MDCG 2018-1

Draft guidance on BASIC UDI-DI and changes to UDI-DI

Introduction

The new Medical Device Regulations 745/2017 and 746/2017 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 (group) 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, colour, language.

A UDI-DI shall be associated with one and only one Basic 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 to be addressed in future guidance.