



# European Database on Medical Devices

from long-awaited project to operational reality

*What's changing?*

As of today, 28 May 2026, the European Database on Medical Devices (EUDAMED) has formally entered into its operational phase. After facing significant delays, what for several years was perceived as a future regulatory infrastructure has now become a reality in the form of a central compliance tool under the EU Medical Devices Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR).

This development takes place in parallel with a broader reassessment of the regulatory framework.

Since 2024, the European Commission has conducted a targeted evaluation of the MDR and IVDR, followed by a legislative proposal in December 2025 aimed at simplifying and streamlining the current regime in response to concerns around complexity, administrative burden and market access.

Against this evolving background, the announcement that a first set of modules of EUDAMED had reached the required functional specifications and the end of the six-month transition period, marks a decisive milestone in the operationalisation of the MDR/IVDR framework.

The use of those modules is mandatory as of today, namely:

- 1 Actor registration
- 2 UDI / device registration
- 3 Notified bodies and certificates
- 4 Market surveillance

From this point onwards, EUDAMED forms part of the core compliance architecture for economic operators.

In practical terms, manufacturers and other operators must be registered in the system and obtain a Single Registration Number, and devices must be recorded in EUDAMED prior to placement on the EU market.

Existing devices will also need to be entered in the database within the applicable transitional timelines, which broadly extend through 2026.

However, this is not the end of the road towards a fully operational EUDAMED as not all modules are yet operational.

The vigilance/post-market surveillance and clinical investigations modules remain under development and are expected to follow at a later stage, becoming mandatory upon their release.

Nevertheless, EUDAMED's operationalisation marks a further step towards a more transparent and data-driven regulatory framework in the EU.

At the same time, the ongoing revision of the MDR/IVDR confirms that the system remains in flux, with further adjustments likely in the near to medium term.

**For companies operating in the sector, this is a dual transition:**

EUDAMED is now immediately relevant from a compliance perspective, while the broader regulatory framework continues to evolve in parallel.

We will continue to monitor these developments and are available to assist with the practical and strategic implications of EUDAMED and the evolving EU medical devices framework.



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Life Sciences & IP Litigation Team