

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 they must be registered in the 'UDI/Device module' (UDI database) of EUDAMED.

Package UDI-DI Basic UDI-DI **UDI-DI** (If applicable)

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.



REGULATION DEVICES

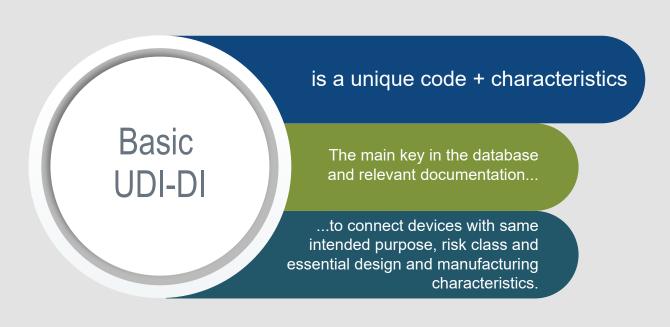
Regulations Devices have to be registered in EUDAMED by their manufacturer. They are defined as 'Medical devices', including 'Systems' and 'Procedure Packs' that are devices in themselves, under Regulation (EU) 2017/745 (MDR), and 'in vitro diagnostic medical devices'

SYSTEM/PROCEDURE PACKS

including 'Kits' under Regulation 2017/746 (IVDR).

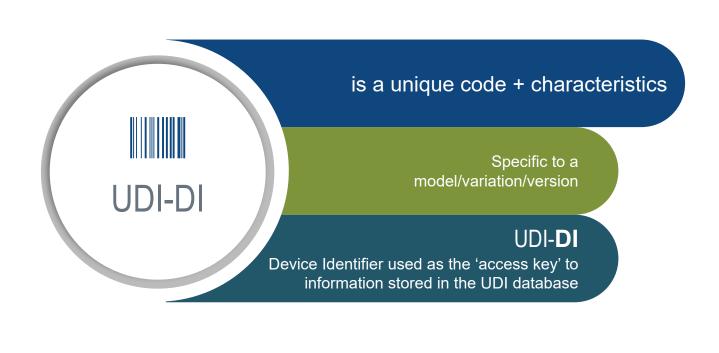
'Systems' and 'Procedure packs', which are not devices in themselves but a combination of devices for a medical purpose, are not considered to be 'Regulation Devices'. They have to be registered in EUDAMED by their system/procedure pack producer

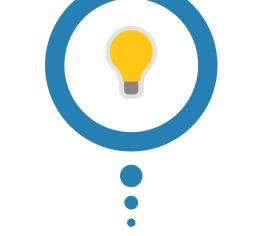
BASIC UDI-DI What is the Basic UDI-DI?



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.

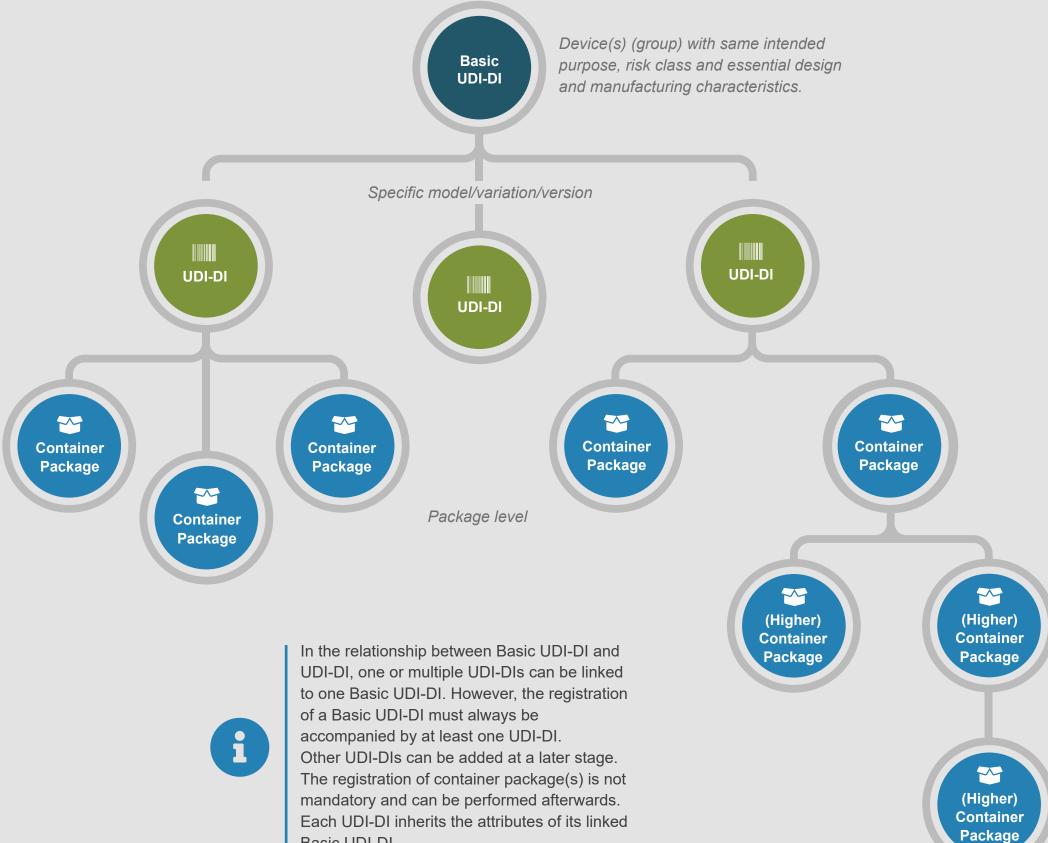
PACKAGE UDI-DI

What is the Container Package UDI-DI?



What is the structure in EUDAMED?

STRUCTURE SAMPLE



Basic UDI-DI.