



CE Roadmap for Medical Devices

Clarity on the requirements, time involved and costs of CE marking.

- What regulatory requirements apply to your medical device?
- How long does the process of obtaining CE marking take?
- What costs can you expect?

A reliable answer is only possible once the fundamental aspects of a conformity assessment have been clarified. The VDE Health CE Roadmap provides a structured basis for decision-making in this regard.

What is the CE Roadmap?

The CE Roadmap is a structured analysis and planning process. It clearly outlines the regulatory path to CE marking for manufacturers and links the requirements profile to a breakdown of costs, potential processing times and specific recommendations on how to proceed.

Your outcome

Upon completion of the CE Roadmap, you will receive a well-founded assessment:

- which regulatory requirements are relevant to your product,
- which documents, evidence and processes are required,
- whether and when a Notified Body must be involved,
- which conformity assessment procedure is likely to be required,
- what costs, risks and timeframes should realistically be factored in,
- which next steps should be prioritised.

The 5-step process

How to create your CE roadmap

1. **Clarify the project status**
Joint workshop on the product, project status and information requirements.
2. **Carry out a gap analysis**
Compare the current status with the target requirements, particularly regarding intended use, qualification, risk class, processes and documentation.
3. **Draw up the roadmap**
Description of the regulatory pathway leading to CE marking.
4. **Prepare a report**
Document the results in a structured report.
5. **Prepare for implementation**
Workshop on implementation steps, risks and recommendations for the way forward.

Your benefits

- Early clarity on regulatory requirements.
- A more realistic assessment of time, costs and resources.
- Avoiding costly missteps.
- Better preparation for Notified Bodies and regulatory requirements.
- A sounder basis for decision-making regarding development, financing and market access.
- Specific recommendations for the next implementation steps.

Are you planning a medical device and would like to assess the regulatory burden?

VDE Health supports you in planning the path to CE marking in a structured way – from the intended purpose right through to implementation planning.

VDE Health

VDE Association for Electrical
Engineering
Electronics and Information
Technology e.V.
Merianstraße 28
63069 Offenbach am Main
Email: meso@vde.com
Website: www.vde.com/health

Please note: This description is intended solely to provide general information about the range of services offered by VDE Health. It does not constitute a binding offer. The nature, scope and specific details of the services will be agreed upon jointly on a case-by-case basis and set out in a separate agreement.