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# CE Marking Checklist

**Regulatory Strategy & Planning**

- Determine if EU MDR or IVDR applies
- Confirm device classification (Class I, IIa, IIb, III / Class A–D for IVDs)
- Choose the correct conformity assessment route
- Appoint an EU Authorized Representative (if outside EU)
- Identify if a Notified Body is required

**Technical Documentation**

- Complete device description and specifications
- Prepare GSPR checklist
- Create risk management file (ISO 14971)
- Add manufacturing process overview and QMS documents (ISO 13485)
- Include software documentation (if applicable)

**Evidence & Evaluation**

- Draft Clinical Evaluation Report (CER) or Performance Evaluation Report (PER)
- Include supporting clinical/literature data
- Prepare Post-Market Clinical Follow-Up (PMCF) or justification

**Labeling & UDI**

- Prepare compliant labels and Instructions for Use (IFU)
- Assign and document Unique Device Identification (UDI)
- Ensure language requirements for EU countries are met

**Final Readiness**

- Draft and sign Declaration of Conformity
- Affix CE mark appropriately
- Submit to Notified Body (if required)
- Register device in EUDAMED (if applicable)
- Implement post-market surveillance and vigilance plan