



Second Opinion

Independent assessment of a regulatory issue

Regulatory decisions concerning medical devices often hinge on specific issues: the interpretation of a requirement, an assumption regarding classification, the wording of an intended purpose, or the question of whether a particular piece of evidence is sufficient. Such issues tie up internal resources, delay decisions and can lead to queries or objections during the formal procedure. An independent and well-founded external perspective helps to review one's own position and establish a sound basis for decision-making.

What is the Second Opinion?

VDE Health's Second Opinion service provides an independent and well-founded assessment of a specific issue relating to interpretation, documentation, classification or conformity in the field of medical devices and in vitro diagnostic devices. We examine the arguments presented, consider the relevant legal basis and assess how sound the assumption made is. The assessment is prepared in such a way that it can be used for internal decision-making as well as for communication with Notified Bodies and regulatory authorities. It is suitable both for reviewing a decision that has already been made and for clarifying an outstanding issue.

Your outcome

By having your regulatory question reviewed, you will receive a second opinion with a clear and well-reasoned justification. You will be able to identify whether your position is tenable, where uncertainties lie, and what alternatives are available. In particular, the following aspects are considered:

- the specific issue and its regulatory context
- the relevant legislation, standards and guidelines
- the arguments put forward and their clarity
- existing scope for interpretation and its limits
- recognisable administrative and review practices
- Risks associated with the chosen position in the formal procedure
- possible alternatives and their respective consequences
- A reasoned recommendation and any outstanding issues

The second opinion process

1. Refining the question

Clarifying the specific question, the product context, the decision-making context and the desired format of the outcome.

2. Reviewing documents

Reviewing the available documentation, evidence, justifications and process descriptions.

3. Reviewing the legal and regulatory framework

Identifying the relevant requirements from the MDR or IVDR, standards, guidelines and related legal frameworks.

4. Assess the position and formulate a recommendation

Assessing the available arguments, the existing scope for interpretation and the associated risks, and formulating a reasoned recommendation, highlighting any remaining uncertainties and suggesting appropriate next steps.

Depending on requirements, the process may include discussions, consultations or workshops, for example to prepare, to clarify any interim questions and to jointly interpret the results.

Your benefits

- Prompt clarification of a specific regulatory issue
- Independent review of internal assumptions and arguments
- A robust basis for management decisions and coordination with third parties
- Transparent justification for the technical documentation
- Early awareness of the risks associated with a chosen approach
- Manageable effort whilst being of great significance for the further course of the project
- Less rework thanks to the early clarification of contentious issues

Do you require an independent assessment of a specific regulatory issue?

VDE Health will examine your enquiry independently and thoroughly. You will receive a clearly reasoned assessment to aid your further decision-making.

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.