EUDAMED Status Update 2021

Understanding The European Database on Medical Devices

CLIN R+

EUDAMED Status Update 2021

Understanding The European Database on Medical Devices

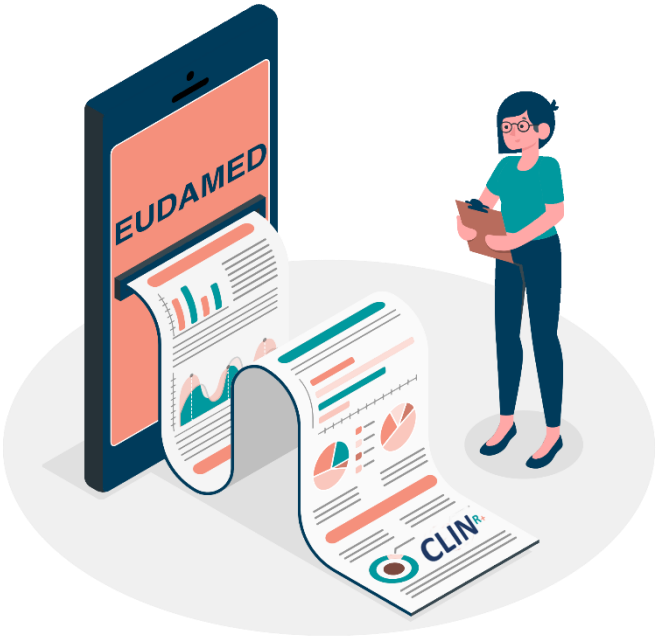
For manufacturers of Medical Devices, following the EUDAMED implementation plan and getting familiar with the information stored in the database's modules, is crucial to gain compliance in the EU market. However, the development and deployment of EUDAMED have recently changed.

What is EUDAMED?

The European Database on Medical Devices (EUDAMED) is the IT system developed by the European Commission to implement Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnosis medical devices.

The multipurpose and interoperable system database is structured around 6 interconnected modules and a public website:

- Actor Registration - ACT
- Unique Device Identification/Devices Registration - UDI
- Notified Bodies and Certificates - CRF
- Clinical Investigations and Performance Studies - CIPS
- Vigilance and Post-Market Surveillance - VGL
- Market Surveillance - MSUEU.



CLIN R+

What is stored in the EUDAMED?

Module ACT – Actor Registration

This module allows actors to register. Actors are defined as manufacturers, system & procedure pack producers, importers and EU authorised representatives. Once an actor registration request has been submitted by an economic operator, upon approval, the selected relevant national competent authority issues the Actor ID/ Single Registration Number (SRN) generated by EUDAMED. The SRN identifies the Actors, who will have access to EUDAMED upon registration and verification of the data provided.

It is important to note that, all actor information registered in EUDAMED has been publicly available since 1st December 2020.

Module UDI – Unique Device Identification/Devices Registration

All device-specific information and data is contained within the UDI module, divided into BASIC UDI-DI and the UDI-DI. The purpose of BASIC UDI-DI is to map all common properties of a product group, whereas the UDI-DI only contains the product-specific information.

Economic Operators are responsible for managing all UDI attributes in their own companies and transferring the data to EUDAMED.

Information on the registered Basic UDI-DI, UDI-DI and Device is publicly available.

Module CRF – Notified Bodies and Certificates

This module is where Certificates issued by Notified Bodies on Quality Management System and Conformity Assessment in accordance with MDR 2017/745 and IVDR 2017/746 are stored. The purpose of this module is to facilitate communication between the Notified Bodies as well as monitoring the consultation procedures for clinical evaluations.

Public access will be granted to the registration of certificates of conformity, their scope and validity period, as well as the reports of the Notified Bodies on the SSCP.

Module CIPS – Clinical Investigations and Performance Studies

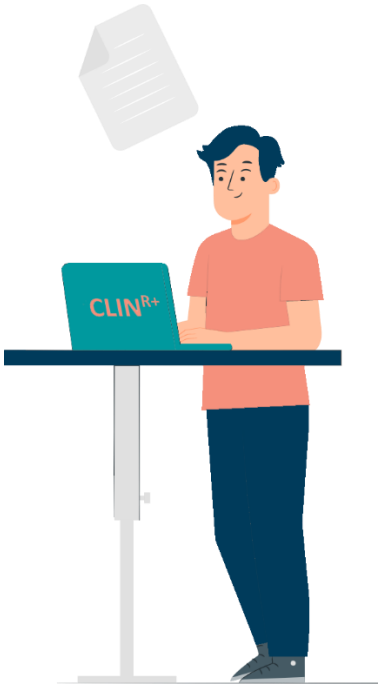
Clinical investigation and performance evaluation data can be managed in this module, as well as applications for clinical performance studies. Clinical follow-ups, post-market product changes and reports, and trials can also be submitted in this module.

Clinical Investigation Registration, Clinical Investigation Results Reporting and Publication are accessible to the public. Clinical Investigation Application Documents will potentially be accessible by the public.

Module VGL – Vigilance and Post-Market Surveillance

Periodic Safety Update Report (PSUR; Periodic Summary Reports (PSR) and Reporting of Serious Incidents and Field Safety Corrective Actions (FSCAs) and Field Safety Notices (FSNs) can all be submitted via the Vigilance Module. After being reported in the Vigilance Module. FSCAs are automatically distributed to the appropriate authorities

Whilst not available to the public like the previous modules, there will be partial public access for manufacturer incident reports and Field Safety Notices.



Module MSU – Market Surveillance

The purpose of this module is to facilitate cooperation and coordination between competent authorities of EU Member States.

The summary of the results of the reviews and assessments of the market surveillance activities will be made available publicly.

What is the state of play of the implementation of EUDAMED?

As previously mentioned, the development and deployment of EUDAMED has been progressing over the years.

The module on **Actor Registration** (first module) went live in December 2020 and the **UDI/Device Registration** and **Notified Bodies and Certificates** modules (second and third modules respectively) have been available since October 2021.

The remaining three modules – **Clinical Investigations and Performance Studies**, **Vigilance and Post-Market Surveillance** and **Market Surveillance** – as well as the mechanism for scrutiny and the CECP will be launched in May 2022 when EUDAMED becomes fully operational.

Whilst the use of EUDAMED is not yet mandatory, the available modules can be used voluntarily. It should be noted that, once the entire EUDAMED system (including all 6 modules) has been declared fully functional, its use will become mandatory for all manufacturers of Medical Devices. This will be made official following an independent audit and a Commission notice being published in the Official Journal and in accordance with the transitional provisions set out in the Medical Device's regulations.

A more detailed timeline, forecasting the next steps for EUDAMED can be found here.