EUDAMED Readiness Guide

Mandatory Registration — 28 May 2026 Deadline

NordMDR AB | Stockholm, Sweden | 2026

What is EUDAMED?

EUDAMED is the European Database on Medical Devices — the EU central registry for all devices, manufacturers, importers, distributors and Authorised Representatives. From 28 May 2026, registration is mandatory. Without it, your products cannot legally be sold in any EU member state.

Who Must Register?

Economic Operator	Must Register?	Who Does It?
Non-EU Manufacturer	YES	Through their EU AR
EU Authorized Representative	YES	Themselves + on behalf of manufacturer
EU Importer	YES	Themselves
EU Distributor	YES	Themselves
EU Manufacturer	YES	Themselves directly

The 5 Registration Steps

1

Step 1 — Appoint EU Authorized Representative
Non-EU manufacturers cannot register in EUDAMED directly. You must first appoint an EU AR. Your AR registers on your behalf and links their SRN to yours.

2

Step 2 — Actor Registration
Your EU AR registers your company as an Actor in EUDAMED. This creates your unique SRN (Single Registration Number) — your permanent EU market identifier.

3

Step 3 — Prepare Device Data
Gather GMDN codes, UDI-DI numbers, device descriptions, risk classifications, and Declaration of Conformity for each device to be registered.

4

Step 4 — Device Registration
Each device is registered in the EUDAMED UDI database and linked to your manufacturer SRN and your EU AR SRN.

5

Step 5 — Annual Maintenance
EUDAMED requires annual updates. Device data must be kept current. NordMDR AB handles ongoing maintenance as part of our AR service.

Key Deadlines

Deadline	Who it affects	Action required
28 May 2026	ALL economic operators	Complete EUDAMED actor + device registration
28 Nov 2026	Devices already on market pre-May 2026	Register devices placed on market before deadline
31 Dec 2027	Class III + IIb implantable devices	Full EU MDR Notified Body certification
31 Dec 2028	Class IIb, IIa, Class Is devices	Full EU MDR Notified Body certification

Start your EUDAMED registration today. NordMDR AB handles complete EUDAMED registration for non-EU manufacturers. Free assessment available. Contact: info@nordmdr.com | www.nordmdr.com