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**

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.

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Haaga-Helia
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Manufacturer, start here!

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

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.

05 Build and maintain quality management practices and a quality management system (QMS)

Build and maintain a QMS conforming with Article 10 of the MDR/IVDR.

Ensure that the QMS also takes into account the operating practices essential for an AI device, such as the management of device development, changes, risks, software, data, cybersecurity and the AI model.

Document the operating practices as process descriptions and codes of practice.

Keep them up to date when the device, software, AI solution and regulations change.

Note! It is advisable to use applicable standards.

Standards provide ready-made and approved ways to meet the requirements. Their use facilitates development and demonstrates compliance.

Remember to include a **human in the loop** in the quality management process!

06 Prepare and compile the technical documentation

Start the dialogue with the notified body well in advance to save you from unnecessary surprises.

Compile all the information showing how the device has been designed, developed and assessed. The documentation consists of the results of the development, risk management, testing and assessments

In the documentation, include at least:

- description and intended purpose of the device
- details of design and development
- risk management results
- outcomes of tests and assessments
- details of software and cybersecurity
- results of clinical assessment and performance assessment
- Instructions for use and labelling

For AI, also add the following to the documentation:

- description of the AI system
- management and description of data and datasets
- performance, limitations and error situations of the model
- bias assessment and management
- log data and controllability

Document only the actual functions and features of the device.

Maintain the technical documentation at all times.

07 Carry out a clinical evaluation (MDR) or a performance evaluation (IVDR)

Demonstrate that the device is safe to use and functions according to its intended purpose. Base the assessment on evidence.

At this stage:

- collect and evaluate the existing research evidence systematically (literature review)
- assess the safety and performance of the device based on evidence
- for IVDR devices, demonstrate scientific validity and analytical and clinical performance
- conduct the necessary clinical investigations and performance studies. Justify if no investigations/ studies are required.

Take AI into account:

- assess the performance of the model in practical situations
- identify limitations and fault situations
- assess possible biases
- ensure the results are reliable and reproducible

If you conduct an investigation/study:

- obtain the necessary statement from the Ethics Committee
- submit the required notification or permit application to Fimea
- carry out the investigation/study according to requirements

Document the results of the evaluation in the technical documentation: evidence used, evaluation method and grounds for conclusions.

IMPORTANT!
If the risk class of the device is MDR Is/m/r, IIa, or IVDR As, B or higher, the AI contained in the device is very **likely a high-risk system,** even if the role of AI is minute.

08 High-risk devices: apply for conformity assessment from the notified body

The notified body verifies that the device meets all the requirements prior to market access.

Does this apply to you?
This step applies to you if the device is subject to:

- MDR: Is, Im, Ir, IIa, IIb, III
- IVDR: As, B, C, D

Take AI into account!

If the device must be inspected by a notified body, the AI contained in the device is very likely to be a high-risk system, regardless of how small its role is.

Make the following part of the technical documentation:

- assessments and reports of the notified body
- changes and corrections made

Important!

Select the notified body carefully. The decision binds you for a long time and may be burdensome to change later.

09 Place the device on the market

Draw up a declaration of conformity under the MDR/IVDR and the AI Act.

Document the declaration of conformity:

- as a document signed by the manufacturer
- as part of the technical documentation of the device

Attach the CE marking to the device, to the instructions for use/terms of use for software, or to the front page for a user interface.

Register the device for the required EU systems.

Document the placement on the market:

- registration details
- documents concerning CE marking

Important!

- When you sign the declaration of conformity, you will be legally responsible for the device.
- If you use a notified body, its assessment is part of this step.
- The requirements concerning AI are included in the same entity.

10 Monitor the use and safety of the device on the market constantly

Continuous process!

Monitor how the device functions in practice and ensure its safety and conformity with regulations throughout its lifecycle.

Do this continuously:

- collect information about using the device and matters affecting it
- monitor safety and performance
- identify and address deviations and risks
- take the necessary corrective measures

Take AI into account:

- monitor the performance of the model in use
- identify changes, errors and limitations
- Make sure that the model also works as expected in the long run

If necessary, report:

Notify deviations and safety incidents to the authorities.

Document:

- follow-up reports
- log data and analyses

Remember!

- This is a continuous process.
- Update risk management and documentation as necessary.
- If you make significant changes, go back to step 01.