MD REGULATORY DIGEST

FOCUS ON

UDI SYSTEM

The **Unique Device Identification system ('UDI system')**, described in **Part C of Annex VI**, is aimed to allow the identification and facilitate the traceability of devices. The distinction between **UDI** and **Basic UDI-DI** is essential to understand the requirements of this UDI system.

UDI

The UDI is a series of **numeric or alphanumeric characters** that is created through a globally accepted device identification and coding standard. It allows the unambiguous identification of a specific device on the market.
The UDI is comprised of :
- a **UDI device identifier ('UDI-DI')** specific to a manufacturer and a device, providing access to the information laid down in the UDI Database;
- a **UDI production identifier ('UDI-PI')** that identifies the unit of device production and if applicable the packaged devices.

The UDI shall be placed on the **label** of the device or on its **packaging** : the manufacturer shall assign a UDI to the device and to all higher levels of packaging **before placing it on the market**. It is aimed be used for **reporting serious incidents and field safety corrective actions**.

BASIC UDI-DI

The Basic UDI-DI is the **primary identifier of a device model**. It is the DI assigned at the level of the device unit of use.*

It is also the main key for records in the **UDI database** and is referenced in relevant certificates and EU declarations of conformity.

The Basic UDI-DI of the device shall appear on the following documents (if applicable):
- the EU declaration of conformity (Art. 27.6);
- EU technical documentation assessment certificates, EU type-examination certificates and EU product verification certificates (Annex XII.4.a);
- The technical documentation (Annex II.1.1.b)**;
- The summary of safety and clinical performance (Art. 32.2.a);
- The certificate of free sale (Art. 60.1).

INCONSISTENCIES IN THE FRENCH VERSION

** Cette phrase n'apparaît pas dans la version française du Règlement 2017/745 mais est essentielle à sa définition : **l'IUD-ID de base correspond à l'IUD-ID assigné au niveau de l'unité d'utilisation de l'appareil**.*

*** La version française fait référence à l'IUD-ID et non à l'IUD-ID de base, mais la version anglaise fait bien référence au **Basic UDI-DI**. Le contexte permet d'affirmer que la version anglaise est correcte.*

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GMDN

GMDN Agency:

The Basic GMDN membership is made available as a free service.

The new free Basic membership will allow users access to the GMDN data, while the existing membership charges will remain for manufacturers needing the time-saving and value-added services provided by the GMDN Agency.

01/04/2019

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