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Information sheet
Medical Device Software

Identification number:	BW630_30_007
Version:	3.0
Valid from:	10.04.2024

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1 Introduction

Software is gaining importance in medicine and healthcare, from software applications (apps) for smartphones or wearable devices, to web or desktop applications, through digital tools to assist with decision-making or systems that control medical devices. This greater importance is underscored not only by a rising number of software application options for medical purposes but also in the corresponding regulations. In fact, software is explicitly included in the definition of medical devices in the Medical Devices Ordinance (MedDO SR 812.213) and in the definition in the Ordinance on In Vitro Diagnostic Medical Devices (IvDO SR 812.219).
In this context, medical device software (MDSW) can mean software that belongs to a physical medical device or it can refer to a separate medical device.
Medical devices under MedDO or IvDO are subject to strict requirements as regards product safety and the quality management of the organisations involved in their development, manufacture, distribution, sale and maintenance. If software is qualified as a device according to the relevant provisions of MedDO or IvDO, a number of regulations and standards must be observed and taken

into account. Guidelines such as the MDCG documents also provide recommendations for implementing the European regulations.
This information sheet is intended for manufacturers/developers of medical device software and for economic operators (importers, distributors, authorised representatives) in the distribution chain for such devices.

2 Framework, guidelines and standards

2.1 Legal framework

EU-IVDR	Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU
EU-MDR	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No. 178/2002 and Regulation (EC) No. 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
FADP	Data Protection Act of 25 September 2020 (SR 235.1)
HRA	Human Research Act of 30 September 2011 (SR 810.30)
IvDO	Ordinance on In vitro Diagnostic Medical Devices of 4 May 2022 (SR 812.219)
MedDO	Medical Devices Ordinance of 1 July 2020 (SR 812.213)
TPA	Therapeutic Products Act of 15 December 2000 (SR 812.21)

2.2 MDCG guidelines[1]

MDCG 2018-5	UDI Assignment to Medical Device Software
MDCG 2019-11	Guidance on Qualification and Classification of Software in Regulation (EU)
MDCG 2019-16	Guidance on Cybersecurity for medical devices
MDCG 2020-1	Guidance on Clinical Evaluation (MDR) / Performance Evaluation (IVDR) of Medical Device Software
MDCG 2020-16	Guidance on Classification Rules for in vitro Diagnostic Medical Devices under Regulation (EU) 2017/746
MDCG Infographic	Is your **software** a Medical Device?
MDCG 2021-24	Guidance on classification of medical devices
MDCG 2023-4	Medical Device Software (MDSW) – Hardware combinations, Guidance on MDSW intended to work in combination with hardware or hardware components

2.3 Technical standards (list not exhaustive)

EN 62304	Medical device software – Software life cycle processes
EN ISO 14971	Medical devices – Application of risk management to medical devices

[1] https://health.ec.europa.eu/medical-devices-sector/new-regulations/guidance-mdcg-endorsed-documents-and-other-guidance_en

EN 62366 - 1	Medical devices – Part 1: Application of usability engineering to medical devices
EN ISO 13485	Medical devices – Quality management systems – Requirements for regulatory purposes
EN ISO/IEC 15408	Information technology – Security techniques – Evaluation criteria for IT security
IEC 80001:	Application of risk management for IT-networks incorporating medical devices
IEC/TR 80002-1:	Medical device software – Part 1: Guidance on the application of ISO 14971 to medical device software
ISO/TR 80002-2:	Medical device software – Part 2: Validation of software for medical device quality systems
IEC/TR 80002-3	Medical device software - Part 3: Process reference model of medical device software life cycle processes
EN 82304	Health software

3 What is a medical device?

Medical devices[2] are instruments, apparatus, appliances, software, implants, reagents, materials or other articles that are intended by their manufacturer to be used for human beings. They do not achieve their intended principal action in or on the human body by pharmacological, immunological or metabolic means, but the action may be assisted by such means.
Medical devices, used alone or in combination, meet one or more specific medical purposes, such as diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease, injury or disability; investigation, replacement or modification of the anatomy or of a physiological or pathological process or condition.
In vitro diagnostic medical devices (IVDs) are a subgroup of medical devices[3]. IVDs are devices to be used in vitro for the examination of specimens, including blood, organ and tissue donations, derived from the human body.
Medical devices[4] also include devices for the control or support of conception, and products specifically intended for the cleaning, disinfection or sterilisation of devices.
Accessory for a medical device[5] means an article which, whilst not being itself a medical device, is intended by its manufacturer to be used together with one or more particular medical devices.
Where provisions apply only to specific medical devices or device groups in an ordinance (MedDO or IvDO), this is explicitly stated.

[2] Art. 3 para. 1 MedDO
[3] Art. 3 para. 1 IvDO
[4] Art. 3 para. 2 MedDO
[5] Art. 3 para. 3 MedDO / Art. 3 para. 3 IvDO

Table 1: Overview of medical devices and in vitro diagnostic medical devices

	Devices under MedDO	**Devices under IvDO**
Common abbreviations	MD (for "medical device")	IVD
Definition	Art. 3 MedDO	Art. 3 IvDO
Regulations	MedDO in conjunction with Regulation (EU) 2017/745 on medical devices (EU-MDR)	IvDO in conjunction with Regulation (EU) 2017/746 on in vitro diagnostic medical devices (EU IVDR)
Risk classes	Classes I, IIa, IIb and III	Classes A, B, C and D

3.1 Terms and definitions

Software	The guideline MDCG 2019-11 defines "software" as a set of instructions that processes input data and creates output data.
Intended purpose[6]	The intended purpose means the use for which a device is intended according to the data supplied by the manufacturer on the label, in the instructions for use or in promotional or sales materials or statements and as specified by the manufacturer in the clinical evaluation.
Active device[7]	"Active device" means any device, the operation of which depends on a source of energy other than that generated by the human body for that purpose, or by gravity, and which acts by changing the density of or converting that energy. Software is considered an active device.
Devices for self-testing[8]	"Medical device for self-testing" means any device intended by the manufacturer to be able to be used by laypersons, including medical devices used for testing services offered to lay persons by means of information society services.

4 Qualification as medical device software

Software is a medical device if it is intended to be used, alone or in combination with another product, for a medical purpose for the benefit of an individual (and not solely for the benefit of a population) and if the processing of medical data is not limited to storage, archiving, simple search, communication or lossless compression[9].

Note: The display of medical images is not limited to storage, archiving, communication, simple search or lossless compression. Therefore, software that displays medical images of an individual person for medical purposes qualifies as a medical device.

The medical purpose is designated in the intended purpose of the medical device.

Thus, the intended purpose of the medical device, as defined by the manufacturer, is definitive for qualification. The obligation to define an intended purpose exists regardless of whether the software is a stand-alone product or it controls or influences the use of a medical device. It is also independent of the installation location (e.g. in the cloud, on a computer, on a mobile phone or as an additional function on a medical hardware device) and of the intended user (e.g. qualified professional, layperson).

[6] Art. 4 para. 2 MedDO in conjunction with Art. 2 no. 12 EU-MDR /Art. 4 para. 2 IvDO in conjunction with Art. 2 no. 12 IVDR
[7] Art. 4 para. 2 MedDO in conjunction with Art. 2 no. 4 EU-MDR
[8] Art. 4 para. 2 IvDO in conjunction with Art. 2 no. 5 EU-IVDR
[9] MDCG 2019-11

The MDCG infographic “Is your software a medical device?” offers a brief summary of decision steps to assist in the qualification of medical device software. Section 3 of the guideline MDCG 2019-11 includes additional explanations and examples:

- Figure 1 of the MDCG infographic, “Is your software a medical device?” can help determine whether software falls under the scope of the two medical device regulations (EU-MDR or EU-IVDR).
- Figure 2 of the MDCG infographic, “Is your software a medical device?” can help determine whether software is a device under the MedDO or EU-MDR or is a device under IvDO or EU-IVDR.
- MDCG 2019-11 also demonstrates in a number of examples that not all medical software is considered a medical device. For instance, software intended only to show the available IVD results using certain functions (e.g. basic arithmetic operations such as calculation of means or conversion of units, plotting results as a function of time, comparison of a result with the limits of acceptance set by the user) is not an in vitro diagnostic medical device.

Certain software applications in the healthcare sector are not medical devices, such as (see also MDCG 2019-11):

- Software for hospital resource planning, reimbursement, management of doctors’ visits.
- Software for the statistical analysis of clinical or epidemiological studies or registers
- Electronic patient records or journal applications that simply replace paper-based health data.
- Electronic reference works, general non-personalised medical information

For additional information on MDSW designated for use in combination with hardware or hardware components, see MDCG 2023-4.

5 Classification of medical device software

Medical devices are divided into classes, taking into account the intended purpose of the devices and their inherent risks. The classification takes account of the potential risks associated with the use of the medical devices in humans. The correct classification of the software is the basis for proper selection and execution of the conformity assessment procedure and any involvement of a designated body.[10]

Annex VIII EU-MDR or Annex VIII EU-IVDR is authoritative for classifying the medical devices and in-vitro diagnostic medical devices[11].

The following implementing rules are of note when using classification rules for software:

- Software which drives a device or influences the use of a device shall fall within the same class as the device. If the software is independent of any other device, it shall be classified in its own right[12].
- If several rules, or if, within the same rule, several sub-rules, apply to the same device based on the device's intended purpose, the strictest rule and sub-rule resulting in the higher classification shall apply[13].

[10] Art. 23 MedDO / Art. 19 IvDO
[11] Art. 15 MedDO / Art. 14 IvDO
[12] Annex VIII no. 3.3 EU-MDR / Annex VIII no.1.4 EU-IVDR
[13] Annex VIII no. 3.5 EU-MDR / Annex VIII no.1.9 EU-IVDR

Decision-making tools and examples for the application of classification rules are set forth in the guidelines MDCG 2019-11, MDCG 2020-16 and MDCG 2021-24.

Where a software intended for use of a hardware medical device includes certain functions that go beyond the control and influencing of the hardware product, e.g. because the software provides information from data generated by the hardware medical device that could be used in decisions for diagnostic or therapeutic purposes, it is possible that this software will be in a higher class than the hardware medical device without this software. One example is cancer image analysis software that is used together with a scanner (see section 4.1 of MDCG 2019-11). Therefore, the entire product, comprising hardware and software, receives the same classification as the higher-classed software.

5.1 Class I medical device software

Rule 11 of Annex VIII EU-MDR, which applies to stand-alone medical device software as well as medical device software embedded in medical devices, puts strict limits on the functionalities for Class I software. However, it permits a number of functionalities for Class I medical device software. Assuming that the software has a benefit for individuals (see MDCG 2019-11, Figure 1) and that it neither controls a higher-class medical device nor influences its application (see Implementing Rule 3.3. of Annex VIII EU-MDR), the following software functionalities can be placed under Class I:

- prevention, monitoring, prediction, prognosis or alleviation of disease
- monitoring, alleviation of or compensation for an injury or disability;
- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state
- devices for control or support of conception
- products specifically intended for the cleaning, disinfection or sterilisation of medical devices and product groups without an intended medical purpose as referred to in Annex I MedDO.

Additional software functionalities can also fall under Class I, such as contact tracing for notifying persons of potential contagion, displaying medical information at a different location (such as using mixed reality glasses) or changing the display of medical information and images (such as by zooming in or out).

5.2 Medical device software produced in healthcare institutions

Art. 9 MedDO and Art. 9 IvDO define the requirements relating to medical devices manufactured and used in healthcare institutions. Medical device software that is produced within a healthcare facility and used solely within that facility is considered to have been put into service. Such a medical device is subject to the relevant general safety and performance requirements stated in Annex I EU-MDR and Annex I EU-IVDR, but not the other requirements stated in the MedDO or IVDO, provided the preconditions specified in Art. 5 para. 5 EU-MDR or Art. 5 para. 5 EU-IVDR are satisfied.
Art. 18 MedDo and Art. 10 IvDO define the reporting obligations for the medical devices produced and used by healthcare institutions before they are put into service.

5.3 Software systems and software modules

If software consists of several modules, the manufacturer is responsible for qualifying and classifying the modules as a whole or each module individually. If the modules are qualified as a whole and if

there are modules with and without medical device properties, the whole system is subject to medical devices legislation[14].

6 Regulatory requirements

6.1 General safety and performance requirements

Any person who places a device on the market in Switzerland must first carry out and be able to produce documentary evidence of an evaluation of the device's conformity with the general safety and performance requirements[15]. Medical devices must meet the general safety and performance requirements set out in Annex I to MDR or EU-IVDR, taking account of their intended purpose[16]. This includes medical devices that are offered via an online service[17]. Additional requirements must be taken into account for devices for self-testing and patient use under IvDO[18].

Medical devices are developed and manufactured so that potential risks relating to the IT environment where they are used and interact can be ruled out or reduced as far as possible[19].
Requirements for electronic programmable systems include repeatability, reliability and performance, usability, IT security; they must be manufactured in accordance with the state of the art taking into account the principles of development life cycle, risk management, including information security, verification and validation[20]. In addition, the definitions of compatibility and interoperability explicitly include software[21].
The guideline MDCG 2019-16 provides software manufacturers with guidance on fulfilment of the relevant fundamental requirements relating to cybersecurity under Annex I of EU-MDR or EU-IVDR.

6.2 Technical documentation

Manufacturers must list in the technical documentation the information required in Annexes II and III to EU-MDR or EU-IVDR[22].

The software must include in its general description the key functional elements of a medical device[23]. Complete data regarding verification and validation of the medical device must be submitted[24]. Information about the design and manufacturing methodology should enable comprehension of the medical devices' development stages. For software for devices under IvDO, this includes a description of the data interpretation methodology[25].

[14] Section 7 of MDCG 2019-11; Annex I no. 14.1 EU-MDR / Annex I no. 13.1 EU-IVDR
[15] Art. 21 para. 2 MedDO / Art. 17 para. 2 IvDO
[16] Art. 6 para. 2 MedDO / Art. 6 para. 2 IvDO
[17] Art. 7 MedDO / Art. 7 IvDO
[18] Annex I EU-IVDR
[19] Annex I no. 14.2 let. d EU-MDR / Annex I no.13.2 let. d EU-IVDR
[20] Annex I no. 17 EU-MDR / Annex VIII no.16 EU-IVDR
[21] Art. 4 para. 2 MedDO in conjunction with Art. 2 no. 25-26 MDR / Art. 4 para. 2 IvDO in conjunction with Art. 2 no. 18-19 IVDR
[22] Art. 47 MedDO / Art. 40 IvDO
[23] Annex II no. 1.1 let. j EU-MDR / Annex II no. 1.1 let. k EU-IVDR
[24] Annex II no. 6 EU-MDR / Annex II no. 6.4 EU-IVDR
[25] Annex II no. 3.1 let. d EU-IVDR

6.3 Clinical evidence and performance evaluation

The demonstration of compliance with the general safety and performance requirements must also include a clinical evaluation or a performance evaluation[26]. This includes evidence of safety, performance, clinical benefit and clinical performance[27]. The guideline MDCG 2020-1 provides instructions and examples of how to determine the appropriate level for clinical evaluation or clinical evidence for medical device software.

Clinical evaluation or performance evaluation require clinical data. These may come from clinical studies for the associated medical device or from other sources (see guideline MDCG 2020-1 for information). Information on clinical studies can be found on the Swissmedic website regarding clinical investigations[28] and performance studies[29] as well as in the relevant information sheets.

6.4 Product identification, information and labelling

Medical devices placed on the market in Switzerland or made available on the Swiss market must bear a conformity marking[30]. Investigational devices or devices that are manufactured and used in healthcare institutions must not bear a conformity marking.
Requirements for attaching the unique device identification (UDI) are specified in Art. 17 MedDO or Art. 16 IvDO. For details on UDI assignment for software, see Annex VI no. 6.5 EU-MDR or no. 6.2 EU-IVDR; further information can be found in the guideline MDCG 2018-5.
Product information comprises the labelling and instructions for use. It is governed by Annex I Chapter III of EU-MDR or EU-IVDR[31]. Additional requirements must be taken into account for medical devices for self-testing under IvDO[32].

6.5 Distance sales

Medical devices that are offered via an information society service, specifically an online service that meets the requirements of Art. 7 para. 4 MedDO or Art. 7 para. 5 IvDO (without physical presence, electronically, at the individual request of the recipient) must meet the requirements of the MedDO or IvDO.
Similarly, medical devices that are not placed on the market but are used in the context of a commercial activity, whether in return for payment or free of charge, for the provision of a diagnostic or therapeutic service offered by means of information society services or by other means of communication must also comply. Suppliers of relevant medical devices must provide Swissmedic with a copy of the declaration of conformity on request[33].

[26] Art. 21 MedDO in conjunction with Art. 61 EU MDR / Art. 17 IvDO in conjunction with Art. 56 EU IVDR
[27] Art. 4 para. 2 MedDO in conjunction with Art. 2 no. 44 MDR / Art. 4 para. 2 IvDO in conjunction with Art. 2 no. 36-43 IVDR
[28] Swissmedic Information sheet “Clinical investigations with medical devices” ,
[29] Swissmedic Information sheet “Performance studies with IVD”
[30] Art. 13 MedDO / Art. 12 IvDO
[31] Art. 16 MedDO / Art. 15 IvDO
[32] Annex I Chapter III no. 20.4.2 EU-IVDR
[33] Art. 7 MedDO / Art. 7 IvDO

7 Obligations of economic operators

Regulations for economic operators are defined in Chapter 6 MedDO and Chapter 5 IvDO. See our website for information sheets on the obligations of economic operators[34] and on the procurement of medical devices in healthcare institutions[35].

8 Device surveillance obligations

Requirements on device surveillance, surveillance after placement on the market, UDI recording and traceability, vigilance and reporting obligations, as well as any safety reports and on the summary of safety and clinical performance are defined in Chapter 7 MedDO and Chapter 6 IvDO.

[34] Swissmedic information sheet *Obligations economic operators*
[35] Swissmedic information sheet *Procurement of medical devices in healthcare institutions*

Change history

Version	Description	sig
3.0	Revisions relating to regulatory requirements and obligations of economic operators. New layout	wru
2.0	Revised owing to revision of IvDO regulatory provisions	wru
1.0	Doc newly created owing to revision of MD regulatory provisions; old doc ID: MU500_00_005e_MB	wru