



Market Access Compass

Regulatory strategy for medical devices.

Innovative medical devices, in vitro diagnostic medical devices, software solutions and data-driven technologies often emerge at the intersection of medicine, digitalisation, AI, the data economy and clinical practice. Consequently, the regulatory path is determined not only by the MDR or IVDR, but also by related legal frameworks, regulatory requirements for data and AI, market requirements and strategic product decisions.

What is the Market Access Compass?

The Market Access Compass from VDE Health helps companies, research institutions and clinics to strategically assess regulatory issues at an early stage and to derive a viable approach for the development, qualification, classification and market access of products.

Your outcome

Through a structured strategy and analysis process for early-stage regulatory decisions, VDE Health supports the development of a sound, comprehensive understanding of the regulatory landscape for a specific medical product or technology project.

The following aspects are considered in particular:

- the medical problem and the relevant healthcare context,
- the technological approach and its regulatory relevance,
- application scenarios and business case options in the target market segment,
- the overall regulatory situation, taking into account related legal frameworks,
- possible regulatory approaches and pathways to conformity assessment,
- intended use, qualification, classification in accordance with the MDR or IVDR,
- key legal requirements, standards and guidelines,
- next steps for the further implementation of the project.

The Market Access Compass process

1. Discuss the current situation

Discussion of the medical need, the technological approach, the product concept, the target market segment and the current status of the project.

2. Analysing strategic options

Analysis of potential application scenarios, business cases, healthcare contexts and possible regulatory classifications.

3. Assessing the overall regulatory situation

Assessment of the relevant regulatory framework, in particular the MDR and IVDR, as well as related legal frameworks such as the AI Act, EHDS, Data Act, data protection and cybersecurity.

4. Developing a regulatory strategy

Support with intended purpose, qualification, classification, possible conformity assessment routes and essential requirements.

5. Derive recommendations for action

Summary of the findings and the resulting next steps for product development, regulatory implementation and market access.

The process includes accompanying workshops in which key aspects of the project are discussed jointly.

Your benefits

- Strategic clarity at an early stage of the project
- Better alignment of medical needs, technology and the regulatory pathway
- Early identification of regulatory opportunities, risks and scope-definition issues
- A more robust intended purpose as the basis for development and market access
- Guidance on qualification, classification and conformity assessment
- A sound basis for decision-making regarding next steps, timelines and market access

Are you planning a medical device or a digital health solution?

VDE Health helps you to address regulatory issues strategically at an early stage and to develop a robust regulatory project from a product idea.

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.