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1 Terms

The term "stand-alone medical device software" describes software that qualifies as a medical device and that is installed on hardware products which are not themselves medical devices, e.g. PCs, laptops, tablets, smartphones.

Stand-alone medical device software that is installed on mobile devices such as tablets or smartphones is referred to in this information sheet (in the sense of a subordinate term) as a "mobile medical application (app)".

2 Regulations and standards applicable to medical devices in Switzerland and the EU

Medical devices are subject to stricter requirements as regards product safety and the quality management of the organisations involved in their development, manufacture, distribution, sale and maintenance than is the case for other types of equipment used in healthcare. If stand-alone software is qualified as a medical device according to the relevant requirements, the following regulations and standards, among others, must be observed and taken into account:

- TPA, Therapeutic Products Act SR 812.21
- MedDO, Medical Devices Ordinance SR 812.213
- HRA, Human Research Act SR 810.30
- ClinO, Ordinance on Clinical Tests with Therapeutic Products, SR 812.214.2
- MEDDEV 2.12-1: Guidelines on a Medical Devices Vigilance System
- MEDDEV 2.1/6: Guidelines on the qualification and classification of stand-alone software used in healthcare within the regulatory framework of medical devices
- MEDDEV 2.4/1: Guidelines for the Classification of Medical Devices
- MEDDEV 2.14/1: Guidelines on Medical Devices – IVD Medical Device Borderline and Classification issues
Manual on Borderline and Classification in the Community Regulatory Framework for Medical Devices
Recommendation NB-MED/2.2/Rec4: Software and Medical Devices
EN 62304: Medical device software – Software life cycle processes
EN 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

(*) the medical devices addressed by this directive are also known in Switzerland as "classical medical devices" in order to differentiate them from in vitro diagnostic and active implantable medical devices, which are also referred to as medical devices.

If stand-alone software is used in the healthcare field, the person who places it on the market for the first time or the manufacturer must qualify the software in order to establish whether it is a medical device on the basis of its intended purpose (see Art. 1 para. 1, last sentence, MedDO). If this is the case, the software should additionally be assigned to a medical device class (classification). Qualification and classification should be based on the following documents:

- Art. 1 para. 1, Art 5 MedDO
- 93/42/EEC
- 98/79/EC
- 90/385/EEC
- MEDDEV 2.1/6
- MEDDEV 2.4/1
- MEDDEV 2.14/1
- Manual on Borderline and Classification in the Community Regulatory Framework for Medical Devices

Stand-alone medical device software must carry CE marking, which confirms compliance with the essential requirements of Directive 93/42/EEC, 98/79/EC or 90/385/EEC. Compliance with this last directive is a prerequisite for the free circulation of the software in the EEA states and Switzerland.

3 Qualification

Stand-alone software qualifies as a medical device (stand-alone medical device software) if it satisfies condition 1a or 1b below, subject to conditions 2 and 3:

1a The person first placing the software on the market or the software manufacturer intends it to be used in humans for one of the following medical purposes (see Art. 1 MedDO and Art. 1 para. 2 of Directive 93/42/EEC or Art. 1 para. 2 of Directive 30/385/EEC):

- diagnosis, prevention, monitoring, treatment or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation or compensation of an injury or handicap;
- investigation, replacement or modification of the anatomy or of a physiological process;
- control of conception or diagnosis associated with conception

1b The person first placing the software on the market or the software manufacturer intends it to be used for the in vitro examination of specimens obtained from the human body, including blood and tissue donations, for one of the following purposes (see Art. 1 para. 3 MedDO and Art. 1 para. 2 a and b of Directive 98/79/EC)

- providing information on a physiological or pathological state
- providing information on a congenital abnormality
- determining safety and compatibility with potential recipients
monitoring therapeutic measures

2 Data processing by the software is not limited to (see MEDDEV 2.1/6):

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

Notes

- Image display is not limited to storage, archiving, communication, simple search or lossless compression because these require mathematical algorithms. Stand-alone software that displays images for an individual person for medical purposes therefore qualifies as a medical device. This means that medical image archiving and communication systems (PACS, Picture Archiving and Communication System) are in most cases medical devices, particularly many PACS not only display images, but can also be used to manipulate and evaluate images or control medical devices.
- As regards criterion 2, IVDs are subject to exceptions under MEDDEV 2.1/6 section 2.1.2: software intended to modify the representation of IVD results is not a medical device for in vitro diagnosis; such software typically performs the following functions:
  - basic arithmetic operations, e.g. calculation of means or conversion of units
  - plotting results as a function of time
  - comparing a result with the limits of acceptance set by the user.

3 The software is to be used for the benefit of an individual (and not for the benefit of a population), see MEDDEV 2.1/6.

4 Classification

- The medical device classes take account of the potential risks associated with the use of the products in humans. Stand-alone medical device software is classified on the basis of the classification criteria listed in Annex IX of Directive 93/42/EEC and on the basis of MEDDEV 2.1/6.
- The classification gives the possible conformity assessment procedures for the software (see 93/42/EEC or 98/79/EC).
- 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 the EEA states and in Switzerland.
- Stand-alone software that is a classical medical device is classified according to the rules for active medical devices (Rules 9, 10, 11 and 12 of Annex IX of Directive 93/42/EEC) since stand-alone software is considered to be an active medical device under Annex IX of Directive 93/42/EEC and MEDDEV 2.1/6.
- Section 2.3 of Annex IX to Directive 93/42/EEC states that "software which drives a device or influences the use of a device, falls automatically in the same class." This means that stand-alone software can be a class I, IIa, IIb or III medical device, depending on the medical device that it drives or influences.

5 Stand-alone medical device software produced in house

Stand-alone medical device software produced in house is intended only for use in the producing company or a partner company that is incorporated into the quality management system of the producing company. Although software that is produced in house is by definition not placed on the market, its use by a professional is regarded as equivalent to its first placing on the market (Art. 3 para. 2, sentence 2 MedDO).
A hospital that produces medical device software for its own use in house becomes a medical device manufacturer. The hospital must satisfy all the preconditions that a person first placing a medical device on the market or a medical device manufacturer has to fulfill.

A hospital that modifies existing medical device software in house and uses it on patients for an intended medical purpose becomes a person first placing a medical device on the market or a medical device manufacturer.

Alternative provisions apply to medical devices produced in house for in vitro diagnosis (see information sheet for in-house IVD manufacturers).

6 Examples of stand-alone software or electronic data used in healthcare which are not medical devices

- Software or apps for fitness, wellbeing or nutrition (e.g. diets)
- Software or apps for hospital resource planning, reimbursement, management of doctors’ visits (see MEDDEV 2.1/6)
- Software or apps for the statistical analysis of clinical or epidemiological studies or registers (see MEDDEV 2.1/6)
- Applications solely for use as a diary
- Electronic patient records that simply replace paper-based health data (see MEDDEV 2.1/6 Annex 1 and the MHRA "Guidance on medical device stand-alone software (including apps")
- Electronic reference works (see FDA), general non-personalised medical information (see MHRA "Guidance on medical device stand-alone software (including apps")