

# CE Marking Roadmap

For Non-EU Medical Device Manufacturers Entering Europe

NordMDR AB | Stockholm, Sweden | 2026

## What is the CE Mark?

The CE mark (Conformité Européenne) is the mandatory conformity marking for medical devices sold in the European Union. It signals that a device meets the essential requirements of EU MDR 2017/745. Without it, your device cannot legally enter any EU market.

## CE Marking Roadmap by Device Class

| CLASS I — Non-sterile, Non-measuring |                                       | Typical timeline: 2-4 months  |
|--------------------------------------|---------------------------------------|---|
| 1                                    | <b>Self-declare</b>                   | No Notified Body required for Class I devices without special functions |
| 2                                    | <b>Prepare Technical File</b>         | Device description, risk assessment, labelling, IFU                     |
| 3                                    | <b>Sign Declaration of Conformity</b> | Manufacturer declares compliance with EU MDR                            |
| 4                                    | <b>Register in EUDAMED</b>            | Mandatory from 28 May 2026  |
| 5                                    | <b>Apply CE Mark</b>                  | CE mark applied to label — no NB number                                 |

| CLASS I STERILE / MEASURING / CLASS IIa |   | Typical timeline: 9-15 months                               |
|---|---|---|
| 1                                       | <b>Appoint EU Authorized Representative</b> | Mandatory for non-EU manufacturers                          |
| 2                                       | <b>Engage Notified Body</b>                 | For QMS audit and/or technical file review                  |
| 3                                       | <b>Prepare Technical Documentation</b>      | Full Annex II technical file including clinical evaluation  |
| 4                                       | <b>Notified Body Review</b>                 | Audit of QMS and/or technical documentation — 6-12 months   |
| 5                                       | <b>Receive EU MDR Certificate</b>           | Certificate valid for 5 years (risk-based renewal proposed) |
| 6                                       | <b>Register in EUDAMED</b>                  | Actor + device registration mandatory                       |

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**Apply CE Mark with NB Number**

Four-digit Notified Body ID on label

**CLASS IIb / CLASS III**

Typical timeline: 15-24 months

1

**Appoint EU Authorized Representative**

Mandatory immediately

2

**Engage Notified Body early**

NB capacity is limited — secure slot immediately

3

**Full Technical Documentation**

Annex II + III, clinical investigation may be required

4

**Notified Body Design Examination**

For Class III — design dossier reviewed

5

**QMS Audit**

ISO 13485 QMS audit by Notified Body

6

**Clinical Evaluation**

Full clinical evidence required per MEDDEV 2.7/1 rev.4

7

**Receive EU MDR Certificate**

Full Notified Body certification — 13-18 months typical

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**EUDAMED Registration + CE Mark**

Full registration and labelling compliance

## Common CE Marking Mistakes to Avoid

- ✗ Using non-EU test reports — EU harmonised standard test reports required
- ✗ Missing Technical File — a test report alone is not sufficient for CE marking
- ✗ Using outdated standards — always verify the current harmonised standard version
- ✗ No EU AR on label — EC REP symbol with AR name and address mandatory
- ✗ Using FDA symbols instead of ISO 15223 symbols on EU labels
- ✗ No UDI carrier on label — required for all Class I devices from May 2025

**Start your CE marking journey today.** NordMDR AB provides EU Authorized Representative services, technical documentation, CE marking support and EUDAMED registration for non-EU manufacturers. Free assessment available. Contact: [info@nordmdr.com](mailto:info@nordmdr.com) | [www.nordmdr.com](http://www.nordmdr.com)