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 report occur or that by end of transition period for device registration there is no equivalent MDR or IVDR device already registered)*

IDENTIFIERS OF 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 work as close as possible like Regulation Devices.
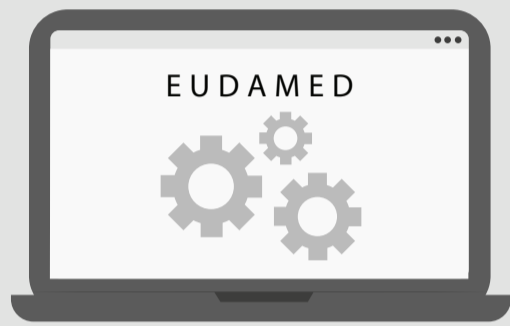
| EUDAMED DI | EUDAMED ID or **UDI-DI** |

The 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

EUDAMED 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?
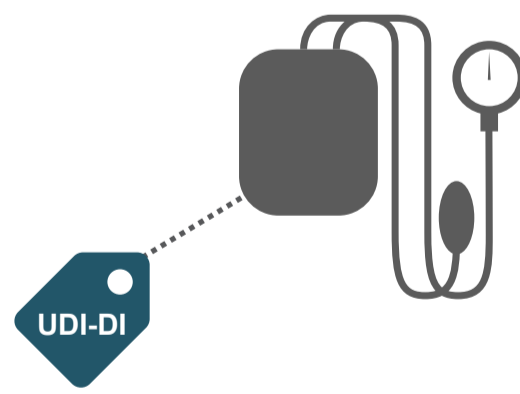
EUDAMED ID   ~   UDI-DI

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.
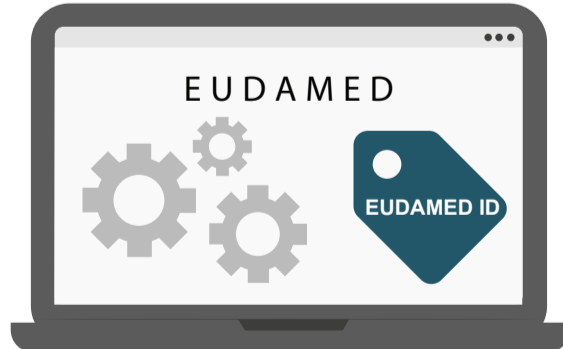
EUDAMED

EUDAMED ID

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

UDI-DI

UDI-DI is (or will be) labelled on the Device

EUDAMED

EUDAMED ID

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.

EUDAMED DI

EUDAMED ID or UDI-DI