

EU MDR Compliance Checklist

For Non-EU Medical Device Manufacturers

NordMDR AB | Stockholm, Sweden | 2026

Use this checklist to track your EU MDR compliance progress. Tick each item as it is completed. If you are unsure about any step, contact NordMDR AB for a free compliance assessment.

STEP 1 — Appoint an EU Authorized Representative

- Confirm your device is in scope of EU MDR 2017/745
- Identify your device risk classification (Class I, IIa, IIb, III)
- Select an EU-registered Authorized Representative (EU AR)
- Sign the EU AR agreement defining scope and responsibilities
- Ensure EU AR name and address is added to your product label
- Confirm EU AR covers all 27 EU member states

STEP 2 — EUDAMED Registration (Mandatory 28 May 2026)

- EU AR registers as Actor in EUDAMED — obtains SRN
- Manufacturer registers as Actor — obtains manufacturer SRN
- Prepare GMDN codes for each device
- Prepare UDI-DI for each device model
- Register each device in EUDAMED UDI database
- Link device registration to both manufacturer and EU AR SRNs
- Annual EUDAMED maintenance scheduled

STEP 3 — Technical Documentation

- Product description and intended purpose documented
- Risk management file per ISO 14971 completed
- Clinical evaluation report (CER) completed
- Post-market surveillance (PMS) plan in place
- Periodic safety update report (PSUR) process established
- Instructions for use (IFU) prepared in all required languages

- Declaration of Conformity (DoC) signed

STEP 4 — CE Marking

- Applicable EU MDR and harmonised standards identified
- Essential requirements and general safety performance requirements (GSPR) checklist completed
- Notified Body engaged (Class IIa, IIb, III devices)
- Conformity assessment procedure completed
- CE mark applied to product label and packaging
- CE mark size meets minimum requirements (5mm height)

STEP 5 — Labelling Compliance

- EU AR name and address on label (EC REP symbol)
- Manufacturer name and registered address on label
- Device name / trade name as registered in EUDAMED
- Batch/lot number or serial number present
- UDI carrier (barcode/QR) on label
- Manufacturing date or expiry date (ISO symbols)
- CE mark on label
- Language requirements met for all target markets
- ISO 15223 symbols used (not FDA symbols)

STEP 6 — Ongoing Post-Market Obligations

- Post-market surveillance system operational
- Vigilance reporting process defined
- Serious incident reporting procedure in place
- EUDAMED annual updates scheduled
- PSUR update frequency defined per device class
- Competent Authority communication routed through EU AR

Need help completing this checklist? NordMDR AB provides free compliance assessments for non-EU manufacturers. Contact us at info@nordmdr.com or visit www.nordmdr.com