Unique Device Identifier (UDI)

Do you know the “Basic-UDI-DI”?

The European Union introduced the UDI for medical devices as per MDR 2017/745. When looking into the details one may not expect too many differences versus the UDI introduced recently by the US FDA. However, some differences exist.

Besides the main difference, that EU will use the EUDAMED database and US will use their GUDID database, another main difference is the “Basic UDI-DI”. The Basic UDI-DI is defined by MDR as “*the primary identifier of a device model. It is the DI assigned at the level of the device unit of use. It is the main key for records in the UDI database and is referenced in relevant certificates and EU declarations of conformity*” [MDR2017/745, Annex VI, Part C].

The Basic UDI-DI is to be seen as the access key to EUDAMED, i.e. the database where all UDI information will be held. It is important to know, that the Basic UDI-DI is different to the UDI-DI itself. The Basic UDI-DI will not be labelled on the packaging and will not be used in supply chain. It is more like a regulatory identifier and will be used in the Declaration of Conformity, Technical Documentation, Free Sales certificates and in the SSCP.

The UDI-DI is to be included in the labelling and in EUDAMED.

There are some more differences between the EU and US UDI. Active implants will have to bear the individual serial number in the UDI-PI in Europe, which is currently not required by FDA. The date format is a given in US (YYYY-MM-DD) whereas it is not defined in Europe. Some more differences, mainly product specific, can be found when digging into Annex VI of the MDR.

So, better start reading now!

Michael Schaefer –Quality Management and Regulatory Affairs in Medical Devices
Heiligkreuzstrasse 59, 72379 Hechingen, Germany, +49 (0) 171 585 1234, +49 (0) 7471 930 1237
For more information visit www.quality-on-site.com or contact michael@quality-on-site.com