26 November 2026

Ref: MMA/MDPCED-003/2026

Notice to Stakeholders: EUDAMED UDI/Device registration deadline

Economic operators - manufacturers, authorised representatives, importers and distributors - are reminded of their respective general obligations as laid out in Subsidiary Legislation S.L. 458.59, Regulation (EU) 2017/745 (MDR) and Regulation (EU) 2017/746 (IVDR).

Following the publication of the Commission Decision (EU) 2025/2371 on 27 November 2025, declaring the functionality of the first four modules of the European Database on Medical Devices, EUDAMED, and in accordance with Regulation (EU) 2024/1860, devices that were being placed on the EU market prior to 28 May 2026, must be registered by manufacturers through the UDI/Device module by no later than 28 November 2026.

All economic operators are to ensure compliance to EU and national legislation.

For more information about using EUDAMED, visit the EUDAMED Information Centre.

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

Clarification requests may be forwarded to: devices.medicinesauthority@gov.mt.

Yours sincerely,

Medical Devices, Pharmaceutical Collaboration and Entrepreneurship Directorate
Malta Medicines Authority

Medicines Authority, Sir Temi Żammit Buildings,
Malta Life Sciences Park, San Ġwann, SĠN 3000, Malta
info.medicinesauthority@gov.mt | (+356) 23 439 000
www.medicinesauthority.gov.mt

SM EN ISO 9001:2015
Reg. No. S082