MDCG 2018-1 Rev.4

Guidance on BASIC UDI-DI and changes to UDI-DI

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MDCG 2018-1 Rev 4 changes	
Section - The Basic UDI-DI	Deletion of the word 'group' in paragraph 3
Section - Changes of UDI-DI	Point 3 on Maximum number of Reuses added.

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Introduction

The new Medical Device Regulations (EU) 2017/745 and (EU) 2017/746 introduce a Unique Device Identification (UDI) system for medical devices.

Main provisions related to the establishment of the UDI system are contained in Chapter III and Annex VI of the two medical device Regulations.

The main features of the UDI system and relevant obligations for operators will be provided in a dedicated Q/A paper to be published by the Commission in spring 2018.

This guidance is intended to provide a clarification on the notion of Basic UDI-DI, its use in relevant documentation and the factors triggering UDI-DI changes.

The Basic UDI-DI

The Basic UDI-DI is the main key in the database and relevant documentation (e.g. certificates, declaration of conformity, technical documentation and summary of safety and clinical performance) 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.

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

Link with between Basic UDI-DIs and certificates or declaration of conformity

In accordance with Annex XII of the medical device Regulations, the scope of the certificates shall unambiguously identify the device or devices covered. The scope of EU technical documentation assessment certificates, EU type-examination certificates and EU product verification certificates shall include, together with the Basic UDI-DI, a clear identification, including the name, model and type, of the device or devices, the intended purpose, as included by the manufacturer in the instructions for use and in relation to which the device has been assessed in the conformity assessment procedure and the risk classification.

Each of the abovementioned certificates shall identify and cover all devices associated with the same Basic UDI-DI, that is referred to in that certificate.

The association between different Basic UDI-DIs, where applicable, shall be identified through the technical dossiers.

In accordance with Annex IV of the two Regulations, the declaration of conformity shall contain the Basic UDI-DI and the product and trade name, product code, catalogue number or other unambiguous reference allowing identification and traceability of the device covered by the EU declaration of conformity.

Changes of 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 sterilization before use, quantity of devices provided in a package, critical warnings or contra-indications (e.g. containing latex or DEHP), CMR/Endocrine disruptors[1] [2].

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

Regarding changes to the specific data elements listed below[3], the following considerations should be noted:

1. Is the Device Directly Marked (Yes/No)

The database design will force the creation of a new UDI-DI only if there is a change from Yes to No and not vice versa for this data element.

2. Manner in which production of the device Is controlled (expiry date or manufacturing date, lot number, serial number, software identification) - Type of UDI-PI

As long as there is no change to the label, a change to this data element will not require the allocation of a new UDI-DI.

[1] It should be noted that a new regulatory decision classifying an existing product as CMR/Endocrine disruptor might not result in a new UDI-DI for products already containing that substance. The decision on whether to assign a new UDI-DI should be based on the conformity assessment of the product with regard to the impact of the information provided and the significance of the change.

[2] Specific attention shall be paid to the fact that changes of colour or language might also require a new UDI-DI when those changes might lead to misidentification of product or change the product safety/performance. For example:

A- Change of colour coding of e.g. connectors, latex-free surgical gloves, blood tubes

B- Two identical self-testing devices, that exist in parallel and cannot be substituted due to local labelling requirements (IVD Article 10(10) of Regulation 746/2017), requires different UDI-DIs

Specifications of EU designated issuing entity should be used as a reference source to identify other possible examples.

[3] Please refer to Guidance UDIWG 2018-1 on "UDI database. Definitions, descriptions and formats of the UDI core elements' available at https://ec.europa.eu/docsroom/documents/28669

3. Maximum number of Reuses

Annex VI Part B, 17 states that the manufacturer shall provide to the UDI database the maximum number of reuses of the device concerned, if applicable.

'If applicable' should be understood to cover those devices where based on clinical evidence and as a result of the risk management process, a manufacturer has demonstrated a maximum number of reuses, which should not be surpassed. This may include but is not limited to devices for which there is evidence of degradation or deterioration beyond a certain number of re-uses.

Whilst the maximum number of re-uses depends on multiple factors such as the material, the user and relevant process changes, examples of devices where this requirement could apply include:

- Minimally-invasive robotic instruments,
- Larynx masks,
- Surgical instruments : scalpels, curettes, clamps, drills, burs,
- Endoscopic devices: biopsy forceps, polyp retrieval basket.

Without prejudice to 'if applicable', it is noted that the MDR generally does not require a maximum number of re-uses for re-usable devices.[1]

If a maximum number of re-uses is established and claimed by the manufacturer, this number shall be provided to the UDI Database in EUDAMED and in addition, reflected in the instructions for use in accordance with Annex I, GSPR 23.4 (n).

For such products whose maximum number of re-uses is determined, a change to this data element will require the allocation of a new UDI-DI.

WARNING: This guidance does not address requirements for reprocessed devices, systems or procedure packs, software, Annex XVI, nor for cases of parallel trade or own brand labelling. Specific requirements for those products are addressed in specific guidance.

[1] For example, re-usable surgical instruments.