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Med-Info

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Medical apps

Software has become more and more prominent in medical devices. This applies for both software which is embedded in an active medical device as well as stand-alone software including medical apps. This Med-Info focusses on stand-alone software and medical apps also called Software as Medical Device (SaMD). The paper outlines the most important regulatory requirements which apply for SaMD within the European regulations MDD and MDR, excluding software in the range of active implantable medical devices. It can be used as starting point for manufacturers of apps in the medical field to help with the decision whether the app has to be rated as a medical device, if yes which class it is, whether a notified body has to be involved, and what standards have to be followed.

1) Is my software a medical device?

The first question to answer is whether the software is a medical device at all. To answer that question you have to check the following documents:

- The corresponding directive or regulation:
  - Medical Device Directive (MDD) 93/42/EEC
    or in future the
  - Medical Device Regulation (MDR) 2017/745
- MEDDEV 2.1/6: Stand-alone software
- MEDDEV 2.1/5: Medical devices with a measuring function

Medical device definition from the MDD

'Medical device' means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

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

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

Medical device definition from the MDR

'Medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, 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,
- providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,

and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

The following products shall also be deemed to be medical devices:

- devices for the control or support of conception;
- products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point.

The key questions are

1. Does your software have a medical intended use?
   To answer that question, you have to check the definitions of a medical device in the MDD or MDR (see boxes above).
2. Does your software influence or drive another medical device? If yes, the software is a medical device and falls into the same class as the influenced medical device.
3. In case you answered question 1 with yes, your software is most likely a medical device. However, you also have to check the additional conditions set out in MEDDEV 2.1/6*. According to MEDDEV both conditions have to be fulfilled to make an app a medical device – however, they are controversial (especially the first condition is questionable in case a medical intended use is given):
   - Is the software performing an action on data different from storage, archival, communication, or simple search?
   - Is the action for the benefit of an individual patient?

* MEDDEV 2.1/6 is only applicable for the MDD; as there is no similar document for the MDR, the key question No. 3 has to be ignored for the MDR.

Examples

Intended use	Decision
An app to show images	No medical intended use and therefore not a medical device
An app to show mammography images on a tablet to allow a second review	App has a medical intended use as it is used for 'diagnosis of a disease', and therefore must be handled as a medical device
An app to remotely control an insulin pump via Bluetooth	This app controls a medical device and therefore is also rated as a medical device

2) Which class of medical device is my software?

In case you concluded that your software is a medical device, in the next step you must check the classification of the medical device. Both MDD and MDR have five classes with increasing requirements based on the risk of the medical device: I, I with measuring function, IIa, IIb and III.

Remark: Although the classification of MDD and MDR follow a risk-based approach there is no one-to-one connection to your risk management severity classes or the software safety classification according to IEC 82304-1 or IEC 62304.

Classification under MDD: The following rules are the most important ones for the classification of SaMD under the MDD (software is an active medical device):

- Implementing rule 2.3: 'Software, which drives a device or influences the use of a device, falls automatically in the same class.' We already learned that for example a remote control app for an insulin pump falls under that rule and therefore would be Class IIb as the insulin pump is Class IIb.
- Rule 9: Active devices which administer energy to the patient are Class IIa or IIb depending on the criticality of the energy level. An app which generates sound sequences to treat tinnitus would e.g. fall into Class IIa.
- Rule 10: Active devices used for monitoring might fall into Class I, IIa or IIb depending on the criticality. An app monitoring vital parameters would be at least Class IIa.
- In case none of the above applies, your SaMD would fall in Class I (rule 12). In case your device is in Class I, you also have to check whether it contains a measuring function (see MEDDEV 2.1/5). In case it contains a measuring function it would be a Class I medical device with measuring function.

Classification under MDR: The following rules are the most important ones for the classification of SaMD under the MDR:

- Implementing rule 3.3: 'Software, which drives a device or influences the use of a device, shall fall within the same class as the device.' Example: see above.
- Rule 9: The rule is comparable to rule 9 of the MDD above.
- Rule 10: The rule is comparable to the rule of the MDD above.
- Rule 11 specifically applies to stand-alone and embedded software. Unfortunately, there is currently a lot of discussion regarding the interpretation** of this rule.
  It says:
  - Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes is classified as Class IIa, except if such decisions have an impact that may cause:
    - death or an irreversible deterioration of a person's state of health, in which case it is in Class III; or
    - a serious deterioration of a person's state of health or a surgical intervention, in which case it is classified as Class IIb.
  - Software intended to monitor physiological processes is classified as Class IIa, except if it is intended for monitoring vital physiological parameters, where the nature of those parameters is such that it could result in immediate danger to the patient, in which case it is classified as Class IIb.
  - All other software is classified as Class I.

** Rule 11 has caused a lot of discussion in the community. There are multiple reasons for this. The first one is that most stand-alone software would be at least Class IIa, and therefore requires the involvement of a notified body. The second one is that a very pessimistic view might easily end up in Class III – the planned adoption of IMDRF N12 might help here. The third reason for discussion is the fact that the rule applies for both stand-alone and embedded software. In case of embedded software, however, the device classification itself also influences the class.

3) Do I need to involve a notified body?

You need a notified body like TÜV SÜD Product Service GmbH to legally put your SaMD on the market in case you classified your device as: I with measuring function, IIa, IIb or III. Only Class I (without measuring function) does not need a notified body.

Please contact us early to avoid misinterpretations!

4) What requirements do I have to cover during development and maintenance?

Relevant for your company: As a manufacturer of SaMD you have to implement a quality management system in your company. Depending on your answer to No. 3, it may also need to get certified by a notified body. You need the quality management system as most of the standards relevant for SaMD (see below) contain requirements regarding your processes.

Relevant for your product: In addition to the quality management system you need to compile a technical documentation for your software. This technical documentation contains all evidence documents which show compliance with the Essential Requirements (MDD, Annex I) or the General Safety and Performance Requirements (MDR, Annex I). The technical documentation contains documents like a risk management file, a clinical evaluation, verification and validation results, etc. The MDR defines the necessary content of the technical documentation in Annexes II and III. A similar table of contents can be found in the so-called STED (summary technical documentation).

Apart from the documents you already know, the following standards are the most relevant for the development of SaMD which help you show compliance with the Essential Requirements (MDD) or the General Safety and Performance Requirements (MDR):

- ISO 13485 'Medical devices. Quality management systems: Requirements for regulatory purposes': This standard contains requirements regarding your company-wide quality management system.
- **IEC 62304 and IEC 82304-1:** These standards describe how a software development process should look like. IEC 82304-1 is intended for pure stand-alone software and refers to IEC 62304. The requirements are scaled based on the criticality of the software. Software safety Class C has the highest requirements, followed by B and A.
- **IEC 62366-1 'Medical devices – Part 1:** Application of usability engineering to medical devices': This standard contains requirements on how to address usability or human factors in your development.
- ISO 14971 'Medical devices – Application of risk management to medical devices': This standard contains requirements regarding risk management of your software. Alongside with this standard there is additional guidance document IEC/TR 80002-1 which describes how ISO 14971 should be applied for software.
- ISO 15223-1 'Medical devices: Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements'

Please keep in mind that not all Essential Requirements (MDD) or the General Safety and Performance Requirements (MDR) are covered by standards. Example: Your device must also comply with IT security requirements. International standards for cybersecurity are currently under development. Until then you have to use state-of-the-art solutions from other industries (e.g. the IEC 62443 series).

Some further examples for steps 1 to 3

Pain diary app: A manufacturer plans to develop an app where patients can record each day their pain level. It calculates a pain index out of the data. The pain index is used by the physician to decide upon the medication. The class would be Class I under MDD as it does not drive or influence another medical device, does not exchange energy nor monitors a vital parameter. Under MDR, rule 11 applies. Depending on the severity of a wrong medication the software might be classified from IIa to III. The involvement of a notified body is only required under MDR.

Pulsimeter app: A manufacturer plans to develop a pulsimeter app for monitoring the fitness level of a person. As this is not a medical intended use the app would not be rated as a medical device.

Wound recording app: A manufacturer plans to develop an app which monitors the healing progress of a wound. It uses the camera to take a picture and contains an algorithm to calculate the wound area in cm^2. This app would also be Class I under MDD but with measuring function. Under MDR, rule 11 applies which would result in IIa (assuming that the app cannot contribute to serious deterioration of health or worse). Both under MDD and MDR the involvement of a notified body is required.

How can TÜV SÜD Product Service help you?

TÜV SÜD Product Service has a comprehensive service offer:

- Conduction of the required audits according to ISO 13485, MDD and the future MDR
- Training regarding the requirements and challenges of the standards
- Assessment of existing processes and documentation regarding IEC 62304, IEC 82304-1 and IEC 62366-1
- Cybersecurity assessment/testing: Perform a cybersecurity assessment of your software regarding state-of-the-art cybersecurity standards like IEC 62443-4-2 or UL 2900-2-1
- Functional Safety testing: Addressing the challenges of software safety classification, commercial software, and segregation with a Functional Safety assessment

Your contact partner at TÜV SÜD Product Service can provide further information.

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