European Commission

EUDAMED

European database on medical devices

A **Regulation Device** has to have an assigned **Basic UDI-DI** and **UDI-DI** and has to be registered in the 'UDI/Device module' of EUDAMED.

REGISTRATION PROCESS FOR REGULATION DEVICES

What's the process to register a Regulation device in EUDAMED?

MANUFACTURER

START REGISTRATION PROCESS

Basic UDI-DI identification

Choose the legislation, enter the Issuing entity with the Basic UDI-DI value and and some special characteristics.

Basic UDI-DI information

Enter Basic UDI-DI attributes information.

Certificate information

Enter Certificate information (if applicable - only for MDR Class III and Class IIb and IVDR Class D, C and B with Self-testing or Near patient testing)

Enter Issuing entity with the UDI-DI value, the Nomenclature code, UDI-DI information and characteritics.

UDI-DI information

Add Container package(s) information if applicable.

Container package information

SUBMIT

CONFIRMATION

DEVICE IS REGISTERED

(publicly available)

High risk class devices, covered by a Type Examination or Technical Documentation Certificate (for devices referred to in MDR Art 29(3) or in IVDR Art 26(2)) **requires the Notified Body confirmation of device data before the device can be publicly available**.

DEVICE IS SUBMITTED

NOTIFY BODY

CONFIRM DEVICE DATA

(by registering the relevant product certificate)

Notifications are sent to inform actors to verify or undertake an action.

CONFIRMATION

DEVICE IS REGISTERED

(publicly available)

DG Health and Food Safety