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?

MANAGER **MANUFACTURER**

START REGISTRATION PROCESS

Basic UDI-DI identification	Basic UDI-DI information	Certificate information

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

Enter Basic UDI-DI attributes 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)

Add Container package(s) information if applicable.

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

CONFIRMATION

DEVICE IS REGISTERED

(publicly available)

SUBMIT

Container package information	UDI-DI information

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)) **require the Notified Body confirmation of device data before the device can be publicly available.**

DEVICE IS SUBMITTED

CONFIRM DEVICE DATA

(by registering the relevant product certificate)

NOTIFY BODY

Notifications are sent to inform actors that they should verify or carry out an action.

CONFIRMATION

DEVICE IS REGISTERED

(publicly available)