



European Commission

# EUDAMED

European Database on Medical Devices

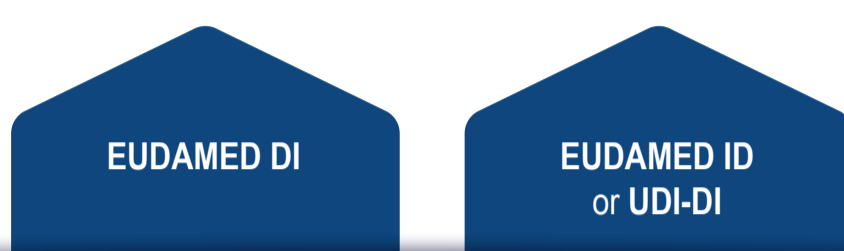
**Legacy devices** are defined as **medical devices, active implantable medical devices** and **in vitro diagnostic medical devices** - covered by a valid Directive certificate - that will continue to be placed on the market after the date of application of Regulation (EU) 2017/745 (MDR) or Regulation 2017/746 (IVDR). Legacy devices shall be registered\* in some cases in EUDAMED without a Basic UDI-DI and without a UDI-DI.

(\*only if post-market surveillance and/or vigilance reporting occurs, or that by the end of the transition period for device registration there is no equivalent MDR or IVDR device already registered)

## IDENTIFIERS FOR A LEGACY DEVICE

What are the different identifiers for a Legacy device?

A **legacy device** has to have an assigned **EUDAMED DI** (instead of a Basic UDI-DI), and in some cases (when no UDI-DI was already assigned) a **EUDAMED ID** (instead of the UDI-DI), and has to be registered in the 'UDI/Device module' of EUDAMED, allowing EUDAMED to treat it as closely as possible to a regulation device.

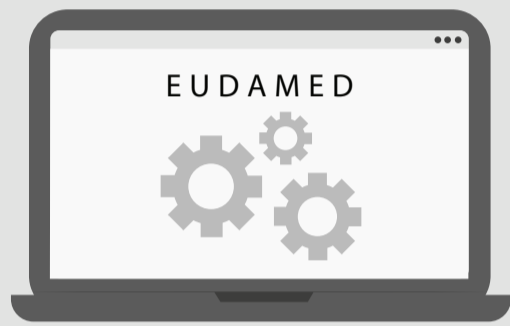


These EUDAMED DI value and EUDAMED ID value (or UDI-DI) will be unique for a given legacy device.

## EUDAMED DI

What is a EUDAMED DI?

EUDAMED DI  BASIC UDI-DI



**EUDAMED DI**

The EUDAMED DI corresponds to the Basic UDI-DI.

It can either be entirely generated by EUDAMED if a UDI-DI has already been assigned to the legacy device, or the DI code can be partly assigned by the manufacturer (EUDAMED is the issuing entity for a EUDAMED DI).

## EUDAMED ID

What is a EUDAMED ID?

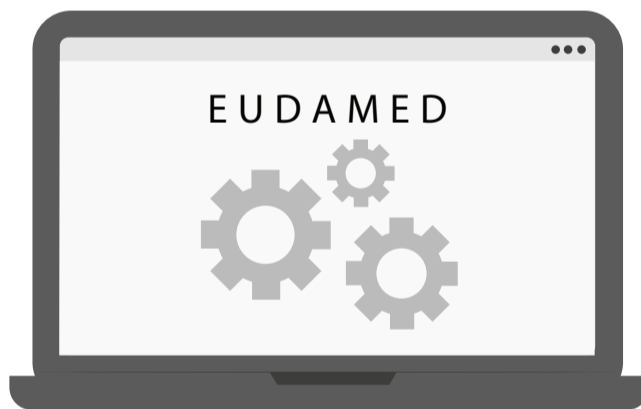
EUDAMED ID  UDI-DI



**EUDAMED ID**

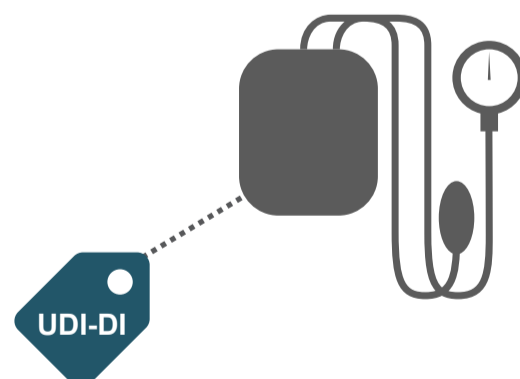
The EUDAMED ID corresponds to the UDI-DI.

In case a UDI-DI has not already been assigned, the EUDAMED ID will always be automatically and fully generated by EUDAMED from the EUDAMED DI.

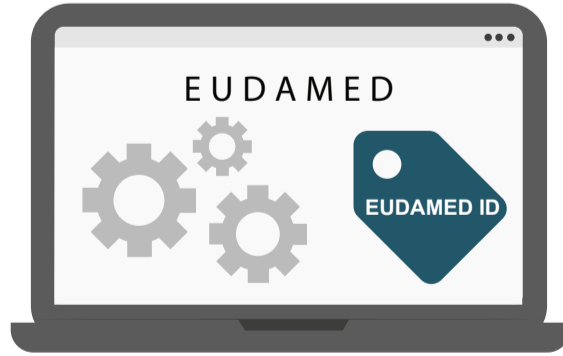


## EUDAMED ID & UDI-DI

What are the differences between EUDAMED ID and UDI-DI?



UDI-DI is (or will be) labeled on the device



The EUDAMED ID is a virtual Device Identifier. It exists in order to keep the structure and format homogeneous for the registration of devices in EUDAMED (similar as for regulation devices). It is not applied on labels.



**ISSUING ENTITY**

The UDI-DI can only be issued by a designated issuing entity, whilst EUDAMED issues the EUDAMED ID.

## STRUCTURE SAMPLE

What is the structure in EUDAMED?



In EUDAMED, the registration of a EUDAMED DI must ALWAYS be accompanied by a EUDAMED ID or a UDI-DI.

And the relationship between the EUDAMED DI and a EUDAMED ID is one to one.

