



Tip!
Also take advantage of the other AI Regu tools to comply with the requirements for the development of medical devices: [List of Experts](#), [Ecosystem map](#)

Manufacturer, start here!

01

What are we developing and why?

Specify the intended purpose of the software or device (hereinafter: device) by describing:

- **what** the device does
- **who** it is intended for
- **what** environment it is used in
- **what** kind of data the device processes or modifies

Provide an **accurate** description of the actual functioning of the device:

- do not add functions that do not exist or methods of use that are not possible
- do not leave out any of the functions performed by the device or any of its effects
- also ensure that marketing refers only to the actual features of the device

Document the intended purpose of the device as a written, compact **description of the intended purpose** and make it part of the technical documentation. The description serves as a basis for classification, risk management and assessments.

Please note that the device or software can be part of a larger whole.

02

Do the features make it a medical device?

Read the MD and IVD regulations carefully.

Compare the intended purpose and functions of the device with the definitions of medical devices compliant with the MD and IVD regulations.

Define whether the device is a medical device or not.

Justify the decision with the intended purpose of the device.

Document the definition you have drawn up.

03

How high may the health risk caused by device use be?

Define the risk class of the device according to the classification rules in the MDR (I, Is/m/r, IIa, IIb, III) or the IVDR (A, B, C, D).

The risk class contributes to how the device must be tested and approved.

Document the risk classification in writing. Include in the information:

- selected classification rule
- determined risk category
- whether the device must be approved by an external inspection body

Prepare a risk management plan, e.g. by using the EN ISO 14971 standard.

04

Does this contain artificial intelligence?

Familiarise yourself carefully with the requirements of the AI Act concerning the development of AI systems.

Assess whether the device contains an AI system compliant with the definition in the AI Act.

If yes, specify whether it is:

- an AI system, or
- a medical device containing an AI feature

Document the definition:

- the AI Act is applicable, or
- the AI Act is not applicable

If the AI Act is applicable, describe in the documentation:

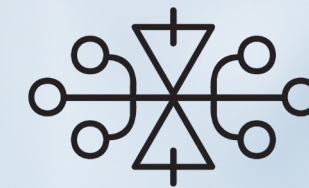
- what AI does
- what the result produced by the device is used for

Take into account the requirements of the AI Act in the risk management plan.

(After the previous steps) Prepare a regulatory strategy for the device.

The AI Regu AI and MDR/IVDR Device Regulatory Pathway provides manufacturers with an overview of the key stages and considerations involved in developing an AI-enabled medical device and placing it on the EU market. The purpose of the tool is to support manufacturers in planning their own work. It does not constitute legal advice and does not replace a device-specific regulatory assessment. Manufacturers should always carefully review the applicable regulations and guidance, as well as the specific measures required for their device. The manufacturer remains responsible for applying the relevant regulatory requirements and ensuring compliance.

Regulatory path for AI & MDR/IVDR device



AI REGU



Key steps and measures of the regulatory path for device manufacturers developing AI-enabled medical devices for the EU market. The content is based on information on the AI Act and the regulations on MD and IVD on 1 May 2026.

Updated 4 May 2026.

NB! Steps 5-10 may take up to 18 months.

