EUROPEAN HIGHLIGHT | 16.05.2019

NEW GUIDANCE DOCUMENTS ON THE UNIQUE DEVICE IDENTIFIER (UDI)

The Medical Device Coordination Group (MDCG) released a new guidance document on the unique device identifier ('**UDI**'), more particularly in respect of the Basic UDI-DUI and changes to UDI-DI.

The Basic UDI-DI identifies the devices (group) in a unique manner. It is the key in the database and all documentation to make a connection between devices with the same intended purpose, risk class and essential design and manufacturing characteristics.

The MDCG also furthermore clarified that 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. This is the case when any of the following elements change: 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 disrupters.

In addition, also guidance documents on data sets to provide in EUDAMED have been made available:

- **MDR – UDI and device data sets to provide in Eudamed** (available here)
- **IVDR – UDI and device data sets to provide in Eudamed** (available here)
- **Eudamed UDI Device Data Dictionary** (available here)

  This document, which is in the form of an Excel spreadsheet, describes what data should be provided to Eudamed and what can be communicated through the data exchange process for the UDI/Device module.

We will inform you whenever new guidance documents become available.

We selected this topic since we understand that the MDR and UDI are relevant topics for the ADDE members.

We hope this information is useful. You should not hesitate to contact us should you have any questions or require further information.

Kind regards,

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