European Commission

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?

REGULATION DEVICES

LEGACY DEVICES

OTHER DEVICES

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

REGULATION DEVICES (MDR)

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

ACTORS INVOLVED?

The **manufacturer (MF)** is responsible for the registration of **medical devices** in EUDAMED.

The **system/procedure pack 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 it is not considered to be a system or procedure pack that is registered by a system/procedure pack producer (PR).

MEDICAL DEVICES

A **'Medical device'** means any instrument, apparatus, 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 for specific medical purposes.

SYSTEMS

A **'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

A **'Procedure pack', that is not to be considered as a medical device**, means a combination of products packaged together and placed on the market, intended for a specific medical purpose.

REGULATION DEVICES (IVDR)

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

IN VITRO DIAGNOSTIC MEDICAL DEVICES

'*In vitro* diagnostic medical device' means any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of 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.

KITS

'Kit', which is a form of medical device, means a set of components that are packaged together and intended to be used to perform a specific in vitro diagnostic examination, or a part thereof.

ACTORS INVOLVED?

The **manufacturer (MF)** is responsible for the registration in EUDAMED of ***in vitro* diagnostic medical devices** including **kits**.

LEGACY DEVICES

What is a Legacy device?

ACTORS INVOLVED?

The **manufacturer (MF)** is responsible for the registration of **Legacy Devices** in EUDAMED.

LEGACY DEVICES

'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 which continue to be placed on the market after the date of application of Regulation (EU) 2017/745 (MDR) or Regulation 2017/746 (IVDR).

DG Health and Food Safety