

#### **EUDAMED**

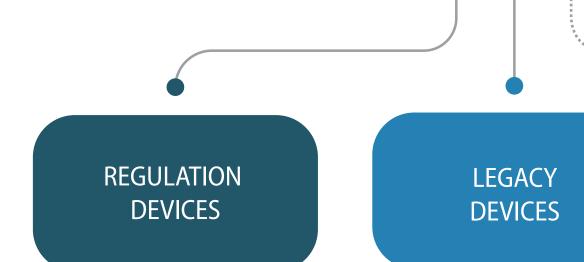
European database on medical devices

**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)**.

**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).

#### CATEGORISATION OF DEVICES

What is the categorisation of devices to be registered in EUDAMED?



## OTHER DEVICES

'Custom-made devices' and 'Devices older than legacy devices' are reported and registered only in Vigilance reports (in the Vigilance module).



What does Regulation Devices in "Regulation (EU) 2017/745 (MDR)" include?



the registration of **Medical devices** in EUDAMED.

The **System/Procedure pack** 

The **Manufacturer (MF)** is responsible for

**producer (PR)** is responsible for the registration of **System/Procedure packs** in EUDAMED.

A system or a procedure pack that is a device in itself has to be registered by a Manufacturer (MF) and is not considered as a system or procedure pack to be registered by a System/Procedure pack producer (PR).

#### MEDICAL DEVICES

appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination (like system/procedure pack which is a medical device in itself), for human beings of specific medical purposes.

'Medical device' means any instrument, apparatus,

#### SYSTEMS

'System', that is not to be considered as a medical device, means a combination of products, either packaged together or not, which are intended to be inter-connected or combined to achieve a specific medical purpose.

### PROCEDURE PACKS

**medical device**, means a combination of products packaged together and placed on the market with the purpose of being used for a specific medical purpose.

'Procedure pack', that is not to be considered as a

#### What does Regulation Devices in "Regulation (EU) 2017/746 (IVDR)" include?

REGULATION DEVICES (IVDR)

## MEDICAL DEVICES 'In vitro diagnostic medical device' means any medical

IN VITRO DIAGNOSTIC

equipment, software or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body.

'Kit', which is a kind of medical device, means a set of

be used to perform a specific in vitro diagnostic

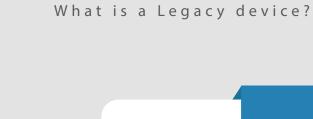
examination, or a part thereof.

components that are packaged together and intended to

device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of



kits.



**LEGACY DEVICES** 



# DEVICES

**LEGACY** 

**'Legacy devices'** are defined as medical devices, active implantable medical devices and in vitro diagnostic medical devices that are covered by a valid certificate issued in accordance with Directive 93/42/EEC or Directive 90/385/EEC or Directive 98/79/EC and that continue to be placed on the market after the date of application of Regulation (EU) 2017/745 (MDR) or Regulation 2017/746 (IVDR)

Food Safety