to be used to perform a specific in vitro diagnostic examination, or a part thereof[21]. According to Annex VI, part C, Section 3.7 IVDR a kit shall be assigned and bear their own UDI.

2. How should UDI requirements be applied to kit components?

According to Annex VI, part C, Section 3.7 IVDR a kit shall be assigned and bear their own UDI. That means that regardless of whether the components in the kit are devices with its own UDI or not.

Thus, a component does not need to bear a UDI but should if the component is considered to be a device on its own and is commercially available on its own. To this end, IVDR Annex VI, Part C, Section 3.6 outlines: "Each component that is considered to be a device and is commercially available on its own shall be assigned a separate UDI unless the components are part of a configurable device that is marked with its own UDI."

Example of a component that does need to be assigned a UDI: A kit component, which meets the definition of a medical device, and is part of multiple different kits but never marketed on its own. The distribution of the kit component is restricted to a closed supply chain. It is exclusively transported in bulk to a manufacturer or distributor and combined into a kit before entering the retail supply chain.

3. Do UDI-DIs of kit components intended for retail points of sale need to appear on the outside of the kit (according to the IVDR)?

Where this is a kit exclusively intended for retail points of sale, the products would require only UDI-DI in the AIDC, but a full UDI in HRI. The identification and traceability of the specific batches of product would be managed through the information presented on the pack i.e. HRI UDI and LOT XXXXX, Expiry date etc. In this case the conclusion would be that printing of component UDI-DIs on the outside of the kit is not required.

[20] Please, for further information on UoU, also see IMDRF Unique Device Identification system (UDI system) Application Guide - Appendix E, as endorsed at EU level in MDCG 2021-10 - 'The status of Appendixes E-I of IMDRF N48 under the EU regulatory framework for medical devices'.
[21] Please, for further information on kits, also see IMDRF Unique Device Identification system (UDI system) Application Guide - Appendix G, as endorsed at EU level in MDCG 2021-10 - 'The status of Appendixes E-I of IMDRF N48 under the EU regulatory framework for medical devices'.
Please also note that a kit is only applicable in the context of IVDs.

UDI-DI, UDI-PI and Basic UDI-DI should be assigned to the kit itself. The UDI carrier should show the UDI-DI of the kit. The UDI-DI of each component does not need to be part of the UDI carrier of the kit.

It can be noted that the exemption regarding retail point of sales packages only applies to the printing of UDI-PI in AIDC format.

G. UDI and Eudamed

1. **Is it possible to create UDI records manually in Eudamed[22]? If yes, can they be updated or deleted, if obsolete?**

   Information on registration of UDIs in the UDI/Device module can be found in the Eudamed section of the European Commission website.

2. **Do manufacturers need to report the UDI-PI to the Eudamed database?**

   The UDI-PI does not need to be reported to the UDI/Device registration module of Eudamed. However, the UDI-PI[23] type (e.g. expiry date or manufacturing date, lot number, serial number) needs to be provided for device registration to the Eudamed UDI/Device registration module.
   When reporting vigilance incidents such as serious incidents and Field Safety Corrective Actions[24], the UDI-PI of the individual device that is involved in the incident should be provided to the Eudamed Vigilance module.

[22] Should you need info on M2M data exchange services, you can consult also Guidelines for Member States on the use of Data exchange solutions.
[23] The manner in which the production of the device is controlled (the type of UDI-PI that is used for production control) is required to be identified in the UDI / device registration module (expiry date or manufacturing date, lot number, serial number or software identification).
[24] Please see Article 27(5) of the MDR and Article 24(5) of the IVDR 'the UDI shall be used for reporting serious incidents and field safety corrective actions in accordance with Article 87 MDR and Article 82 IVDR'.