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Short communication

Practical examples of implementation of the Unique Device Identifier (UDI) requirements for Medical Devices

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Introduction

The new European Medical Device Regulation 2017/745 (MDR) introduces a Unique Device Identification (UDI) system for medical devices. The UDI system should allow the identification of medical devices, facilitate appropriate traceability of medical devices, enhance the effectiveness of the post-market safety-related activities for devices, improve incident reporting, enhance targeting field safety corrective actions, lead to better surveillance, reduce medical errors, and help fight against falsified devices. As such, the UDI system is intended to be incorporated into the life-cycle of the device (MDCG 2018-1 Rev.4; MDCG 2021-19).

Unique Device Identifier ('UDI') means a series of numeric or alphanumeric characters that is created through internationally accepted device identification and coding standards and that allows unambiguous identification of specific devices on the market (MDR (EU) 2017/745).

EUDAMED is the IT system established by the MDR and developed by the European Commission. One of the six interconnected modules in the EUDAMED is the UDI/Devices registration. This requires that manufacturers submit in EUDAMED the UDI/Device information of all devices they place on the EU market, and that they should keep the information updated (EC: MD - EUDAMED Overview).

The structure of UDI

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 (MDCG 2018-1 Rev.4).

UDI (UDI-DI and UDI-PI)

The UDI 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 (EC: FAQs: UDI System):

- A UDI device identifier ('UDI-DI') is specific to each device. It is a unique numeric or alphanumeric code, specific to a model/variation/version. It is the device identifier used as the "access key" to all information stored in the UDI database, which is part of the EUDAMED database.
- A UDI production identifier ('UDI-PI') identifies the unit of device production and if applicable the packaged devices. It is a numeric or alphanumeric code. The different types of UDI-PIs include the serial number, lot number, software identification, manufacturing and/or expiry date. (EC: (EU) UDI Helpdesk).

UDI Carriers

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. Higher levels do not include shipping containers (MDR (EU) 2017/745).

The UDI must appear in a plain-text version/human readable information (HRI) and in a form that uses AIDC

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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. The AIDC format can be presented as 1D barcodes, 2D barcodes, dot-matrix codes, biometrics, RFID (Radio Frequency Identification).

If linear bar codes are used, the UDI-DI and UDI-PI may be concatenated or non-concatenated in two or more bar codes. All parts and elements of the linear bar code shall be distinguishable and identifiable. If the manufacturer is using RFID technology, a linear or 2D bar code in line with the standard provided by the issuing entities shall also be provided on the label.

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.

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 (EC: (EU) UDI Helpdesk).

The UDI carrier shall be readable during normal use and throughout the intended lifetime of the device. 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.

In the case of single finished devices made up of multiple parts that must be assembled before their first use, it shall be sufficient to place the UDI carrier on only one part of each device.

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

Device contents of system or procedure packs shall bear a UDI carrier on their packaging or on the device itself. UDI carrier shall as a general rule be affixed to the outside of the packaging.

Designated Issuing Entities for UDI Provision

Only the manufacturer may place the UDI on the device or its packaging. However, the UDI must be unique, and obtained by Designated Issuing Entities for UDI Provision. The European Commission has designated 4 issuing entities: GS1 AISBL, HIBCC (Health Industry Business Communications Council), ICCBBA (International Council for Commonality in Blood Banking Automation) and IFA GmbH (Informationsstelle für Arzneispezialitäten) (EC:UDI).

Implementation period of UDI

The obligation for placing the UDI carrier on the labels of MDR certified medical devices applies according to the following timelines:

- Implantable and Class III devices: from 26th May 2021.
- Class IIa and IIb devices: from 26th May 2023.
- Class I devices: from 26th May 2025.

Conclusion

Taking into consideration the entire medical device related information that the UDI is caring, the UDI is not just an ordinary barcode. The implementation process of the UDI Requirements is still ongoing, for the majority of the medical device manufacturers. It is rather challenging process that requires constant follow up to legislation and related guidelines in order to fulfil the MDR requirements, and ultimately to offer improved protection and safety for patients and users, guaranteeing transparency and information.

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