CE Marking - Conformity Assessment

CE Marking is a **mandatory conformity marking** required to **sell medical devices in the EU market**

✅ CE Mark Meaning

Declares that the product complies with EU medical device directives and regulations

🛡️ Legal Requirements

Legal requirement for sale within the EU

Conformity Assessment Routes

Class I: Manufacturer self-declaration

Class IIa: Technical documentation review by Notified Body

Class IIb: Quality system + design review by Notified Body

Class III: Full quality assurance audit by Notified Body

Steps to Obtain CE Marking

1. Device classification and applicable regulations identification

2. Technical documentation preparation

3. Clinical evaluation conduct

4. Quality management system establishment (ISO 13485)

5. Notified Body audit (if applicable)

6. Declaration of Conformity (DoC) preparation

7. CE mark affixing and EUDAMED registration

💡 **Key Point:** CE Marking is not a one-time event but requires ongoing compliance maintenance, with regular technical documentation updates and post-market surveillance required