28 November 2025

Ref: MMA/MDPCED-002/2025

Notice to Stakeholders – EUDAMED First Four Modules

On 27 November 2025, the Commission Decision (EU) 2025/2371 of 26 November 2025 has been published in the Official Journal of the European Union (OJEU). This publication is regarding the functionality and the fulfilment of the functional specifications of certain electronic systems included in the European Database on Medical Devices declaring the functionality of the first four modules.

In accordance with the transitional provisions set out in Regulation (EU) 2024/1860, this publication triggers a **transition period of 6 months**, for manufacturers, system and procedure pack producers, importers and authorised representatives to comply with the registration obligations. As from **28 May 2026**, the EUDAMED first four modules will be **mandatory**:

- Actor registration
- UDI/Devices registration
- Notified Bodies & Certificates
- Market Surveillance

Reference/s:
Commission Decision (EU) 2025/2371 of 26 November 2025: http://data.europa.eu/eli/dec/2025/2371/oj

Clarification requests may be forwarded to the general medical devices mailbox: devices.medicinesauthority@gov.mt.

Yours sincerely,

Medical Devices, Pharmaceutical Collaboration and Entrepreneurship Directorate

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