THE EUROPEAN CE MEDICAL DEVICE APPROVAL PROCESS EXPLAINED

**Step1**  
To obtain CE Marking, you must comply with European Commission Regulation (EU) No. 2017/745, commonly known as the Medical Device Regulation (MDR).

**Step2**  
Appoint a Person Responsible for Regulatory Compliance. Determine classification of your device using Annex VIII (Classification Criteria) of the MDR - Class I (self-certified); Class I (sterile, measuring or reusable surgical instrument); Class IIa, Class IIb, or Class III.

**Step3**  
For all devices except Class I (self-certified), implement a Quality Management System (QMS) in accordance with the MDR. Most companies apply the EN ISO 13485 standard to achieve compliance. Your QMS must include Clinical Evaluation, Post-Market Surveillance (PMS) and Post Market Clinical Follow-up (PMCF) plans. Make arrangements with suppliers about unannounced Notified Body audits.

For Class I (self-certified), you must implement a QMS though Notified Body intervention is not required.

**Step4**  
In accordance with Annex II and III, prepare a [**CE Technical File or Design Dossier (Class III)**](https://www.emergobyul.com/services/europe/technical-file-preparation) providing information about your device and its intended use plus testing reports, Clinical Evaluation Report (CER), Risk Management File, IFU, labeling and more. Obtain a Unique Device Identifier (UDI) for your device. All devices, even legacy products in use for decades, will require clinical data. Most of these data should refer to the subject device. Clinical studies are generally required for implantable and Class III devices. Existing clinical data may be acceptable. Clinical trials in Europe must be authorized by the National Competent Authorities of all European countries in which the trials will be conducted as well as by the Ethical Committees responsible for the trial sites.

**Step5**  
If as a manufacturer you do not have your registered place of business in Europe, appoint an Authorized Representative (EC REP) located in the EU who is qualified to handle regulatory issues. Place your EC REP name and address on device label. Obtain a Single Registration Number from the regulators.

**Step6**  
For all devices except Class I (self-certified), your **QMS** and Technical File or Design Dossier must be audited by a Notified Body, which is a third party accredited by European authorities to audit medical device companies’ QMS and devices.

**Step7**  
For all devices except Class I (self-certified), you will be issued a European CE Certificate for your devices and an ISO 13485 certificate for QMS following successful completion of your Notified Body QMS audit and Technical Documentation review. ISO 13485 certificates are valid for a period of three years CE certificates are valid for a period of 5 years. Both are subject to periodic (annual) surveillance audits.

**Step8**  
Prepare a [Declaration of Conformity in accordance with Annex IV](https://www.emergobyul.com/resources/articles/white-paper-europe-ce-marking), a legally binding document prepared by the manufacturer stating that the device is in compliance with the applicable European requirements. You may now affix the CE Marking the devices covered by your CE-certificate.

**Step9**  
Register the device and its Unique Device Identifier (UDI) in the EUDAMED database. UDI must be on label and associated with the regulatory documents.

**Step10**  
For Class I (self-certified), annual NB audits are not required. However, CER, Technical File, and PMS activities must be kept updated.

For all other classes, you will be audited each year by a Notified Body to ensure ongoing compliance with the MDR. Failure to pass the audit will invalidate your CE certificate. You must perform Clinical Evaluation, PMS, and PMCF activities to maintain certification.

This is a simplified overview of the process. Your Notified Body may choose to audit your submission and request more documents, which will add time to your approval.