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1 Introduction

The guideline MDCG 2019-11 “Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR” defines software as a set of instructions that processes input data and creates output data.

Unlike Directive 93/42/EEC and the guideline MEDDEV 2.1/6, the term "standalone software" is no longer used in the EU Regulation 2017/745 (EU-MDR) or the corresponding guideline MDCG 2019-11. The rationale for this change is that software should be qualified and classified solely according to its intended purpose, regardless of its installation location (see guideline MDCG 2019-11). Medical device software can be installed, for example, in the following locations:

- in a hardware medical device
- in a product that is not a medical device (computer, smartphone, cloud)

2 Qualification

Art. 3 MedDO and Art. 3 IvDO in conjunction with Art. 2 no. 1 of the EU Regulation 2017/745 (EU-MDR), Art. 2 no. 1 of the EU Regulation 2017/746 (EU-IVDR) and the guideline MDCG 2019-11 state that software is a medical device if it has a medical purpose for the benefit of an individual person (and not only for the benefit of a population) and if the data processing of the software is not just restricted to the following functions:

- storage
- archiving
- communication (flow of information from a source to a recipient)
- simple search
- lossless compression (i.e. compression allowing exact reconstruction of the original data)

Software with these properties is deemed to be medical device software. A list of medical purposes can be found in the definitions of medical devices and in vitro diagnostic medical devices (see Art. 3 MedDO and Art. 3 IvDO).

A critical factor for qualification is not just the intended purpose explicitly described in the instructions for use, since promotional materials (e.g. website, app store information) or the information displayed about the specific device in the user interface should also be considered if it deviates from the intended purpose described in the instructions for use (see also definition of intended purpose in Art. 4 para. 2 MedDO in conjunction with Art. 2 para. 12 EU-MDR, and Art. 4 para. 2 IvDO in conjunction with Art. 2 para. 12 EU-IVDR).

2.1 Remarks

Software that is intended to modify the presentation of available IVD results is not an in vitro diagnostic medical device; according to MDCG 2019-11 this includes the following software functions:

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- Basic operations of arithmetic, e.g. 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.

There are numerous software applications in the healthcare sector that are not medical devices, e.g.:

- Software or apps for hospital resource planning, reimbursement, management of doctors' visits (see guideline MDCG 2019-11)
- Software or apps for the statistical analysis of clinical or epidemiological studies or registers (see guideline MDCG 2019-11)
- Electronic patient records that simply replace the paper-based health data (see guideline MDCG 2019-11)
- Electronic reference works, general non-personalised medical information

Medical image display is not limited to storage, archiving, communication, simple search or lossless compression. Software that displays images for an individual person for medical purposes therefore qualifies as a medical device.

3 Classification

Medical device software that is not used for in vitro diagnosis is classified according to Art. 15 MedDO in conjunction with Annex VIII of EU-MDR and the guideline MDCG 2019-11. Medical device software that is used for in vitro diagnosis is classified according to Art. 14 IvDO in conjunction with Annex VIII of EU-IVDR and the guideline MDCG 2019-11.

According to Art. 2 no. 4 EU-MDR, software is considered to be an active device. Annex VIII of EU-MDR (no 3.3) and EU-IVDR (no 1.4) states: "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".

The medical device classes take account of the potential risks associated with the use of the products in humans. The classification indicates the possible conformity assessment procedures for the software (see EU-MDR or EU-IVDR). The conformity assessment procedure selected or specified on the basis of the classification determines whether, and if so to what extent, a notified body must be involved in order to place the software on the market in Switzerland (see Art. 23 MedDO and Art. 19 IvDO).

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 of this is cancer image analysis software that is used together with a scanner (see section 4.1 of MDCG 2019-11). The entire product comprising hardware and software has the class of the higher-classed software.

3.1 Medical device software produced in healthcare institutions

According to Art. 9 para. 1 MedDO and IvDO, a medical device software or in vitro diagnostic software that is produced within a healthcare facility and used solely within that facility is considered to have been put into service. Such a device is subject to the relevant general safety and performance requirements stated in Annex I EU-MDR or EU-IVDR, but not the other requirements stated in this Regulation, provided the preconditions specified in Art. 5 para. 5 EU-MDR or EU-IVDR are satisfied. According to Art. 18 MedDO and Art. 10 IvDO, the use of medical device software or in vitro diagnostic software produced in healthcare facilities is subject to mandatory notification.

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3.2 Software systems and software modules

If a 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 (see guideline MDCG 2019-11).

4 Regulations and standards

Medical devices 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 medical device according to the relevant provisions, the following regulations and standards, among others, must be observed and taken into account:

- Therapeutic Products Act (TPA; SR 812.21)
- Medical Devices Ordinance (MedDO; SR 812.213)
- In vitro Diagnostic Medical Devices Ordinance (IvDO; SR 812.219)
- Human Research Act (HRA; SR 810.30)
- Ordinance on Clinical Trials with Medical Devices (ClinO-MD; SR 810.306)
- Regulation (EU) 2017/745 on medical devices (EU-MDR)
- Regulation (EU) 2017/746 on in-vitro diagnostic medical devices (EU-IVDR)
- Federal Act on Data Protection (FADP; SR 235.1)

- MDCG 2018-5: UDI Assignment to Medical Device Software
- MDCG 2019-11: Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR
- 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 2021-24: Guidance on classification of Medical Devices

- EN 62304: Medical device software – Software life cycle processes
- EN ISO 14971: Medical devices – Application of risk management to medical devices
- EN 62366: Medical devices – 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

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Change history

Version	Valid and binding as of:	Description, comments (by author)	Author's initials
2.0	26.05.2022	Revised owing to revision of IvDO regulatory provisions	wru
1.0	26.05.2021	Doc newly created owing to revision of MD regulatory provisions; old doc ID: MU500_00_005e_MB	wru

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