European Commission

EUDAMED

European database on medical devices

Regulation Devices are defined as **medical devices** and **in vitro diagnostic medical devices** that are placed on the market under Regulation (EU) 2017/745 (MDR) or Regulation 2017/746 (IVDR).

IDENTIFIERS

What are the different identifiers?

A **Regulation Device** and a **System/Procedure Pack**, must have an assigned **Basic UDI-DI** and **UDI-DI** and must be registered in the 'UDI/Device module' (UDI database) of EUDAMED.

The Basic UDI-DI code, UDI-DI code and Package UDI-DI code will be unique for a given Regulation device or System/Procedure Pack.

BASIC UDI-DI

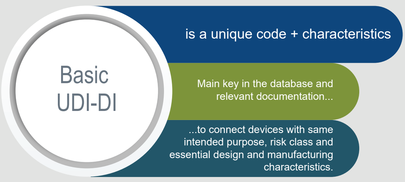
What is the Basic UDI-DI?

REGULATION DEVICES

Regulations Devices have to be registered in EUDAMED by their manufacturer.
They are defined as 'Medical devices', including 'Systems' and 'Procedure Packs' that are devices in themselves, under Regulation (EU) 2017/745 (MDR), and 'In Vitro Diagnostic Medical devices' including 'Kits' under Regulation 2017/746 (IVDR).

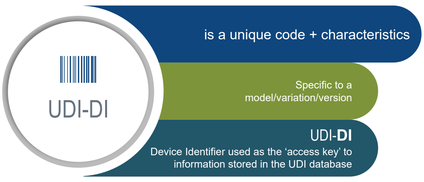
SYSTEM/PROCEDURE PACKS

'Systems' and 'Procedure packs' which are not devices in themselves but a combination of devices for a medical purpose are not considered as 'Regulation Devices'.
They have to be registered in EUDAMED by their system/procedure pack producer



UDI-DI

What is the UDI-DI?



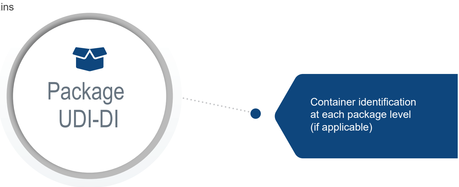
UNIQUE DEVICE IDENTIFIER

Unique Device Identifier ('UDI') is a series of numeric or alphanumeric characters that is created through internationally accepted device identification and coding standards and allows unambiguous identification of specific devices on the market (Regulations Def. 15).

PACKAGE UDI-DI

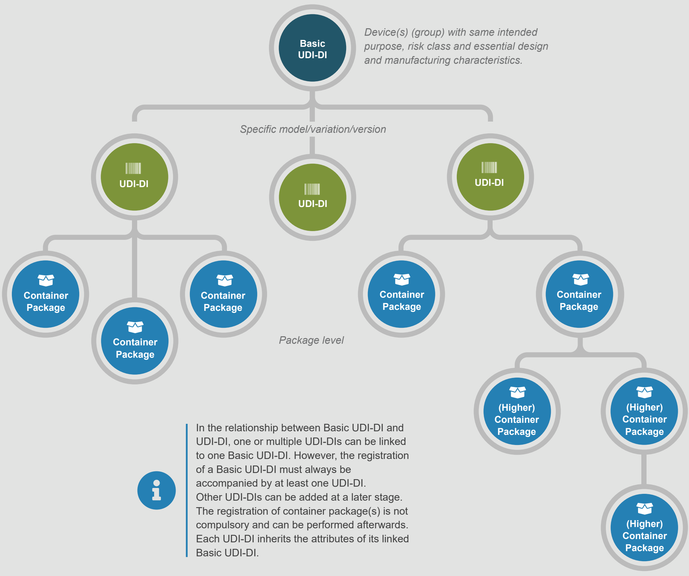
What is the Container Package UDI-DI?

The package is not a device.
It is a container which contains device(s).



STRUCTURE SAMPLE

What is the structure in EUDAMED?



In the relationship between Basic UDI-DI and UDI-DI, one or multiple UDI-DIs can be linked to one Basic UDI-DI. However, the registration of a Basic UDI-DI must always be accompanied by at least one UDI-DI.
Other UDI-DIs can be added at a later stage.
The registration of container package(s) is not compulsory and can be performed afterwards.
Each UDI-DI inherits the attributes of its linked Basic UDI-DI.

DG Health and Food Safety