



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

Basic UDI-DI

UDI-DI

Package 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.



## 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 to be 'Regulation Devices'. They have to be registered in EUDAMED by their system/procedure pack producer

Basic UDI-DI

is a unique code + characteristics

The main key in the database and relevant documentation...

...to connect devices with same intended purpose, risk class and essential design and manufacturing characteristics.

## UDI-DI

What is the UDI-DI?

is a unique code + characteristics



UDI-DI

Specific to a model/variation/version

UDI-DI

Device Identifier used as the 'access key' to information stored in the UDI database



### 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?



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

Package UDI-DI

Container identification at each package level (if applicable)

## STRUCTURE SAMPLE

What is the structure in EUDAMED?

