A Whitepaper from DDi

UDI updates for EU MDR & IVDR

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The UDI is a code of alphanumeric characters that acts as the access key to information about a specific medical device on the market. The EU MDR and EU IVDR require that a UDI be assigned to all medical devices except for custom-made or investigational devices.Within the EU, the manufacturer is legally responsible to assign both Basic UDI-DI and UDI-DI to their medical devices. The detailsare provided to operators on the application and practical implementation of the UDI requirements according to the Regulation (EU) 2017/745 on medical devices (MDR) and Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR).

The Basic UDI-DI

The Basic UDI-DI is the main key in the database and relevant documentation to connect devices with same intended purpose, risk class and essential design and manufacturing characteristics. The decision on how to assign the Basic UDI-DI to devices should be taken by the manufacturerbecause themanufacturer has the relevant technical knowledge about their devices and can evaluate which assignment solution would be the most appropriate based on their internal processes.

Regarding groupings to be established under the Basic UDI-DI the manufacturer should align with the respective notified body for devices that require a product certificate from a notified body.This is to facilitate effective handling withrespect 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.

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 including all the relevant responsibilities related to UDI. This involves Basic UDI-DI and UDI assignment and wherever required the UDI-carrier is placed on the label.

In above case if 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. The distributor must 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. However 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.

The DoC may reference more than one Basic UDI-DI. In addition, the same Basic UDI-DI can be referenced in more than one DoC.

List of data elements that triggers New UDI-DI

- Name or trade name
- Device version or model

- 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

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.A new UDI-DI is created in compliance with the rules of the designated issuing entities &required in the case of any change as mentioned in above data elements.

Role of Economic Operators

The distributors and importers shall cooperate with manufacturers and authorised representatives to achieve an appropriate level of traceability. 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. Whilst solutions to implement full traceability should be put in place, the "storing" of all UDIs is not required. However, storing of UDIs may be a useful tool to ensure traceability.

UDI Carrier location on Device Label

The UDI Carrier shall be placed on the label or on the device itself and on all higher levels of device packaging. If significant space constraints on the unit of use packaging, the UDI carrier may be placed on the next higher packaging level.For single-use devices of classes I and IIa packaged and labeled 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.

USA vs. EU UDI requirements

The EU and US UDI systems were established through collaborative work at International Medical Device Regulators Forum (IMDRF) level. The two 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.If 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 labeling could be the same. However ifthere is a change in UDI-DI, the product label should be adapted accordingly.in accordance with the rules of that jurisdiction.

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