

Feedback From Swissmedic



From health software to artificial intelligence in medical devices: Navigating the regulatory landscape

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doi: [10.54920/SCTO.2026.RAWATCH.11.16](https://doi.org/10.54920/SCTO.2026.RAWATCH.11.16)

Health software can encompass a broad range of functions and may qualify as a medical device under Swiss and European Union (**EU**) law if it is intended to be used for a medical purpose, thus making it subject to medical device regulations. Medical device software incorporating artificial intelligence (**AI**) introduces additional considerations, including data dependency, limited interpretability, and the potential for adaptive systems to change behaviour after deployment. Even though Switzerland has not yet adopted dedicated AI legislation, the existing medical device regulatory framework, along with international standards and best practice guidance, provides the necessary foundation for ensuring adequate safety and performance of AI-based medical devices. As the regulatory landscape continues to evolve rapidly, developments should be continually monitored by manufacturers and regulators alike.

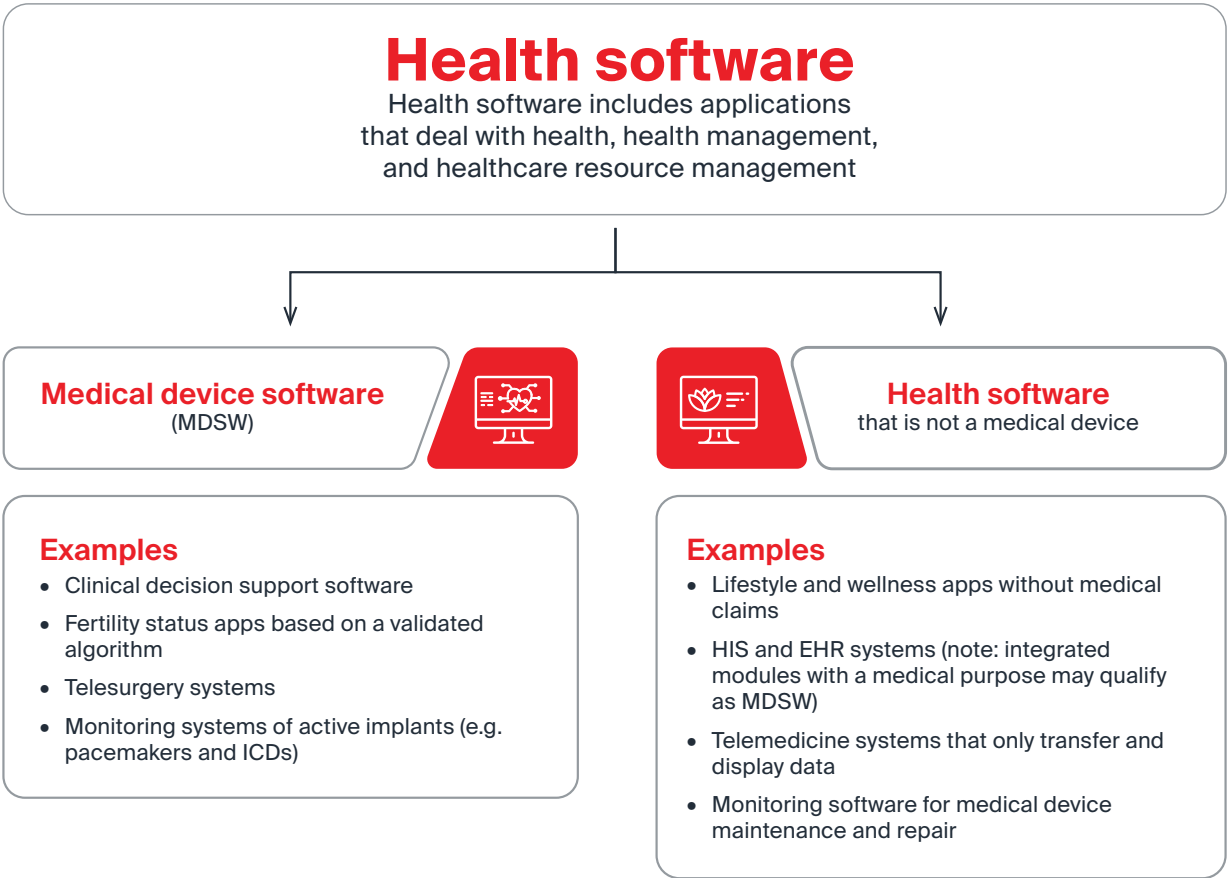
Health software: Scope and categories

Modern health software performs a wide range of functions, such as data management, patient monitoring, and clinical decision support. It can be deployed across a variety of platforms, from software embedded in a specific medical device (e.g. a pacemaker) to desktop applications, mobile applications, and cloud-based systems.

The International Electrotechnical Commission (IEC) defines health software in its [IEC 82304-](#)

1:2016 standard as software intended to be used specifically for managing, maintaining, or improving the health of individual persons or the delivery of care. As illustrated in **Figure 1**, health software includes applications dealing with health, health management, and healthcare resource management. Within health software, two categories can be distinguished depending on whether medical device regulations apply: medical device software (**MDSW**) and health software that is not a medical device.

Figure 1: Regulatory distinctions of health software



EHR: electronic health record
HIS: health information system
ICD: intra-cardiac defibrillator
MDSW: medical device software

Medical device software is subject to medical device regulations. The following are examples of MDSW:

- clinical decision support software (e.g. for drug planning in chemotherapy or for the automatic analysis of X-ray images)
- applications intended to support conception by calculating fertility status based on a validated algorithm
- telesurgery systems
- web systems used to monitor active implants such as pacemakers or intra-cardiac defibrillators (**ICDs**).

In contrast, health software that is not considered a medical device is not subject to medical device regulations. The following are examples of such health software:

- lifestyle software without medical claims (e.g. fitness, nutrition, or sleep applications)
- hospital information systems (**HIS**) and electronic health record (**EHR**) systems (modules integrated into or operating alongside such systems may, however, qualify as MDSW if they fulfil a medical purpose)
- telemedicine systems that only transfer or display information for monitoring purposes without interpreting data
- software used in hospital systems for the monitoring, maintenance, or repair of medical devices.

Which health software is subject to medical device regulations?

In Switzerland, software qualifies as a medical device^A if it meets the criteria set out in Article 3, paragraphs 1 and 2 of the Medical Devices Ordinance (**MedDO**) or Article 3, paragraphs 1 and 2 of the Ordinance on In Vitro Medical Devices (**IvDO**). These criteria are

materially aligned with the corresponding definitions in the European Union's Medical Device Regulation (**MDR**) and its In Vitro Diagnostic Medical Devices Regulation (**IVDR**). In essence, the manufacturer must intend for the software to be used (alone or in combination with other products) for a medical purpose such as the diagnosis, prevention, monitoring, prediction, prognosis, treatment, or alleviation of a disease. More specifically, and according to the EU's Medical Device Coordination Group's (**MDCG's**) guidance document MDCG 2019-11 Rev. 1 on the qualification and classification of software under the MDR and IVDR, software will generally qualify as MDSW if all of the following three criteria apply:

- It has a medical purpose as defined in the applicable regulation.
- It performs an action on data beyond mere storage, archiving, communication, simple search, or lossless compression.
- It is intended for the benefit of individual patients.

Whether software has a medical purpose depends on its intended purpose as defined by the manufacturer. Intended purpose means the use for which a product is intended according to the information supplied by the manufacturer on the product's label, instructions for use, promotional or sales materials, or as specified in the clinical or performance evaluation (MDR, Art. 2(12); IVDR, Art. 2(12)).

Qualification as a medical device is independent of its location (e.g. desktop, mobile app, or embedded in hardware) and its intended user (e.g. healthcare professional or layperson). Even if software itself does not qualify as a medical device, it may still be covered by medical device legislation if it qualifies as an accessory to a medical device or falls within the scope of an MDR Annex XVI product.

^AFor the purposes of this text, references to a "medical device" include both medical devices under the Medical Devices Ordinance (MedDO) and in vitro diagnostic medical devices under the Ordinance on In Vitro Diagnostic Medical Devices (IvDO).

Crafting a clear and precise intended purpose is therefore critical for correct qualification and regulatory compliance. MDCG 2019-11 Rev. 1 and the European Commission's infographic *Is Your Software a Medical Device?* (see **Figure 2**) both provide useful guidance regarding the qualification and classification of software. Additional information can be found in the MDCG's guidance on MDSW meant to be used with hardware or hardware components (MDCG 2023-4) and the MDCG's *Manual on Borderline and Classification for Medical Devices under Regulation (EU) 2017/745 on Medical Devices and Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices*.

Medical device software incorporating artificial intelligence

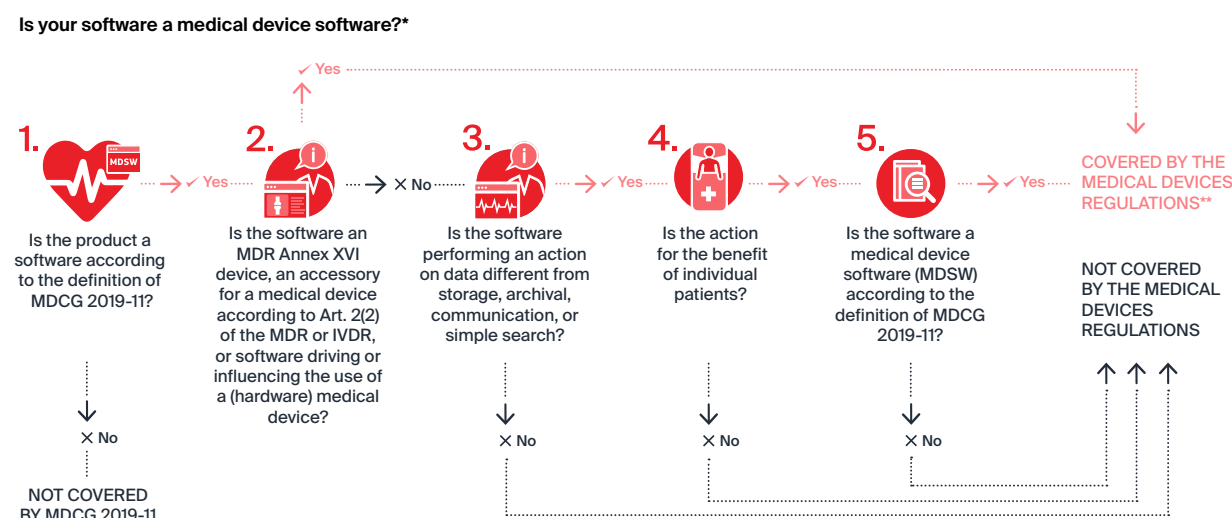
Medical device software can incorporate artificial intelligence (AI). AI refers to the use of computational models to perform tasks that typically require human intelligence. The EU's *Artificial Intelligence Act (AI Act)* defines an AI system as "a machine-based system that is designed to operate with varying levels of autonomy

and that may exhibit adaptiveness after deployment, and that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content, recommendations, or decisions that can influence physical or virtual environments" (Article 3(1)). The predominant form of AI in MDSW is machine learning models, which are most commonly used for image analysis, clinical decision support, or risk prediction.

The use of AI introduces unique considerations, including the following:

- the data-driven nature of model development
- the limited interpretability of many models
- the dependence of performance on the quality and representativeness of training data
- challenges of reliably evaluating system behaviour
- the potential of adaptive systems to change behaviour after deployment.

Figure 2: Decision steps to assist the qualification of medical device software



* Medical device software (MDSW): Software that is intended to be used alone or in combination for a purpose as specified in the definition of a medical device in the Medical Device Regulation (MDR) or In Vitro Diagnostic Medical Devices Regulation (IVDR)

** Medical devices regulations refer to two applicable regulations: The EU's Medical Device Regulation (MDR) and the EU's In Vitro Diagnostic Medical Devices Regulation (IVDR)

Currently, Switzerland does not have a dedicated AI regulation. Rather than adopting a comprehensive, cross-sectoral AI framework comparable to the AI Act, legislative developments are expected to follow a sector-specific approach.

In the absence of a direct regulation, the unique characteristics and risks of MDSW incorporating AI must be addressed within the existing regulatory framework, which includes the following regulations and international standards, among others:

- MedDO/MDR
- IvDO/IVDR
- MDCG endorsed documents and guidance relevant to MDSW
- International Organization for Standardization (**ISO**) standards for quality management systems (ISO 13485), for risk management (ISO 14971), for clinical investigations of medical devices for human subjects (ISO 14155), and for clinical performance studies using specimens from humans involving in vitro diagnostic medical devices (ISO 20916)
- International Electrotechnical Commission (**IEC**) standards for medical device software life cycle processes (IEC 62304), for the application of usability engineering to medical devices (IEC 62366 Part 1 and Part 2), and for health software (IEC 82304 Part 1).

Global AI standards are only applicable to a limited extent in the medical device context, and dedicated standards for AI in medical devices are still under development. Therefore, useful orientation can be found in the following best practice principles and other guidance documents, among others:

- International Medical Device Regulators Forum (**IMDRF**) Good Machine Learning Practice for Medical Device Development: Guiding Principles
- German Notified Bodies Alliance for Medical Devices (**IG-NB**) and The European Association of Medical devices Notified Bodies' (**Team-NB**) joint position paper Questionnaire: Artificial Intelligence in Medical Devices (Version 1.1)

- British Standards Institution (**BSI**) and Association for the Advancement of Medical Instrumentation (**AAMI**) Application of ISO 14971 to Machine Learning in Artificial Intelligence: Guide (BS/AAMI 34971:2023).

Swiss manufacturers operating in the EU market must comply with the AI Act's requirements. Under the AI Act, AI systems intended for use as medical devices are currently classified as high risk and are subject to various obligations. Swiss manufacturers are therefore well advised to align their development and quality management practices with these requirements from the outset. At the same time, the regulatory landscape for AI in the healthcare sector is evolving rapidly. Recent legislative amendments and proposals at the EU level – notably the Digital Omnibus on AI (in force since 27 July 2026) and the proposed MDR/IVDR amendments (December 2025) – indicate that the regulatory framework is subject to ongoing change. These developments should be continually monitored by manufacturers and regulators.

Ultimately, manufacturers must demonstrate that software incorporating AI achieves an adequate level of safety and performance and meets its defined intended purpose. While Switzerland currently lacks AI-specific legislation, the existing medical device regulatory framework provides the necessary foundation. This framework must be applied in a way that appropriately addresses the specific risks and characteristics of AI-based medical devices, thus ensuring robust assurance of safety and performance throughout the product life cycle.

Note: Swissmedic is the competent authority responsible for the surveillance and enforcement of medical device regulation in Switzerland; it is not responsible for the development of the legislative framework.