Tabea Lukas, Keywan Sohrabi, Volker Gross, Michael Scholtes*

Health Software Product or Software as Medical Device

An Orientation Guide for Young Entrepreneurs

Abstract: The number of software products in the field of health and medicine increases excessively. Self-tracking, fitness, health advice, dose calculation, and analysis of physiological data – apps are popular and commonly used. Some of the products are affected by the medical device regulation, consciously or unconsciously. For young entrepreneurs, it is difficult to recognize and understand the distinction between software as medical product and health software products. A product-related orientation guide could help start-ups to understand the difference and to find the right strategy for placing their product on the market. All relevant information were collected and analyzed. Input came from a systematic literature research, an evaluation of the CHARISMHA study and a consideration of the medical device regulation as well as the relevant standards (e.g. IEC 62304 and IEC 82304). The guide was adapted to the particular situation of start-ups and microenterprises, *inter alia* having regard to missing regulatory affairs competences. A product-related orientation guide for young entrepreneurs was developed, which helps to identify whether products are affected by the medical device regulation or not. The guide uses a few simple questions, and it allows the entrepreneurs to estimate the related effort. Furthermore, it provides an overview of relevant standards and needed competences for the chosen path. The guide brings certainty and can help young entrepreneurs to identify the upcoming workload at an early stage. Due to the decision tree concept, it is easy to adapt the product-related strategy and see the consequences. This might help entrepreneurs to find the right strategy for placing their product on the market. Nevertheless, field testing with the guide is necessary to validate its benefit.

Keywords: Software as Medical Device, Health App

<https://doi.org/10.1515/cdbme-2021-2164>

1 Introduction

Software products for smartphones and tablets, so called apps, are widespread and popular, even in the health sector [1]. It is

to be expected, that the market for apps in this field will prospectively grow [2].

In the third quarter of 2020, the Google Play Store contained 47,140 mHealth apps (for comparison: Q3 2015 ca. 27,417) and the mHealth apps market grew at a rate of 14.3% from 2019 to 2020. A rising number of healthcare professionals recommend mHealth applications and platforms for patient care. [3]

The scope of apps ranges from self-tracking, through fitness and healthcare information to the analysis of physiological data or the calculation of drug dosages. There are general concerns about the quality and the safety of those apps. Additionally, there are uncertainties, whether and when an app is a medical device and thereby the Medical Device Regulation (MDR) will be applicable [1]. For entrepreneurs, especially for start-ups and unexperienced or small enterprises, it is often unclear which regulatory requirements must be met in detail and what legal consequences arise from the classification as medical device [2]. Furthermore, the terminology is not unambiguous. It is not trivial to understand the difference between medical app and health app. Both terms are often used synonymously, or distinction is vague [4]. Apps related to the health care sector are not necessarily medical devices, therefore a clear definition of the terms is very important [2].

The MDR involves substantial changes for the development and distribution of medical devices, including and notably for software and mobile apps as medical device. Legal manufacturers need to know the regulatory framework exactly. [5]

In particular, the new classification rule 11 of the MDR Annex VIII states, that software “...intended to provide information which is used to take decisions with diagnosis or therapeutic purposes...” must be at least class IIa. If there might be a serious deterioration of a person's state of health, it must even be class IIb [6]. Combined with the definition of a medical device (Article 2, MDR), it can be anticipated, that most medical stand-alone software will be classified as class IIa or higher.

1.1 Young Entrepreneurs

The overall goals of the MDR (see Preamble 1 and 2) are among others a positive effect on innovations and a smooth functioning of the internal market, taking the small- and medium-sized enterprises into account. [6]

The Neue Zürcher Zeitung and Conceplus estimate, that due to MDR up to 30,000 additional professionals will be needed (despite shortage of specialists) and financial damage up to 18 billion Euros. They conclude that small companies might disappear and that thereby the MDR's goal was missed [7]. Hagen and Lauer have published a survey of start-ups that indicates that 67% of the enterprises consider the duration of the CE-certification process as significant barrier and 66% are not well informed regarding the role of the notified body and the conformity assessment procedure [8].

Funding lines for young entrepreneurs usually flank supporting processes using advisors or coaches e.g., business plans and foundation preparation [9]. In contrast, regulatory know how and approval processes are hardly considered while the demands continuously increase.

1.2 Objective

The aim of this orientation guide is the development of a decision tree using plain questions to identify whether the planned software product is a medical device or a health software product. Additionally, the terminology should be clarified, and the necessary competences will be pointed out. Later might help the young entrepreneurs or unexperienced small enterprises to find the right strategy for placing their product on the market.

2 Material and Methods

Based on a literature research, all relevant European standards and guidelines were sighted. Requirements for the software development and scopes were worked out to develop the decision tree. The following literature was used, and relevant information was extracted and condensed:

- Regulation (EU) 2017/745
- IEC 62304
- IEC 82304-1
- IMDRF- Software as a Medical Device Working Group. Software as a Medical Device (SaMD): Clinical Evaluation
- MEDDEV-Guidance 2.1/6
- MDCG 2019-11

3 Results

3.1 Terminology and scope summary

Software as a Medical Device (SaMD) or Medical Device Software (see Fig. 1 A) is defined as stand-alone software that meets the definition of a medical device according to the MDR (Article 2). This means that legal manufacturer must comply with the MDR and the applicable standards.

Health Software Products are defined in IEC 82304-1 chapter 3.6 as: “software intended to be used specifically for managing, maintaining or improving health of individual persons, or the delivery of care”. This includes but is not limited to SaMDs (see Fig. 1 A&B).

Software out of scope (regarding IEC 82304-1) is for example (see Fig. 1 C inter alia):

- Software that does not treat health issues of individuals.
- Hospital billing software
- Software for epidemiological studies
- Training software
- Electronical logbooks
- Software for scheduling the maintenance of medical devices.

Figure 1: Regulatory scopes for software in the health sector (Own representation based on IEC 82304)

3.2 Decision Tree

Software apps are intended for patients/users on the one hand and for healthcare professionals (physicians, nurses, therapists) or health organisations on the other. If the app is used for conception control for individual patients, it

Figure 2: Decision tree for the qualification of software as a medical device for the European Market. (A): is a medical device thereby covered by MDR and DIN EN 82304-1. (B): no medical device but is covered by DIN EN 82304-1. (C): Does neither fall under the scope of DIN EN 82304-1 nor the MDR. *Means a typical hospital information system that is also used for data processing, not only for archiving purposes.

fulfils the requirements of a medical device and is covered by DIN EN 82304-1 and the Medical Device Regulation. If the software is for self-tracking activities, such as tracking step counters or nutrition and weight control tools, and the app provides applications for fitness, nutrition, wellness, or applications for better understanding of health and disease, the requirements of a medical device are not fulfilled [4]. However, it can still be covered by DIN EN 82304-1.

An essential indicator for the qualification of software as a medical device is the decision support for physicians about therapeutic and diagnostic measures. For example, for the presentation of clinical documents/images or for monitoring a patient. If data are influenced by the app, for example by drug dosages or measurement value recordings, they also fulfil the requirements of a medical device, provided that the results influence the diagnosis or therapy of the patient. Software that is used for health organisations for purely administrative purposes is explicitly not intended to be a medical device [2]. Pure data storage, documentation, communication, knowledge provision, training, study organisation or billing do neither lead to a qualification as a medical device nor fall under the scope of DIN EN 82304-1. Software that is not

considered to benefit individual patients does neither fall in the scope of 82304-1 nor MDR. [10].

3.3 Competences

Table 1: Overview for manufacturers what competences are important based on the categorization of Fig.2.

Cat. (Fig. 2)	Competences and Effort
A	MDR must be fulfilled. Following standard might be relevant: <ul style="list-style-type: none">– EN 62304– EN 82304-1– EN 62366-1– EN 14971– EN 13485 (certification might be necessary)
B	EN 82304-1 must be fulfilled. This includes a risk assessment but no risk management according to EN 14971
C	No explicit regulations of the health sector applicable

4 Discussion

The developed orientation guide uses a few simple questions/ assumptions that try to figure out the overall intended purpose and the user profile.

The decision tree will help young entrepreneurs to roughly estimate the related effort and preliminary assess whether the application is a medical device or not. Furthermore, it provides an overview of relevant standards and needed competences for the given path. The guide brings certainty and can help young entrepreneurs to identify the upcoming workload at an early stage. Due to the decision tree concept, it is easy to adapt the product-related strategy and see the consequences. This might help entrepreneurs to find the right strategy for placing their product on the market.

Nevertheless, field testing with the orientation guide is necessary to validate its benefit. In addition, this approach needs further fine tuning and feedback from manufacturers. Due to the simplicity of this decision tree, it does not cover all conceivable applications. In case of doubt, further considerations are necessary, and we would recommend contacting a notified body.

Prospectively, we will test the decision tree with the start-ups, spin-offs and other small enterprises that contact the University of Applied Sciences searching for support and clarification for the development process of their innovative applications in the field of health care.

Author Statement

Research funding: The author state no funding involved. Conflict of interest: Authors state no conflict of interest. Informed consent: Informed consent has been obtained from all individuals included in this study. Ethical approval: The research related to human use complies with all the relevant national regulations, institutional policies and was performed in accordance with the tenets of the Helsinki Declaration, and has been approved by the authors' institutional review board or equivalent committee.

References

- [1] Rämisch-Günther N, Stern S, Lauer W. Abgrenzung und Klassifizierung von Medical Apps: Was ist zu beachten und welche Unterstützung bietet das BfArM? Bonn: Bundesgesundheitsblatt, Gesundheitsforschung, Gesundheitsschutz. Springer-Verlag GmbH Deutschland. 2018 January 18; 61: 304-313. Institute of Medicine (US). Looking at the future of the Medicaid program. Washington: The Institute 1999.
- [2] Pramann O. Gesundheits-Apps als Medizinprodukte. In: Albrecht U.V. Chancen und Risiken von Gesundheits-Apps. Hannover: Charismha; 2016: 228-243.
- [3] Grand View Research. mHealth Apps Market Size, Share & Trends Analysis Report By Type (Fitness, Medical), By Region (North America, APAC, Europe, MEA, Latin America), And Segment Forecasts, 2021 – 2028. Report ID: GVR-1-68038-555-7. 2021.
- [4] Kramer U. Wie gut sind Gesundheits-Apps: Was bestimmt Qualität & Risiko? Welche Orientierungshilfen gibt es? Stuttgart: Georg Thieme Verlag KG. 2017; 42: 193-205.
- [5] Keutzer L, Simonsson US. Medical Device Apps: An Introduction to Regulatory Affairs for Developers. JMIR MHealth and UHealth. 2020.
- [6] The European Parliament and the Council of the European Union. Regulation (EU) 2017/745. Official Journal of the European Union 2017.
- [7] Giorgio V. Müller. Gesalzene Rechnung für die Medtech-Firmen in Europa. 10.10.2017. URL: <https://www.nzz.ch/wirtschaft/gesalzene-rechnung-fuer-die-medtech-firmen-in-europa-ld.1320973>. Accessed: 19.11.2019.
- [8] Julia Hagen und Wolfgang Lauer. Reiseführer gesucht – Ergebnisse einer Umfrage bei E Health-Start-ups. Bundesgesundheitsblatt - Gesundheitsforschung – Gesundheitsschutz. March 2018, Volume 61, Issue 3, pp 291–297.
- [9] Richtlinie zur Förderung von Unternehmensgründungen (EXIST-Gründerstipendium) im Rahmen des Programms „Existenzgründungen aus der Wissenschaft“ – Neufassung – Vom 21. April 2020. Bundesministerium für Wirtschaft und Energie. Bundesanzeiger (Bekanntmachung Veröffentlicht am Mittwoch, 13. Mai 2020).
- [10] MDCG 2019-11: Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR. Medical Device Coordination Group. 2019. ..

***Corresponding author: Michael Scholtes:** Faculty of Health Sciences - University of Applied Sciences Giessen, Wiesenstraße 14, Giessen, Germany, e-mail: michael.scholtes@ges.thm.de

Tabea Lukas, Keywan Sohrabi, Volker Gross: Faculty of Health Sciences - University of Applied Sciences, Giessen, Germany