TALLINN UNIVERSITY OF TECHNOLOGY
School of Information Technologies

Silja Elunurm 204748YVEM

mHealth application as a class I medical device: implementation of MDR classification rules in practice

Master's thesis

Supervisor: Riina Hallik
MSc, MMS, RN

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Silja Elunurm 204748YVEM

M-tervise rakendus kui I klassi tarkvaraline meditsiiniseade: MDR liigitamisreeglite rakendamine praktikas

Magistritöö

Juhendaja: Riina Hallik
MSc, MMS, RN

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Author’s declaration of originality

I hereby certify that I am the sole author of this thesis. All the used materials, references to the literature and the work of others have been referred to. This thesis has not been presented for examination anywhere else.

Author: Silja Elunurm

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Abstract

EU Medical device regulation changed the risk classification rule for the software as medical device (SaMD), including here also mobile medical devices. As the EU guidelines explaining the MDR risk classification rules make almost no reference to class I devices, and scope of Rule 11a, Annex VIII, MDR that regulates SaMDs is grammatically interpreting extremely broad (leading to up-classification), then there is unclarity when mHealth SaMD could be classified into lowest (I) risk class. At the same time classification to lowest risk class would be desirable for the manufacturers, as the product could be placed on the market faster, cheaper and without extra regulatory hindrances. Thereby, the aim of the thesis was to identify the criteria for classifying an mHealth application into lowest risk class based on the existing EU market practice from the manufacturers´ perspective provided that the device has been placed to the market under the MDR.

This study used qualitative method for data collection (document analysis based on codebook development), whereby the main data source was EUDAMED. The codebook was created in two steps: first based on MDR, EU guidelines and IMRDF guideline the initial codebook was developed that included preliminary set of codes, with definitions, and exemplar text from the transcripts, that could be relevant in determining the risk class of a device. Subsequently during the coding process, the deductive approach was used to develop the codebook further to map the additional common characteristics of the mobile medical devices that could be relevant in determining the risk class.

The results of this study show that most of class I mobile medical devices are solely aimed at patient. The prominent special medical purpose that such devices fulfil is “alleviation of the disease” as provided in art 2 (1) MDR (self-care, self-management). Usually, the devices are multifunctional, and they consist of both medical purpose and non-medical purpose functionalities. The devices are mostly aimed at medical conditions related with mental, behavioral, and cognitive disorders and nervous system disorders. The most common computational functionality that fulfils the special medical purpose is

therapeutic function in the form of digitalized cognitive behavioral therapy sessions, also different type of digitalized therapeutic exercises are represented in the numerous devices. Multi-user devices are represented, but their classification into class I is limited, especially in case the intended purpose is (home)monitoring of physiological processes (then class IIa) or vital signs monitoring (then class IIb) or if they include analytical component directed to the health care professional.

As the conclusion of this thesis and to ease the risk classification process the author provides indicative risk classification guidance, that could be used by manufacturers in the CE conformity assessment route.

This thesis is written in English language and is 73 pages long, including 6 chapters, 7 figures and 7 tables.

Annotatsioon

M-tervise rakendus kui I klassi tarkvaraline meditsiiniseade: MDR liigitamisreeglite rakendamine praktikas

EL-i meditsiiniseadmete määrus muutis tarkvaraliste meditsiiniseadmete (SaMD), sealhulgas ka m-tervise rakenduste kui meditsiiniseadmete riskiklassidesse liigitamise reegleid. Kuna EL-i juhised, mis selgitavad neid liigitamisreegleid, ei viita peaaegu üldse I klassi seadmetele ja MDR-i, VIII lisa reegel 11a, mis reguleerib tarkvaraliste meditsiiniseadmete liigitamist, annab grammatilise tõlgendamise teel äärmiselt laia rakendusala, siis on ebaselge, millal võiks m-tervise rakendus liigutuda madalamasse (I) riskiklassi. Samas on tootjad huvitatud enda seadme liigitamisest madalamasse riskiklassi, kuna selline seade saaks turule kiiremini, odavamalt ja ilma täiendavate regulatiivsete takistusteta. Sellest johtuvalt oli lõputöö eesmärgiks EL turupraktika alusel välja selgitada kriteeriumid MDR alusel turule pandud m-tervise rakenduse liigitamiseks madalaimasse riskiklassi.

Uuringus kasutati andmete kogumiseks kvalitatiivset meetodit (koodiraamatu abil toimuv dokumendianalüüs). Koodiraamat koostati kahes etapis: esmalt MDR, EL-i juhiste ja IMRDF juhendi alusel töötati välja esialgne koodiraamat, mis sisaldas esialgset koodide komplekti koos definitsioonide ja transkriptsioonide näidistekstiga, mis võiksid olla olulised seadme riskiklassi määramisel. Seejärel kasutati kodeerimisprotsessi käigus koodiraamatu edasiarendamiseks deduktiivset lähenemisviisi, et kaardistada seadmete täiendavad ühised omadused, mis on olulised riskiklassi määramisel.

Uuringu tulemused näitavad, et enamik I klassi m-tervise rakendusi kui meditsiiniseadmed on suunatud ainult patsientidele. Meditsiiniline eesmärk, mida sellised seadmed täidavad, on üldjuhul "haiguse leevendamine", nagu on sätestatud MDR-i artikli 2 lõikes 1 (nö eneseabi või haigusega toimetuleku toetamine). Tavaliselt on seadmed multifunktsionaalsed ja need koosnevad nii meditsiinilisest kui ka mittemeditsiinilise otstarbega funktsioonidest. Seadmed on enamasti suunatud psüühika-, käitumis- ja kognitiivsete häirete ning närvisüsteemi häiretega seotud haigusseisunditega toimetuleku

parandamiseks. Levinuim meditsiinilist eesmärki täitev funktsionaalsus on digitaliseeritud kognitiiv-käitumisteraapia seansid, samuti on erinevad digitaliseeritud terapeutilised harjutused esindatud paljudes seadmetes. Uuring tuvastas ka mitme kasutajaga seadmeid (kasutajateks samaaegselt nii patsient kui tervishoiuteenuse osutaja), kuid pigem liigutuvad need IIa klassi, eriti juhul, kui seadme kasutuseesmärgiks on füsioloogiliste protsesside seire või IIb, kui tegemist on elutähtsate näitajate monitooringuga või kui tervishoiutöötajale suunatud komponent sisaldab analüütilist funktsiooni.

Käesoleva töö kokkuvõtteks ja seadmete riskiklassi liigitamise hõlbustamiseks annab autor indikatiivse juhise, mida tootjad saaksid kasutada CE-vastavuse hindamisel.

See lõputöö on kirjutatud inglise keeles ja on 73 lehekülge pikk, sisaldab 6 peatükki, 7 joonist ja 7 tabelit.

List of abbreviations and terms

CE	*conformité européenne*
EU	European Union
EUDAMED	The European Database on Medical Devices
FDA	U.S Food and Drug Administration
HCP	Health care provider
IMDRF	International Medical Device Regulators Forum
IVDD	In vitro Diagnostic Device Directive
IVDR	In vitro Diagnostic Device Regulation
MDD	Medical device directive
MDR	Medical device regulation
MHRA	UK Medicines and Healthcare products Regulatory Agency
SaMD	Software as a medical device
WHO	World Health Organisation

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1 Introduction

The availability and wide adoption of powerful smartphones and mobile apps have drastically transformed the delivery of healthcare services and information on both organizational and personal levels. [1] Last years have witnessed the tremendous growth of mHealth market as the global market for mobile health (mHealth) technologies are expected to grow from $55.4 billion in 2021 to $224.0 billion by 2026 with a compound annual growth rate (CAGR) of 32.2% for the period of 2021-2026. [2] Respective European mobile health (mHealth) technologies market is expected to multiple four-times from $15.5 billion in 2021 to $64.3 billion by 2026. [2] As mHealth market is booming then also the global market for software as a medical device (SaMD)[1] is expected to grow rapidly: to double from $4.4 billion in 2021 to $8.2 billion by 2027, where respective EU market share is roughly about ¼ of the global market size. [2]

Although the Covid-19 pandemic gave a sudden boost to mHealth (incl SaMD) markets, as traditional face-to-face appointments were restricted, then the primary causes for the mHealth market growth has been the major challenges that the EU healthcare systems face for example shrinking of budgets and the ageing of the population that has given rise to the growth of chronic diseases. [3] These underlaying market drivers are continuing to be relevant in upcoming years and there will be increasing need for newly developed digital solutions, that would make a process more efficient, and more user-friendly. [4]

Due to the rapid advancements in digital health technologies European Commission declared prior drafting MDR that: "*a fundamental revision of those Directives is needed to establish a robust, transparent, predictable and sustainable regulatory framework for medical devices which ensures a high level of safety and health whilst supporting innovation*". [5] Additionally, the new regulation was spurred by The Poly Implant Prothèse (PIP) scandal that showed the weaknesses of post market quality control mechanisms applied based on MDD. [6]

[1] Software as a medical device (SaMD) means any software product that meets according to the Medical Device Regulation (EU) 2017/745 following two criterions: a) it is intended by the manufacturer to be used for a medical purpose; b) it meets the MDR Article 2 definition of "medical device". Hence not all mHealth applications are not qualifying as SaMD.

EU Medical device regulation [7] changed the risk classification rule for the software as medical device (SaMD) leaving market stakeholders to an uncertainty, when mobile application (provided it qualifies as a medical device) could be classified into the lowest (I) risk class, as even the EU guidelines explaining the MDR risk classification rules make almost no reference to such devices. [8] [9] [10] Numerous articles claim that almost all I class SaMDs placed on the market under MDD need to be up-classified and under the MDR there is no room for I class SaMDs. [11] [12] [13]

Regulatory unclarity and overregulation might restrict market access of new and innovative devices. [14] [4] However, it is economically understandable that MedTech company wishes to place its product to the market with the most optimal market access strategy. The possibility to classify the mHealth application into class I according to Rule 11, in Annex VIII of MDR would be desirable for manufacturers, as the conformity assessment procedure in the form of self-declaration, is faster, cheaper, and simpler. If placing a product on the market under the MDR becomes too burdensome for manufacturers, it can lead to regulations bypassing as claimed by Pashkov, V et (2021) in recent study [15]. The question is, however, of the criteria and conditions that should be fulfilled for classifying device into class I, instead of higher risk class. Literature review showed that there is no research made on the implementation practice and interpretation of MDR classification rules, especially regarding class I from the manufacturer`s perspective.

The problem statement of the thesis is that despite the fact that there are considerable amount of publications that describe the new rules of MDR, provide the overview of MDR regulation compared to old MDD, there is a lack of EU guidance and academical research that would assist the manufacturers of mHealth SaMD in conducting the risk classification assessment by providing interpretation assistance in classifying the device into the I class, based on Rule 11, Annex VIII, MDR.

The aim of the thesis is to identify the criteria for classifying an mHealth SaMD into lowest risk class (I class mobile medical device according to Rule 11 Annex VIII MDR) based on the EU market practice from the manufacturers´ perspective.

To best address the aim, **following research questions were raised**:

1. Who are the intended users of the class I devices? Whether the risk classification is different depending upon the intended user?

2. Which types of medical disorders /situations / conditions are the most common that the class I devices are intended to?

3. Which special medical purpose as provided in article 2 (1) MDR and as described in the intended purpose of the device, are the class I mHealth SaMDs usually fulfilling?

4. Which are the most common functionalities of the class I devices, that fulfil the special medical purpose provided in article 2 (1)?

5. How do the intended purposes of class I devices correspond to the IMDRF risk classification guideline categories?

Thus, this research analyzes the intended purposes and functionalities of class I mHealth SaMDs placed on the EU market under the MDR (so no legacy devices placed on the market under MDD that have currently transition period), and registered in EUDAMED, by identifying the common characteristics of such devices. Based on the results of the study and by applying the literal and systematical (including here the historical) legal interpretation methods [16] the indicative guidance for SaMDs classification is concluded, that can assist manufacturers in determining the risk class of their device in the CE conformity assessment procedure.

This thesis is written in English and structured in 6 chapters and the content can be summarized as follows: Chapter 1 introduces the thesis topic, aims to be achieved, research questions and includes an overview of the current state of the research. Chapter 2 constitutes an overview of European regulatory framework for the software as medical device, provides background information about the MDD and the changes that were implemented with MDR and also theoretical overview of the decision steps to qualify solution as a medical device and regulatory framework for determining the applicable risk class. Chapter 3 focuses on the methods applied in the study and explains in detail how the analysis was done. Chapter 4 presents the results of the analysis. Chapter 5 discusses the results and provides indicative guidance for risk classification, points out the limitations and gives an outlook towards further research. The thesis is concluded with chapter 6 which summarizes the whole research.

2 Background

Mobile health (mHealth) is defined by the World Health Organization's (WHO) as "*medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices*" [17]. When the digital health product is aimed for the patient self-monitoring, self-management, or treatment purposes (devices has been placed to the market as digital therapeutics) then mostly, they are placed on the market as native mobile apps [18].

2017/745/EU Regulation (hereinafter "MDR") [7] was enforced, replacing the existing directives the Active Implantable Medical Devices Directive 90/385/EEC (1990) [19] and the Medical Devices Directive 93/42/ EEC (1993) (hereinafter "MDD") [20]. The aim of the MDR is according to recital 2: "*to ensure the smooth functioning of the internal market as regards medical devices, taking as a base a high level of protection of health for patients and users, and taking into account the small- and medium-sized enterprises that are active in this sector. At the same time, this Regulation sets high standards of quality and safety for medical devices in order to meet common safety concerns as regards such products. Both objectives are being pursued simultaneously and are inseparably linked whilst one not being secondary to the other.*"

The implementation of MDR has changed the risk classification rules for software as a medical device, compared to MDD. In addition, a completely new classification rule (MDR rule 11, annex VIII, hereinafter "Rule 11") specifically for software was introduced. Such amendments have meant up-classification (from lowest risk class (I) to higher (IIa or IIb) risk class) of many devices. The same applies to mHealth SaMDs (or we can call them also mobile medical devices as is common in US [21]). Recent study by Pashkov, V et (2021) showed, that there are numerous stand-alone software in the categories Medicine and Health and Fitness available in the online stores (GooglePlay, AppStore), some of which could be also considered as medical devices, which have never passed any conformity procedure (even self-declaration of conformity for Class I SaMD). [15] So this may indicate, that up-classification could ultimately lead to regulations bypassing or even ignoring.

Thus, despite the fact, that the aim of MDR, was to have clearer rules and support to patient-oriented innovation, not ignoring the interests of SME-s [5], then the actual outcome is different. The result is unclarity of the scope and borders of the lowest risk class. Adding here the extra financial burden for fulfilling the regulatory standards and time resource needed, to place IIa class SaMD into the EU market [4], then it is clear that the MDR implementation is a huge challenge to all innovative SME-s. [22] [23]. Especially problematic is that in EU the notified bodies, whose task it is to conduct the conformity assessment procedure of any medical device having risk class Im or higher, have not been able to fulfil their tasks efficiently and timely, which resulted recently repeated extension of transition periods. [24] This step does not however provide any relief to the manufacturers that aim to bring to the market new innovation, as new devices need to fully comply with MDR, including the unclear risk classification rules.

There is no scientific research on the implementation practice and interpretation of MDR classification rules, especially regarding class I classification (as of March 2023). There are numerous publications that describe the new rules of MDR and also rule 11 Annex VIII [25] [26] [27], provide overview of MDR compared to MDD [28] [4], analyse the similarities and differences of the EU, US medical devices conformity assessment processes and regulations [29] [30], but none of them are focusing on the class I risk classification problems in EU, to relieve the lack of regulatory clarify.

There are different publications that provide structure and guidance by proposing a variety of classifications of health apps, for example on the basis of the functions that app provides [31] [32], or another dimensions [33], but they are also not providing legal classification of the relevant apps into the risk class, nor provide any additional input for interpreting Rule 11 of Annex VIII MDR, besides merely citing the relevant text of the rule itself.

There is also quite extensive research made on the impact of the transition from MDD to MDR on medical device manufacturers, especially focusing on the impact on the innovation and market access of new devices. Many of them state that transition from MDD to MDR will delay market access and reduce innovation and investments in the medical device sector, especially due to the additional regulatory constraints and requirements. [34] [14] [22] [31] Although some mention the positive impact of increased patient safety, then at the same time they also outline the high price

of the implementation of the new regulation. [35] [36] So, although they usually highlight the additional regulatory burden that MDR might cause, they are not focusing on the legal analysis of the new risk classification rules or provide the information on the market practice of the actual implementation of classification rules.

Thus, the research gap consists of studies that analyze the risk classification practice of class I mHealth applications (SaMDs) placed on the EU market (implementation of Rule 11, Annex VIII, MDR by the manufacturer´s perspective) that would serve as an interpretation assistance for the manufacturers aiming to place class I mHealth SaMD to the EU market. This work aims to contribute to filling this research gap.

2.1 Software as a medical device (SaMD) regulation in the EU

2.1.1 The main changes introduced by MDR compared to MDD

The MDR is applicable for placing a medical device on the market in the EU. After many years of discussion, the European Parliament and Council adopted the Medical Device Regulation (MDR) in May 2017. The MDR regulates the required steps until a medical device for human use can be placed on the European market as well as the resulting post-market actions. It is fully applicable from 26 May 2021 onwardsö The MDR is applicable for the EEA (EU and Iceland, Liechtenstein and Norway) and other countries that have an agreement with the EU to follow the MDR [37].

The MDR aimed to establish a strong and durable regulatory framework to ensure the proper functioning of the internal market, to overcome the existing differences between Member States, to guarantee a high level of protection of human health and to promote innovation and competitiveness of the medical device industry [5]. MDR also targets to strengthen the evaluation of the safety and performance of medical devices before CE marking, to reinforce post-market surveillance and to improve transparency via dissemination of information on the risk–benefit balance of the devices [26].

The main regulatory changes relevant to mHealth sector and mHealth apps manufacturers:

1. MDR is a regulation, meaning that it is a binding legislative act in all EU member states and must be applied in its entirety across the EU. This contrasts with the previous MDD, which was a directive. and not directly applicable legislative act [16].

2. MDR clearly states that software alone can be a medical device, in contrast to MDD, where software was not mentioned in the medical device definition and Court of Justice of the European Union needed to provide relevant MDD interpretation of SaMD in the Snitem case [38].[2]

[2] CJEU stated that: "*software constitutes a medical device where it is specifically intended by the manufacturer to be used for one of the purposes set out in Article 1(2)(a) of Directive 93/42 and where it is intended to create or modify*

3. As mHealth was (and is) an emerging and rapidly developing field which has the potential to play a part in the transformation of healthcare and increase its quality and efficiency [3], then software independent of software's location or the type of interconnection between the software and a device may qualify as a medical device. Hence also mHealth apps could qualify as medical devices [9] .

4. The MDR did not actually modify the core principle of the categorizing solution as a medical device, but classification rules and conformity requirements were revised, and also new requirements added (e.g. obligation for the manufacturers of a new role, within the organization, responsible for regulatory compliance) and stricter measures (e.g., more rigorous post-market surveillance and vigilance) [39].

5. Regarding software (including here mHealth) it should be noted that MDR Annex I "*General Safety and Performance Requirements*" includes now specific requirements relating to the devices that incorporate electronic programmable systems and software that are devices in themselves (art 17).

6. The whole MDR compliance system is rather complex. Risk related to the device has to be managed not only in the classification phase, but for the whole lifecycle of a device. MDR (Article 10, 2) requires manufacturers to establish, document, implement and maintain a safety risk management system for the product throughout the life of the device [25].

7. Medical devices (and SaMDs and Apps as SaMDs) are classified in MDR according to a risk-based approach considering safety of users a priority and evaluating the potential risks associated with use of the device [25]. Annex VIII of MDR provides classification rules [7]. These rules lead to four main classes: I (lowest risk) (special classes Is and Im), IIa, IIb, III (highest risk). In addition, a new classification rule specifically for software was introduced with MDR (annex VIII, Rule 11).

8. Manufacturers of class I devices, other than custom-made or investigational devices, shall declare the conformity of their products by issuing themselves the EU declaration of

medical information, in particular by means of calculation, quantification or comparison of the recorded data against certain references, in order to provide information about a particular patient".

conformity after drawing up the technical documentation (self-declaration process) (MDR art 52 (7). Higher risk classes (Is, Im, IIa) need to prepare technical documentation and a conformity test carried out by a Notified Body (art 52): class IIb has same as Is, Im and IIa, but added requirement of a device type examination by a Notified Body, class III conformity approval includes a full quality assurance system audit, along with examination of both the device's design and the device itself by a Notified Body [40].

9. More rigorous clinical evidence about safety and performance is required by MDR compared to MDD. Clinical evaluation is strictly related to the risk management mentioned above and applied in whole life-cycle of the product. Once a system is approved for use, clinical data have to be continuously updated through a post-market activity [25].

10. MDR also reinforces and supports the implementation of device traceability with the introduction of the UDI system (unique device identification, art 28 MDR). In addition, MDR introduced European database on medical devices (Eudamed) (art 33, 34 MDR), aimed to provide a living picture of the lifecycle of medical devices that are made available in the European Union (EU). It will integrate different electronic systems to collate and process information about medical devices and related companies (e.g. manufacturers) on the EU market [41]. The actual implementation of Eudamed has been however considerably delayed (initial plan 2021), currently the Commission aims Eudamed to be fully functional by end of 2024, and mandatory for use as of Q2/2026 [42]. However as a voluntary option, manufacturers have been registering their devices already now in Eudamed. Interestingly, Finland is requiring class I devices to be registered already now to Eudamed by the manufacturers (no national notification process for class I devices as was under MDD) [43].

2.1.2 EC guidance documents

European Commission has issued marginal guidance in respect of application of MDR to SaMDs (incl mHealth devices). It should be noted that these documents are not a European Commission official documents, they are not legally binding and only the Court of Justice of the European Union can give binding interpretations of Union law.

1. Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR defines the criteria for the qualification of software falling within the scope of the new medical devices regulations and provides guidance on the application of classification criteria for software under Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR. The guidance also provides information related to placing on the market. The criteria specified in this document shall also apply to applications (commonly referred to as apps), may they be operating on a mobile phone, in the cloud or on other platforms. [9] Problem of this guidance is however that it does not provide any information about I class SaMDs.

2. Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD is intended to provide clarification on the changes to a device that should be considered a "significant change in design or a significant change in the intended purpose" under MDR Article 120(3), especially relevant for the legacy devices placed on the market based on MDD, as they have considerable transition periods where they do not need to fully apply MDR. [44]

3. Guidance on classification of medical devices provides information about the risk classification principles in regard of all types of medical devices not only software as medical devices. It acknowledges class I SaMDs, by providing an example of mobile medical app intended to support conception by calculating the user's fertility status based on a validated statistical algorithm, but there is no other explanation about class I SaMDs. [8]

4. The Member State members of the Borderline and Classification Working Group (BCWG) following the exchanges under the Helsinki Procedure under Regulation (EU) 2017/745 on medical devices (the MDR) and Regulation (EU) 2017/746 on in vitro diagnostic medical devices (the IVDR) have recorded the agreements reached by the working group into Manual on borderline and classification for medical devices under Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnostic medical devices. The BCWG is chaired by the European Commission and consists of

representatives of competent authorities from all Member States with a number of stakeholder associations as observers. Sadly, however the latest version of the Manual does not consist of any SaMD related cases. [10]

The following sections explain the legal rules for qualification and classification of SaMD based on MDR, as this theoretical background is relevant for understanding the research problem and how the initial codebook was developed.

2.1.3 Decision steps for determining whether a mHealth app (application) is a medical device and risk classification rules

Software must have a medical purpose on its own to be qualified as a medical device software (SaMD) (recital 19 MDR). The intended purpose of the software is relevant for the qualification and classification of any device. “Intended purpose” means according to art 2 (12) of MDR 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. So, the intended purpose defines the scope of the device, it also refines the safety and efficacy questions that require evidencing through the production of technical documentation, risk management and clinical evidence [45]. The most important, the intended purpose defines which functionalities of the device must have sufficient evidence documented against them [46]. So taken together, the intended purpose must be sufficiently clear and specific.

To be qualified as medical device software, following elements should be fulfilled:

1. The product must be a stand-alone software according to the guidance and the definition of a medical device according to art 2(1) of MDR;

2. This software should not be accessory for a medical device - art 2 (2) MDR, and it should not be component of the other (quite often hardware) medical device (then it can be considered as software in the medical device - SiMD);

3. This software should be performing an action on data other than storage, archival, communication or simple search;

4. The action performed on data should be on the benefit of individual patient.

5. The intended purpose of the software should reflect at least one of the special medical purposes provided in art 2 (1) MDR. [9]

So, the last step in decision whether the software qualifies as a medical device, is to ensure that the software's intended purpose meets the definition of a medical device under MDR Article 2 definition. In specific, the provision of information by software should relate to one or many of the specific medical purposes as defined in art 2(1) MDR. It means that SaMD should have some computational function that fulfils or clearly assists the fulfilment of the special medical purpose listed below:

1. diagnosis, prevention, monitoring, prediction, prognosis, treatment, or alleviation of disease.

2. diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability

3. investigation, replacement, or modification of the anatomy or of a physiological or pathological process or state.

4. control or support of conception.

Hence, not all software (or mHealth applications) used in the clinical setting or in regard of one´s health qualify as medical device, for example, devices that conduct only "simple search" function, data storage (documentation) or mere data communication does not qualify as medical device, as they do not generate themselves information for the clinical purpose (they merely allow to access to input data or transfer the data *as is*). [9]

In regard of boundaries between the wellness apps and mHealth applications as SaMD the clear distinction is still evolving. But already in the case C-219/11 - Brain Products, CJEU made clear that in situations where a product is not conceived by its manufacturer to be used for medical purposes, its certification as a medical device cannot be required. So, the intended purpose defined by the manufacturer, was considered the most relevant factor in qualifying the product as a medical

device. [47] And this interpretation has not changed with MDR, as there is no additional case-law on this matter.

Provided that the product (software) is qualified as a medical device, the next step is to determine the risk class of a medical device (risk classification).

In MDD Annex IX, article I.1.4 stated that all standalone software is classified as active devices. Therefore, rules 9 to 12 of annex IX, article III.3 applied to software (there was no specific rule for software). Software, which drives or influences a medical device: Annex IX, art II.2.3 stated that such software falls into the same class as the device (so here was possible that software was class IIa, class IIb or class III, if it was driving or influencing another medical device), but as mHealth SaMDs are usually not aimed for influencing any other medical device (they are independent medical devices themselves), then Annex IX, rule 12 could have been applicable to these which simply stated that: "All other active devices are in Class I." [20]

MDR created new classification rule dedicated to software (Rule 11, Annex VIII MDR), which provides that:

"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 of vital physiological parameters, where the nature of variations of those parameters is such that it could result in immediate danger to the patient, in which case it is classified as class IIb.

<u>All other software is classified as class I."</u>

EU commission has stated that Rule 11 of MDR Annex VIII was introduced to mirror the regulatory guidance developed at international level and notably in the context of the International Medical Device Regulators Forum (IMDRF) [9]. The IMDRF framework for risk categorization of software as a medical device (SaMD) categorizes the risk of software based on the combination of the significance of the information provided by the software to the healthcare decision and the healthcare situation or patient condition, overview provided in Table 1 [48].

Table 1: SaMD risk categories EU (adapted by the author according to [48])

State of Healthcare situation or condition	**Significance of Information provided by SaMD to healthcare decision**		
	Treat or diagnose	Drive clinical management	Inform clinical management
Critical	IV	III	II
Serious	III	II	I
Non-serious	II	I	I

Reference to IMDRF as a basis for classification rule is provided in EU repeatedly. Even MDR itself states that: "*To the extent possible, guidance developed for medical devices at international level, in particular in the context of the Global Harmonization Task Force (GHTF) and its follow-up initiative, the International Medical Devices Regulators Forum (IMDRF), should be taken into account to promote the global convergence of regulations which contributes to a high level of safety protection worldwide, and to facilitate trade, in particular in the provisions on Unique Device Identification, general safety and performance requirements, technical documentation, classification rules, conformity assessment procedures and clinical investigations* (recital 5 MDR)". Also, EU SaMD qualification and classification guideline, refers to the IMDRF risk framework as a basis for the EU risk classification framework [9], but leaves Class I category completely out from the framework, as provided in Table 2.

Table 2: SaMD risk categories IMDRF (adapted by the author according to [9])

State of Healthcare situation	**Significance of Information provided by the MDSW to a healthcare situation related to diagnosis/therapy.**		
	High	Medium	Low

	Treat or diagnose *IMDRF 5.1.1.*	Drives clinical management *IMDRF 5.1.2*	Informs clinical management *(everything else)*
Critical	Class III	Class IIb	Class IIa
Serious	Class IIb	Class IIa	Class IIa
Non-serious	Class IIa	Class IIa	Class IIa

So, although the MDR and EU guideline itself states that it has based its opinion on IMDRF Risk Framework, the actual outcome is entirely different. To make things even worse, there is no reasoning provided in the guideline or any other EU interpretation document, why such amendment in the application of the criterion: "The significance of the information provided by SaMD" is made in the EU.

3 Methodology

3.1 Research method

Pragmatic research philosophy was the starting point of this research which highlights the importance of using the best tools possible to investigate phenomena [49]. This approach was taken as currently there is lack of EU regulatory guidance on the relevant topic, also the legal literature is insufficient on this topic, but using predicate (similar) devices for qualification and classification purposes common in EU. MDR Annex II Tehnical documentation p 1.2 b) even requires the manufacturer to provide in the technical documentation an overview of identified similar devices available on the Union or international markets, where such devices exist.

The current thesis is conducted from the manufacturer´s perspective by reviewing and analyzing the intended purposes and core functionalities of the class I SaMDs registered in EUDAMED. The perspective of the manufacturer has been chosen because class I medical devices needs to be correctly classified by the manufacturer themself[3] and thereafter assessment of the conformity of that device needs to be undertaken.[4] As the interest of the researcher was manufacturer´s view,then devices already placed on the EU market were included to the study. As the timeframe for conducting the study was limited then no input from the competent authorities was requested. Although this might seem like a weakness of the study, then actually it is unlikely that competent authorities would be willing to share their interpretation of the MDR independently. Helsinki Procedure is a system to allow consultation among competent authorities (CAs) on borderline and classification issues concerning medical devices and to ensure that appropriate guidance is published in the Manual on Borderline & Classification for Medical Devices. [10] [50]

An inductive approach was chosen, as currently there is lack of information on common criterions and characteristics that the I class mHealth SaMDs entail, and the research was the prerequisite for developing indicative classification assistance chart.

[3] Article 51 (1) MDR

[4] Article 52 (7) MDR

Research was conducted based on Bowen (2009) methodological framework for conducting document analysis as qualitative research. [51] Usage of pre-existing data was chosen as this reflects the devices already placed on the market and this was also the most time efficient method of collecting the data. Currently, interviews with manufacturers would not add quality to the study, as the aim was to identify objectively the common characteristics of class I mHealth SaMDs that are already placed on the EU market.

In the area of legal scholarship systematic content analysis in form of document analysis (in most cases applied for analyzing case law) has gained more prominence lately. Salehijam 2018 provides analytical procedure for conducting systematic content analysis in legal research. It divides it into five steps: (1) determination of a suitable research question or hypothesis for SCA; (2) identification and collection of sufficient data for analysis; (3) coding of the data, which has its own stages; (4) drawing of conclusions/observations; and (5) reporting the findings in a manner comprehensible to the legal community [52]. The same process is followed in this research. In discussion part findings are analyzed in conjugation with Rule 11, using the linguistic and systematic legal interpretation methods. As a tangible result the author provides indicative risk classification guidance.

3.2 Ethical considerations

Ethical committee approval for this study was not needed as this study was about market practice and legal interpretation of Rule 11, MDR, Annex VIII. All data included in the study was disclosed by the manufacturers, so no use of confidential information. Legal analysis is never completely objective, as lawyers are trained to be advocates for one side of the dispute, legal situation, or problem [53]. The author acknowledges that she is working as a Head of Regulatory and Legal in a medical device manufacturer. This has provided in-depth knowledge about the relevant regulations in question. The author has tried to minimize the possible bias by being clear and transparent about the research problem and about the process by which the data has been collected, analyzed and presented.

3.3 Research process

According to Salehijam 2018 the first step of analytical procedure was to determine the research questions (see page 14-15), secondly the identification and collection of data was conducted. EUDAMED database was selected as a primary data source, as it is the only pan-European medical devices database established on the basis of MDR and IVDR. [41] Although EUDAMED is currently not compulsory, then manufacturers are using it actively as a platform to provide relevant information about their device to the whole European market and generate trust in potential users. Finland even requires that manufacturers would register their device already now in EUDAMED (national notification process is not applicable anymore, despite the fact that EUDAMED is not fully functional). [43] Initial data derived from EUDAMED in the data collection phase was supplemented by the public sources: mostly manufacturers websites, but also from GooglePlay, AppStore to clarify the intended purpose, functionalities of the devices and intended user of the device as the manufacturer has aimed. According to MDR art 2 (12) the intented 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. In case manufacturer´s website provided information about intended purpose (or user manual was disclosed which includes intended purpose), then GooglePlay and AppStore were not reviewed. Braun et al. (2019) identified three schools of conducting content analysis, including codebook approach [42]. Roberts, K et al. (2019) provided sample of the codebook development which contributed to content analysis of qualitative data [43]. The similar approach in developing codebook was applied.

Subsequently the data selection process and coding the data will be explained in more detail.

3.2.1 SaMD selection process

A structured review process was used to guide the collection of SaMD data as provided in Figure 1.

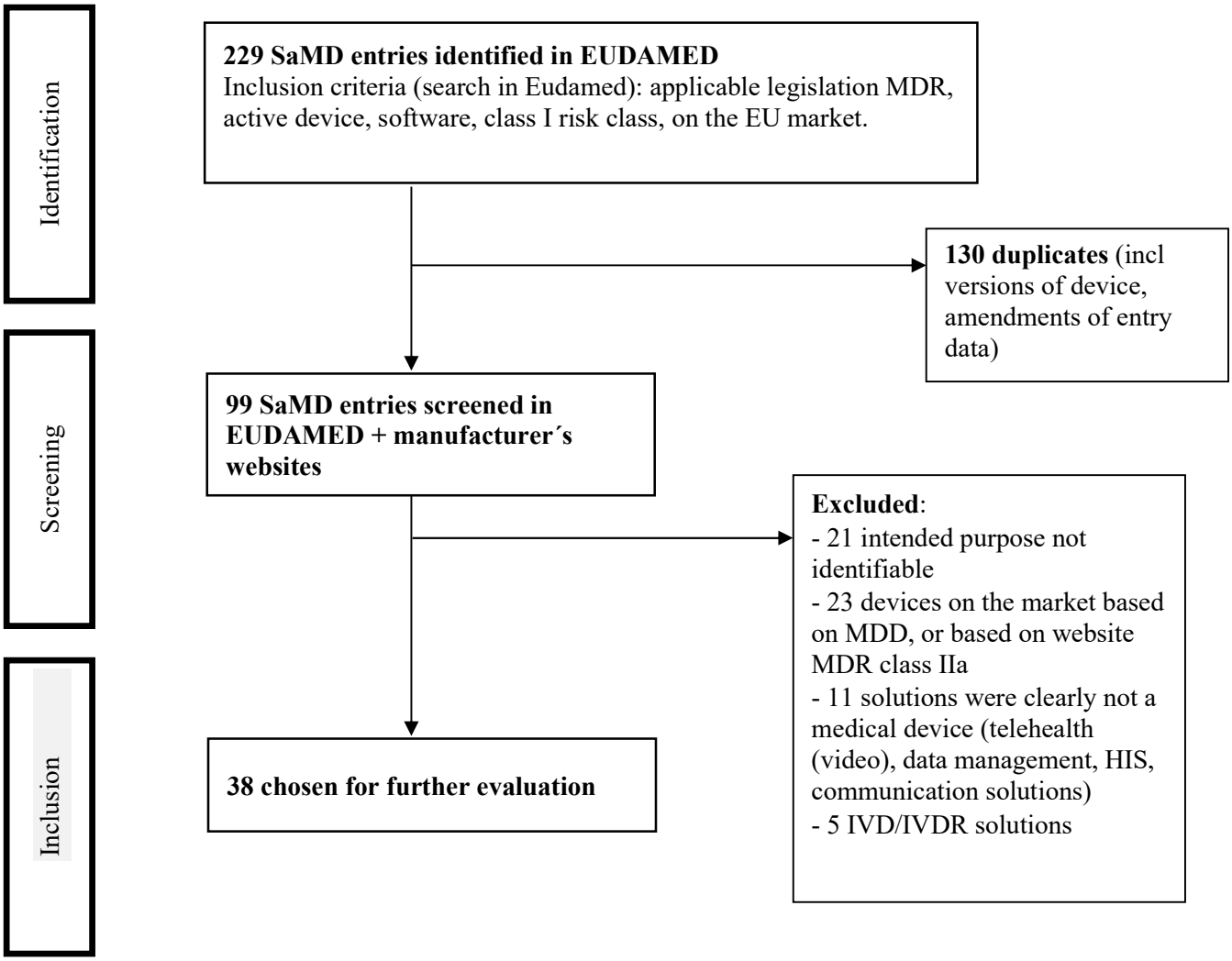

Figure 1: Data selection process, source: author

3.2.2 Codebook creation and synthesis

Current study followed the same process of codebook development as provided by Roberts, K et al. (2019) [54]. Based on the research questions being asked, the initial analysis of the literature, art 2 (1) of MDR regulation and Rule 11 in Annex VIII, and IMDRF framework, initial themes for codebook were developed. Additionally, during the revision of the data, the deductive approach was followed to develop the codebook further to map the common characteristics of the mobile medical devices in class I.

The data synthesis followed such process: 1) the line-by-line coding of the intended purpose texts provided by the manufacturer to Eudamed or website based on the initial codebook; 2) the extraction from intended purpose text additional terms and notions transformed into codes according to its meaning and content; 3) codebook review and updating; 4) application of the codebook to the full dataset.

The initial codebook used in this study is provided in the subsequent Table 3

Table 3: Initial codebook, source: author

Code	Definition	Example in Intended Purpose
1. Significance of information provided by SaMD to healthcare decision	**The intended purpose of the device stipulates the significance of the information**	
1.1. It is referenced that information from device is aimed for diagnosing or treating	The intended purpose of the device states the information provided by the SaMD will be used *to take an immediate or near term action*: To treat/prevent or mitigate by connecting to other medical devices, medicinal products, general purpose actuators or other means of *providing therapy to a human body* or to *diagnose/screen/detect a disease or condition* (i.e., using sensors, data, or other information from other hardware or software devices, pertaining to a disease or condition).	No such example found
1.2. It is referenced that information from device is driving clinical management	Driving clinical management infers that intented purpose states that the information provided by the SaMD will be used to aid in treatment, aid in diagnoses, to triage or identify early signs of a disease or condition will be used to guide next diagnostics or next treatment interventions: *To aid in treatment by providing enhanced support to safe and effective use of medicinal products or a medical device*. • To aid in diagnosis by analyzing relevant information to help predict risk of a disease or condition or as an aid to making a definitive diagnosis. • To triage or identify early signs of a disease or conditions.	"Neptune generates continuous and objective motor symptom and treatment response insights, enabling each person living with Parkinson's *to attain optimal symptom control with treatment* that is personalized and tailored to their needs."
1.3. It is referenced that device is	Informing clinical management infers that the information provided by the SaMD will not trigger an immediate or near term action: • To	"The Levvel Platform is a software-based medical device that can collect health data via a mobile app and compatible medical devices. Data is transferred to clinicians in the Clinician Portal, *where it can be viewed,*

informing clinical management	inform of options for treating, diagnosing, preventing, or mitigating a disease or condition. • To provide clinical information by aggregating relevant information (e.g., disease, condition, drugs, medical devices, population, etc.)	*assessed and acknowledged.* The software solution is *intended as a tool for remote monitoring and home care of patients to provide clinicians with more data points,* empower patients to be involved in their care and reduce unnecessary consultations and hospitalizations."
2. Special medical purpose of the device categorised as in definition MDR art 2 (1)	**The intended purpose of the device allows to determine the special medical purpose of the device, as categorised in definition MDR art 2 (1)**	
2.1. Diagnosing of the disease	The mentioned functions provided in the intended purpose are aimed for the diagnosing of the disease	No such example found
2.2. Prevention of the disease	The mentioned functions provided in the intended purpose are aimed for the prevention of the disease.	"The Emy Kegel trainer, designed for pelvic floor exercises at home. Its innovative technologie aims to *aid the prevention of urinary leaks* and the control of the pelvic floor. Emy is a connected, user-friendly medical device, linked to a mobile application that offers training of the pelvic floor through intuitive and easy-to-use serious games."
2.3. Monitoring of the disease	The mentioned functions provided in the intended purpose are aimed for the monitoring of the disease.	"Diabetes:M is a software platform solution with a mobile app for tracking and management of the condition for people with all types of diabetes or pre-diabetes. By considerable improvement of the *self-monitoring* and self-management capabilities of the diabetic, it lowers the risks of complications and provides the user and medical specialists with a tool that helps in taking quick and informed decisions about the therapy."
2.4. Prediction of the disease	The mentioned functions provided in the intended purpose are aimed for the prediction of the disease.	"Symptom checker gives, on the basis of the information entered by the user, an *indication of correlation* between symptoms and various diseases. The results *indicated* by symptom checker, refers to an external source with in-depth information about diseases (www.sundhed.dk).The information provided in Symptomtjekker's user interface must therefore should not be equated with a clinical diagnosis and must not be used for self-diagnosis. Symptom checker always encourages the user to consult their own doctor if they suspect illness. Enter symptoms, age and gender for yourself or someone else, answers to questions that relate to the symptoms entered

		see which diseases may *relate* to what you have entered SymptomTjekker does not give you a diagnosis, but *guides you to which disease may be associated with the entered symptoms*."
2.5. Prognosis of the disease	The mentioned functions provided in the intended purpose are aimed for the prognosis of the disease.	No such example found
2.6. Treatment of the disease	The mentioned functions provided in the intended purpose are aimed for the prognosis of the disease.	"Kranus Edera is a digital health application for the *holistic treatment* of erectile dysfunction and its causes. *The stand-alone therapy* supports men with erectile dysfunction to actively participate in their *treatment* and helps doctors to *implement the recommendations of the guidelines for the treatment* of erectile dysfunction and thus expand the therapy options. Users of the app complete a 12-week program *consisting of pelvic floor training, physiotherapy exercises, cardiovascular endurance training*, mindfulness and *sex therapy* exercises. Patients receive new exercises weekly, the intensity and complexity of which are continuously adjusted. *The therapy* is supplemented by knowledge transfer about the disease and helpful tips, e.g. on nutrition and preventive measures."
2.7. Alleviation of the disease	The mentioned functions provided in the intended purpose are aimed for the alleviation of the disease.	"The app includes an evidence-based, personalized and multimodal intervention that provides an lifestyle adaptation combined with repetitive therapy content. It contains educational content on mild cognitive disorders and dementia, cognitive and physical training content as well as educational and instructional content on evident, esp. cardiovascular, risk factors of dementia, to change the diet, the general lifestyle and to strengthen the social exchange. Purpose is *alleviating the symptoms of their chronic neurodegenerative disease*."
2.8. diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability.	The mentioned functions provided in the intended purpose are aimed for the compensation for an injury or disability.	"With the eCtouch app, you combine audio, video and real-time text according to your needs. *Use e.g. sign language, speech, lip reading and text for clarification.* With eCtouch, you can call the Swedish relay services bildtelefoni.net and texttelefoni.se, which in turn can call people who use regular voice phones. eCtouch is suitable for use on your mobile phone, tablet or computer. You can install eCtouch on Windows 10, Android and iOS."

2.9. Devices for the control or support of conception.	The mentioned functions provided in the intended purpose are aimed for the control or support of conception.	"Clue is the period tracker and pregnancy app that puts the power of science and the support of fertility experts in your own hands. Understand your body and start living in sync with your cycle, instead of in spite of it, with Clue. Discover patterns in your menstrual cycle, access expert advice for things like your birth control and fertility questions*, get pregnant faster,* and track your developing pregnancy, all in one easy-to-use app. Clue is more than a period diary. *It's an ovulation tracker, period calendar,* and *pregnancy calendar r*eady to guide you through all your cycle's stages."
3.0 Intended user		
3.1. Healthcare professional	Intended purpose or description of the device states that aimed only to health care professional	"The Aether Digital Platform (ADP) is an online platform to monitor Zeus V1 device, monitor the usage of the device and incudes remote connection with the patient. *Clinician's would have access to patients and their devices.* They would be able to look at the data associated with the patient's device usage. *Clinicians will be redirected to the Zeus configurator software (Part of the Zeus hand).* The Zeus Configurator is designed to be used *solely by clinicians certified by Aether Biomedical.* Patients, as the users of the prosthesis, are not allowed to make any changes to it via this software. The Zeus Configurator is intended to be used to configure the Zeus hand and customize it for the user. Additionally, the software also provides the required tools to service and repair the Zeus hand."
3.2. Patient (layperson)	Intended purpose or description of the device states that aimed only to patient (user, or layperson), there might be also other non-healthcare professional involved: carer, support person etc.	"The smartphone application kontina supports *patients* with an overactive bladder through behavioral training and physiotherapeutic interventions alleviate symptoms themselves and improve their quality of life."
3.3. Both – healthcare professional, patient.	It is possible to determine that the device is aimed to patient and health care professional (there might be several medical purposes). There might be also third party involved – support person etc, but this is not mandatory.	"EMDR (Eye movement desensitization and reprocessing) Platform is an online tool for *EMDR therapists* to deliver remote EMDR therapy. EMDR platform contains video calling and visual and auditory EMDR tools. EMDR Platform is the first platform in which video calling and EMDR tools are fully integrated in one web page. *You and your client can use the platform immediately*, without installing any software. *For clients with only a smartphone or tablet, there is a free EMDR Platform-app.* This is the only app in which the video calling and EMDR tools are fully integrated."

As it was detected during the initial coding of the intended purpose statements of the mHealth SaMDs included to the study, that the devices entail different functionalities that might fulfil the special medical purpose as provided in article 2 (1) MDR, that might assist in fulfillment of special medical purpose as provided in article 2 (1) MDR, but also there are functionalities that do not fulfil the special medical purpose, or are clearly excluded from this scope (like mere data transfer, storage, simple search or telehealth (chat, videocalls), then additional codes were developed during the coding process to fully grasp common functionalities of class I mHealth SaMDs that would provide basis for interpretation guidance to be developed.

Using deductive method, the codebook was further developed. After upgrading the codebook, the intended purpose statements, and user manuals of the mHealth SaMDs included in the study were one more time reviewed, data examined, and additional codes applied. This was the basis for the creation of software functionality tables. Additional codebook is presented in the Table 4.

Table 4: Additional codebook, source: author

Code	Definition	Example in Intended Purpose
4.0 Function that fulfils or is assisting the medical purpose	Function of the software that is aimed to fulfil the medical purpose as defined in art 2 (1) MDR	
4.1. Digitalized therapy (medical purpose is treatment, alleviation)	Software is aimed to provide digitalized (behavior) therapy (same strategies and techniques as face-to-face therapy)	"The online course consists of seven weekly units with a processing time of 45-60 minutes each. In addition to well-founded psychoeducation using texts, videos and audios, *the online program conveys effective strategies from cognitive behavioral therapy and acceptance-commitment therapy* based on the latest scientific findings. These include mindfulness techniques, cognitive restructuring, value work and instructions for self-reflection. The exercises are learned as part of the online program and can be integrated into everyday life."
4.2. Therapeutic exercises (medical purpose is treatment, alleviation)	Software instructs the user in conducting the therapeutic exercises	Kranus Edera is a digital health application for the holistic treatment of erectile dysfunction and its causes. The stand-alone therapy supports men with erectile dysfunction to actively participate in their treatment and helps doctors to implement the recommendations of the guidelines for the treatment of erectile dysfunction and thus expand the therapy options. Users of the app complete a *12-week program consisting of pelvic floor training, physiotherapy exercises, cardiovascular endurance training,* mindfulness and sex therapy exercises. Patients receive *new exercises weekly, the intensity and complexity of which are continuously adjusted.* The therapy is supplemented by knowledge transfer about the disease and helpful tips, e.g. on nutrition and preventive measures
4.3. Patient data monitoring function (medical purpose is monitoring) by patient itself	Software functions allow us to collect, store, analyze data for self-monitoring (might include also goal setting and results analysis).	"The MindDoc monitoring and self-management application medical device provides continuous long-term *sign and symptom monitoring of common mental disorders*. This protocol is supplemented by courses and exercises. This enables users to recognize patterns in their symptom trajectories which then can be shared with a mental health care expert and used for self-management."

4.4. Digitalized diary (self-monitoring)	Software functionality that allows to collect, store, analyze data for self-monitoring purposes in the form of digitalized diary (patient generated data or connected device)	"There is also an online diary a companion app and repeated symptom checks to track your progress and to be able to evaluate." (HelloBetter Depression Prävention)
4.5. Patient data: physiological processes or vital signs monitoring by healthcare professional	Software functions allow to collect, store, physiological processes or vital signs in clinical setting (incl home-monitoring, distant-monitoring) using connected devices (might be also accessory device)	"Actimi Telecare is a software application designed for use on mobile devices by users with Heart Failure risks. The application can be connected with various EC certified medical devices for *measuring physiological parameters* of the patient at a given point of time. The devices are stand-alone, have their own display and the app is not influencing or driving them in any manner. It only receives the data. (it is not intended for continuous monitoring of physiological parameters). The data, received from measuring devices, are then processed without any change of parameters, to a format suitable for a medical device software / dashboard, which then uses these data for further processing and displaying. The application is explicitly not intended to directly provide a diagnosis."
4.4. Decision support (any medical purpose)	Software functionality includes taking input data, processing it and providing output data that is basis for making clinical decisions	"Diabetes:M is a software platform solution with a mobile app for tracking and management of the condition for people with all types of diabetes or pre-diabetes. By considerable improvement of the self-monitoring and self-management capabilities of the diabetic, it lowers the risks of complications and provides the user and *medical specialists with a tool that helps in taking quick and informed decisions about the therapy."*
4.5. Alerts and notifications	Software functionality that triggers alarm or sends notifications/reminders	"includes "connected monitoring" module, managing alerts, sending questionnaires and responses to healthcare professionals." (Engage)
4.6. Automated guidance	Clinical patient guidelines have been transformed into digitalized flow of instructions	"The mebix app supports and empowers patients with diabetes mellitus, cardiovascular disease and/or obesity in self-management of their chronic disease. The aim is to bring about a lifestyle change and thus a modification of risk factors. In self-management, patients must learn to set therapeutic goals and to achieve these goals through appropriate measures (e.g.

		activity/exercise, nutrition). For this purpose, *recognized guidelines have been implemented in the app in such a way that the patient receives specific instructions for the next few days, months and years.* This takes place in the form of regular disease-specific knowledge transfer with implementation recommendations, reminders and motivation for everyday life, bundled with knowledge tests. Exercise tasks are gradually suggested at timed intervals (e.g. creating an exercise plan, setting individually achievable health goals, logging vital signs and food consumed, finding healthier food alternatives, etc.). This enables targeted integration into the patient's environment without overtaxing them."
5.0. Function that does not fulfill the medical purpose but supports its fulfillment	**Function of the software that is aimed to support the medical purpose as defined in art 2 (1) MDR**	
5.1. Educational content about the disorder/disease/condition	Software functionality includes provision of educational content about the disorder/disease/condition	"In addition to well-founded *psychoeducation using texts, videos and audios*, the online program conveys effective strategies from cognitive behavioral therapy and acceptance-commitment therapy based on the latest scientific findings."
5.2. Wellness or lifestyle tips, instructions, content	Software functionality includes provision of wellness or lifestyle tips, instructions or content.	"The app includes an evidence-based, personalized and multimodal intervention that provides an lifestyle adaptation combined with repetitive therapy content. It contains educational content on mild cognitive disorders and dementia, cognitive and physical training content as well as educational and *instructional content* on evident, esp. cardiovascular, risk factors of dementia, *to change the diet, the general lifestyle and to strengthen the social exchange*. Purpose is alleviating the symptoms of their chronic neurodegenerative disease."
5.3. Communication (telehealth, video consultation)	Software functionality provides means of communication (video consultations, chat function)	"EMDR (Eye movement desensitization and reprocessing) Platform is an online tool for EMDR therapists to deliver remote EMDR therapy. EMDR platform contains *video calling* and visual and auditory EMDR tools. EMDR Platform is the first platform in

		which video calling and EMDR tools are fully integrated in one web page. You and your client can use the platform immediately, without installing any software. For clients with only a smartphone or tablet, there is a free EMDR Platform-app. This is the only app in which the *video calling and EMDR tools are fully integrated.*
5.4. Data transfer for facilitating care process, care support	Software functionality allows to transfer data between patient and health care professional or devices (at home) and health care professional.	"Actimi Telecare is a software application designed for use on mobile devices by users with Heart Failure risks. The application can be connected with various EC certified medical devices for measuring physiological parameters of the patient at a given point of time. The devices are stand-alone, have their own display and the app is not influencing or driving them in any manner. It only receives the data. (it is not intended for continuous monitoring of physiological parameters). The data, received from measuring devices, are then processed without any change of parameters, to a format suitable for a medical device software / dashboard, which then uses these data for further processing and displaying. The application is explicitly not intended to directly provide a diagnosis." ."

4 Results

The present chapter explains the results of the class I SaMDs, listed in EUDAMED and available on the EU market, as identified with current study. It provides overview of the analyzed I class SaMDs: their medical purpose according to article 2 (1) MDR, main function(s) as deducted from the intended purpose of the device, that fulfil the indicated medical purpose, main supporting functions of the devices (that might be, but usually are not fulfilling medical purpose as defined in article 2 (1) MDR, devices intended users, medical conditions and/or types of disorders that the devices are meant to be used.

It should be noted that this research is intended to detect tendency,patterns and common criterions in class I SaMD classification, rather than to evaluate specific SaMD conformity with applicable rules and correctness of their classification, nor has the author reviewed the clinical validation of the devices as full technical documentation is usually not fully available on the website of the manufacturer.

4.1. Results for research question 1 - Who are the intended users of the class I devices? Whether the risk classification is different depending upon the intended user?

In total 38 SaMDs listed EUDAMED were analyzed for this research. 22 SaMDs out of 38 had intended user patient or non-professional user (layperson), 12 were multi-user devices (systems), aimed for patient (non-professional user, layperson) and health care professional at the same time, or that device is aimed to be used only with the control of the professional (for example all VR devices). 4 devices analyzed were aimed solely at professionals (Figure 2).

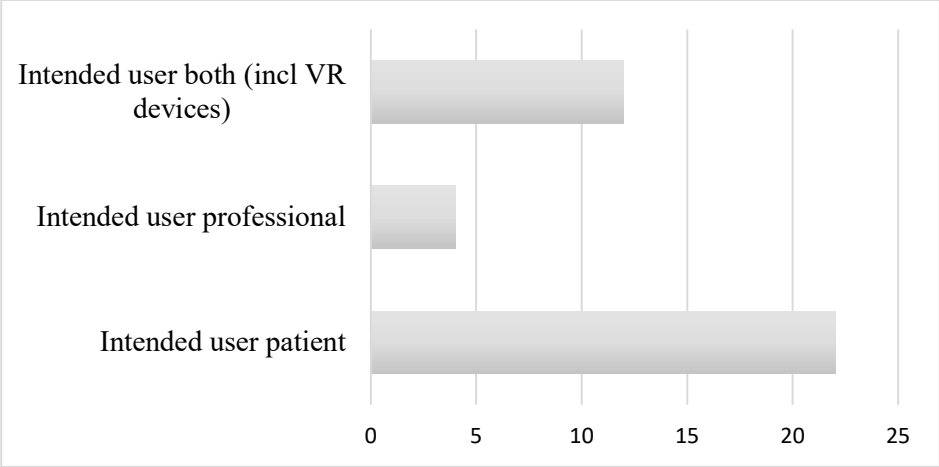

Figure 2: Intended user of device, source: author.

4.2. Results for research question 2 - Which types of medical disorders /situations / conditions are the most common that the class I devices are intended to?

Most of the devices are aimed at alleviating mental, behavioral, and cognitive disorders (14), second largest group of devices are aimed at nervous system disorders (6), Musculoskeletal system disorders, oncology specific and rehabilitation had each 3 devices, it is also remarkable that 5 devices did not specify any type of disorder (all of them were multi-user or system devices). But also, other areas were represented, like devices aimed for alleviating endocrine, nutritional and metabolic diseases (2), circulatory system disorders (2), ophthalmology disorders (2), male reproductive system disorders (1) and also women´s health (2) (Figure 3)

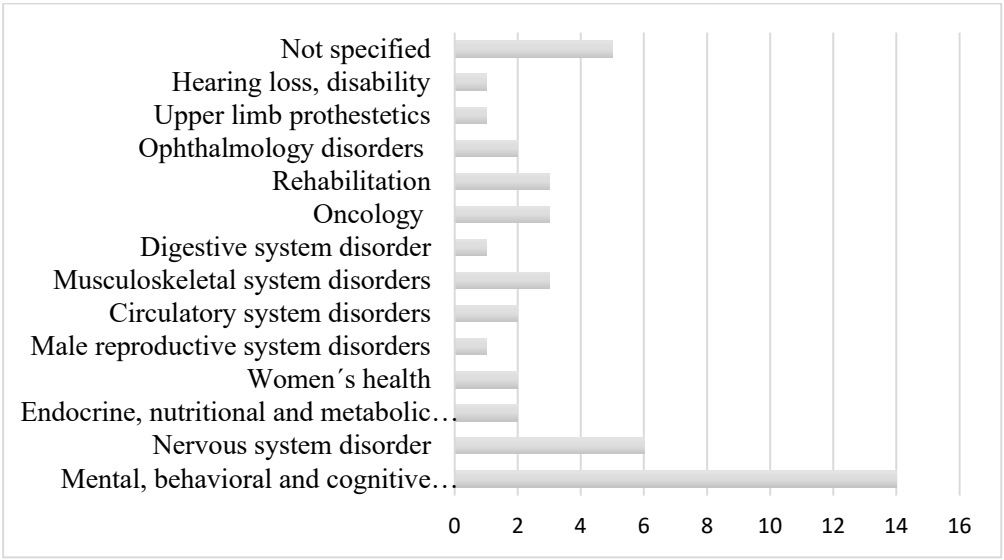

Figure 3: Medical disorder, condition device is intended to, source: author

4.3. Results for research question 3 - Which special medical purpose as provided in article 2 (1) MDR and as described in the intended purpose of the device, are the class I mHealth SaMDs usually fulfilling?

As the aim of the study was to identify class I mHealth applications, then out of 38 SaMD included in the study, 27 were satisfying this category. Out of these class I mHealth applications, 18 were smartphone apps or online-programs accessible via mobile phone, tablet, or computer; 8 were multi-component systems, where smartphone app was part of the system (for patient), 1 device was solely web-application. So, the user manuals and technical descriptions on the websites of these devices were more thoroughly analyzed.

Other 11 SaMDs that intended purpose was analyzed, but it showed that they are not actually mHealth SaMDs. There were software in combination with VR hardware identified mostly aimed for rehabilitation or digital medical hypnosis (4); software in combination with other types of devices (4) (incl medical devices, like contactless thermometers, blood pressure, saturation and body composition monitors etc), where the aim of the software is to collect the readings captured by these devices, and to pass the collected readings as-is (with-out altering the readings, without performing diagnostics or analysis) to either an EHR, or other remote healthcare services (system-to-system), also two devices were identified by the manufacturers as accessories to a medical device (2) (Vaye Engine and Zeus Bionic hand configurator), and lastly RT-Connect software was identified to be a tele-diagnostic solution to allow eyecare professionals (ophthalmologists, orthopticians, opticians and optometrists) to perform subjective eye refraction examinations to establish and/or check an eyeglass prescription remotely. So, this device actually had diagnostic purpose, and it is should be classified into IIa risk class.

Information about the type of software in SaMDs is provided in Figure 4.

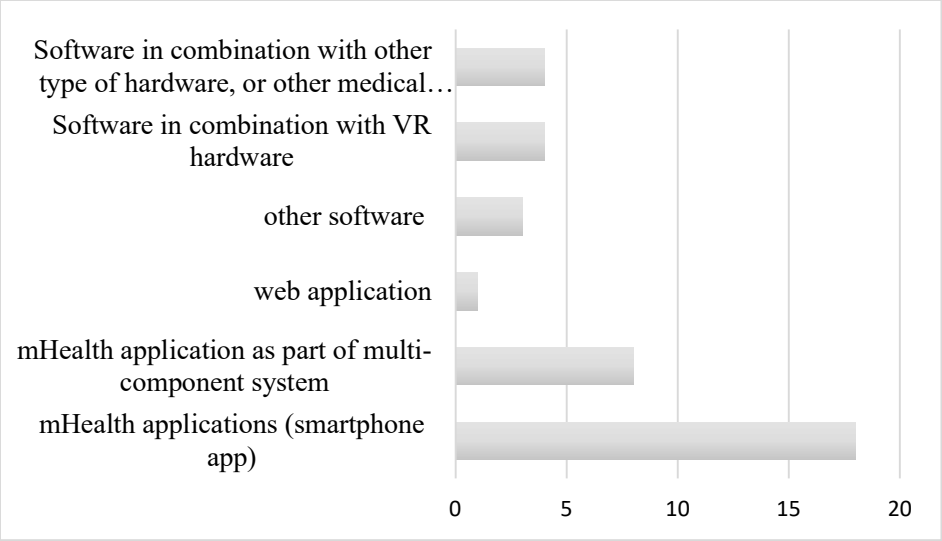

Figure 4: type of software, source: author

Patient facing mHealth SaMDs

The mHealth applications, where the intended user was patient, 11 had special medical purpose according to art 2 (1) MDR alleviation of the disease, 5 had dual medical purpose: alleviation of the disease and prevention of the disease. There was one device that claimed in intended purpose both alleviation and (self)monitoring of the disease, and following medical purposes were all represented one time: prediction of disease, control or support of conception, compensation for disability.

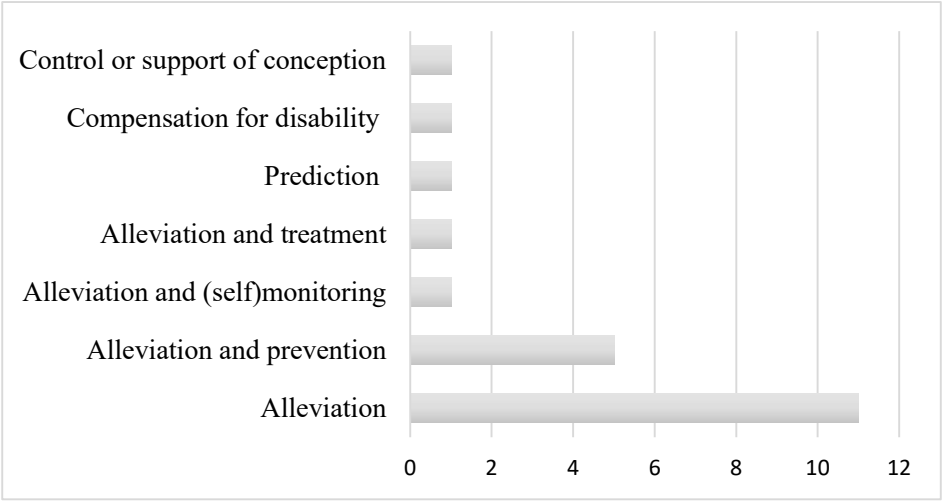

Figure 5: Special medical purpose of patient facing mHealth SaMDs, source: author

Multi-user mHealth SaMDs

Other big group of mHealth devices are such that are multi-user and multi-component devices, that are aimed at patient and health care professional (incl here also nursing specialties) at the same time, but the patient facing application is in mHealth form (usually smartphone application). Such device's special medical purpose was pursuant to art 2 (1) MDR mostly monitoring (either clearly specifying self-monitoring, or simply monitoring) (4 devices identified). 1 device had medical purpose that included alleviation and monitoring (Diabetes:M), 1 device that was aimed for the provision of treatment (EMDR Platform), and 1 device which functions included stand-alone separate medical devices data format configuration, mobile application (dashboard) for the patient to display the data coming from different medical devices, and web application for displaying same data to the healthcare professional (Actimi Telecare).

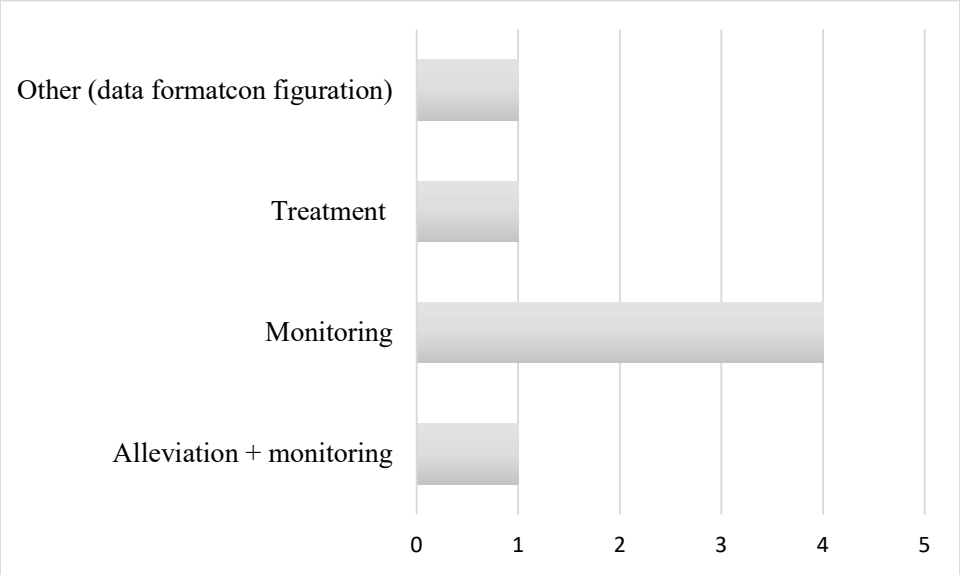

Figure 6: Special medical purpose of multi-user mHealth SaMD, source: author

4.4. Results for research question 4 - Which are the most common functionalities of the class I devices, that fulfil the special medical purpose provided in article 2 (1)?

Analysis showed that all of the mHealth SaMDs are multi-functional devices, including both - such functions that could be seen fulfilling MDR art 2 (1) special medical purpose, but also such functions that are clearly excluded from the medical device definition (like mere data storage, data transfer, telehealth or communication, simple-search function or wellness aimed functions). [9]

Relevance in defining which of the functions are fulfilling the special medical purpose as defined in MDR art 2 (1) and which are simply assisting or supplementing functions of the device is important for the manufacturer, as this will assist in drafting the intended purpose wording of the device. The intended purpose statement is relevant however for determining a) where the medical device fits within the regulatory pathway, b) whether it qualifies as a medical device, c) into which risk class the device belongs, and d) the clinical evidence that needs to be generated.

Functionalities of patient facing mHealth SaMDs

Tabel 5 provides an overview of the functions of the patient facing mHealth SaMDs (intended user solely patient). In light grey are marked the functions of the device that can be considered fulfilling MDR art 2 (1); and also which are supporting the special medical purpose defined in MDR art 2 (1) (like alarms, digitalized diary, health goals setting), and in dark grey are other software functions that simply supplement the operation of the device, but which are not itself fulfilling MDR art 2 (1) special medical purpose.

Devices which intended purpose was prevention (Symptomtjekker), and compensation for disability (eCtouch – hearing and speaking aid system) is left out of Table 5, as these devices do not exhibit any of the listed functions below. Only one device in this Table 5 had a special medical purpose other than “alleviation of the disease”, this was Clue Conceive application aimed for the support of conception.

All other mHealth devices had a special medical purpose alleviation of disease, or alleviation of disease together with self-monitoring of the disease or together with prevention of the disease.

Table 5 lists also the non-medical functionalities of the mHealth SaMDs, the most prominent ones being “wellness” (for example yoga exercises) and “educational” functionalities (information about nutrition, or diet -related information and instructions). Some devices have telehealth functionality (patient can either chat with healthcare specialist, or make video calls). Ultimately all functionalities are supporting patient self-aid, self-management of the disease or condition.

Table 5: Main functions of the patient facing mHealth SaMD, source: author

Device name	Medical indication	Decision support	Alerts and notifications	Health tracking	Auto-mated guidance	Clinical remote monit-oring	There-peutic: prevent, manage, treat	Health goal setting, self-monitoring	Digitalized diary	Functionality not fulfilling special medical purpose
Memodio app	Mild cognitive impairment, Mild dementia				x		x			Wellness educational
Kontina	OAB, overactive bladder		x				x	x	x	Wellness educational
The Left	Gastroesoph ageal reflux disease		x	x			x			
Emy	Urinary incontinenc eweak pelvic floor		x		x		x	x		Wellness
HelloBetter Depression Prävention	Depressive symptoms						x	x	x	Wellness educational
HelloBetter ratiopharm chronic pain	Chronic pain						x	x	x	Wellness educational
HelloBetter Stress and Burnout	depression, anxiety, sleep, quality of life, and work-						x	x	x	Wellness educational

	related health							
HelloBetter Diabetes and Depression	Type 1 or type 2 diabetes mellitus, depressive symptoms				x	x	x	Wellness educational
HelloBetter Sleep	Insomia				x	x	x	Wellness educational
Mamly	Pregnant women and mothers in the first year of the child's life				x			Wellness educational telehealth
Mebix APP	Diabetes mellitus, cardiovascular disease and/or obesity	x		x	x	x	x	Wellness educational telehealth
UpBalance	Stress, burnout				x	x	x	Wellness educational
HeartFish	Chronic diseases such as Diabetes, high blood pressure, cancer and multiple sclerosis		x		x	x	x	Wellness educational
Kranus Edera	Men with erectile dysfunction	x		x	x	x		Wellness educational

MindDoc	no, minimal, mild, and moderate mental disorders,				x	x		Wellness educational
HerzBegleiter	Mobility problems, postural disorders				x	x		Wellness educational telehealth
Clue concieve	Women who want to get pregnant	x					x	Wellness
Kalmeda	Tinnitus				x	x	x	Wellness
Meine Tinnitus App	Tinnitus				x	x	x	Wellness

When to look more closely the patient facing devices listed in Table 5, which have "alleviation of the disease" as their main special medical purpose, then most of these mHealth SaMDs have computational function(s) that fulfil the special medical purpose in the form of digitalized cognitive behavioral therapy (or module that has been developed on the basis of cognitive behavioral therapy) (10); second mostly prominent function in such devices is digital physiotherapeutic interventions or exercises (4); thirdly there are devices that entail functions aiming for the enforcement of digitalized clinical guidelines (4); Some interesting examples were: a devices that entail digitalized pelvic floor exercises (the device is combined with biofeedback kegel trainer to assist the user in exercising by instructions); device that monitors the sleeping body position and triggering alarms in case of wrong position.

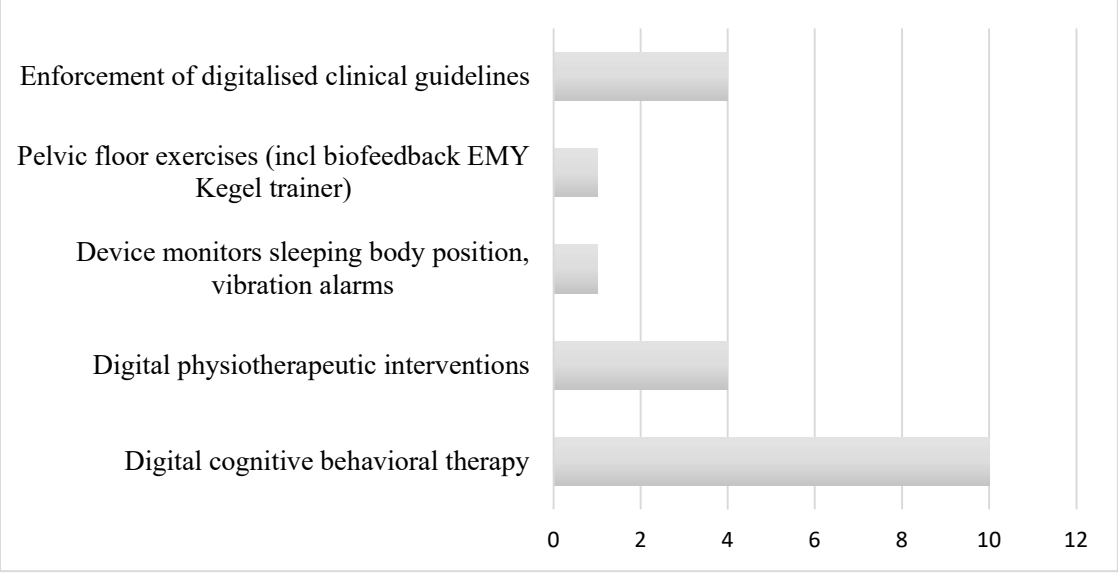

Figure 7: Functionalities fulfilling the alleviation medical purpose in patient-facing mHealth SaMDs, source: author

Functionalities of multi-user mHealth SaMDs

Most of the multi-user devices had marked monitoring as their special medical purpose as provided in art 2 (1) in the MDR, however it must be noted that "monitoring" here might have different meaning in the different devices. For example, Actimi Telecare, MedCor4U and Levvel Platform main function is to collect data from different CE certified medical devices that the patient is using in the home setting and to pass it to the EHR or other device (system-to-system devices), so they

are facilitating the monitoring by transferring the data from CE certified medical devices into the other system (or device) or EHR.

Diabetes-M main computational functions were directed to the patient (the core functions of the device are self-management and self-monitoring capabilities of diabetes), but health care professionals could have access to limited functions and data. Engage was the most complex system device, and the list of different functions aimed at patients and professionals were extensive. It included also function of "monitoring vitals" in the patient component of the device, but it should be noted that according to Rule 11, Annex VIII, MDR "*Software intended to monitor physiological processes is classified as class IIa, except if it is intended for monitoring of vital physiological parameters, where the nature of variations of those parameters is such that it could result in immediate danger to the patient, in which case it is classified as class IIb.",* then this device cannot be clearly classified into class I.

Also, Neptune Care had functions aimed at the health care professional that rather led into class IIa by Rule 11, Annex VIII, MDR, for example the device includes functions that provides health care professionals patients' symptom insights through the web app and health care professionals can update treatment regime through the device on the basis of the insights received. So, it could be reasoned that the device is informing clinical management, and therefore Rule 11 a) applies and the device should be classified into class IIa, but as this manufacturer had limited information disclosed then the correctness of classification cannot be confirmed.

Table 6: Main functions of the multi-user mHealth SaMD, source: author

Device name	Medical indication	Decision support	Alerts and notifications	Health tracking	Automated guidance	Clinical remote monitoring	Therepeutic: prevent, manage, treat	Health goal setting, selfmonitoring	Digitalized diary	Functionality not fulfilling MDR 2 (1) special medical purpose
EMDR Platform	Trauma, memory loss						x			Telehealth data transfer
Engage	Different home care patients	x		x		x				Telehealth data transfer
Neptune Care	Parkinson	x	x	x	x	x	x		x	Data transfer
Diabetes-m	Diabetes	x	x	x	x		x	x	x	Wellness data transfer
Actimi Telecare	Chronic heart failure, heart failure risk			x		x				Data transfer
MedCor4U	Different home care patients			x		x				Data transfer
Levvel Platform	Different home care patients			x		x				Data transfer

4.5. Results for research question 5 - How do the intended purposes of class I devices correspond to the IMDRF risk classification guideline categories?

Analysis of the intended purpose statements of the devices revealed that it is not common to state the significance of the information provided by the device (as described in IMDRF guideline and that could be assisting in determining device´s risk class) in the intended purpose statement.

So, there are no examples where the intended purpose of the device would clearly state that the device is aimed for "*providing information for the diagnosing or treatment of the disease*", or that the device "drives the clinical management" or that device "*informs the clinical management*." Such outcome for the code "*providing information for the diagnosing or treatment of the disease*" is also understandable as such devices would be classified into the highest risk classes (IIa and above), and study included lowest class devices.

There is also no direct usage of the code "*driving clinical management*" and "*informing clinical management*" in the intended purpose statements, but some intended purpose statements could be interpreted to have a similar meaning. Intended purpose and description of Neptune Care device (Parkinson disease management solution) could be seen as corresponding to the "informs clinical management" code, it states:

"*Neptune Care generates continuous and objective motor symptom and treatment response insights, enabling each person living with Parkinson's to attain optimal symptom control with treatment that is personalized and tailored to their need. Doctors can access patients' symptom insights through the web app. Doctors can update treatment regime through the web app.*"

Diabetes-m intended purpose statement provided that:

"*Diabetes:M is a software platform solution with a mobile app for tracking and management of the condition for people with all types of diabetes or pre-diabetes.*
By considerable improvement of the self-monitoring and self-management capabilities of the diabetic, it lowers the risks of complications and provides the user and medical specialists with a tool that helps in taking quick and informed decisions about the therapy."

So, this might be also seen as corresponding to the code "*informing clinical management*".

Also, Actimi Telecare, MedCor4U and Levvel Platform that were devices aimed at data transfer were referring in their device description for "*better information management*" or "*more data points*" etc. However, these devices are not generating themselves any output information, but simply transfer data in "*as is*" from the CE certified medical devices to other systems (EHR, or other platform, that could use this data in another SaMD).

So, they could be classified as accessory to medical device according to art 2 (2) provided that they are intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable the medical device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device(s) in terms of its/their intended purpose(s). Relevant to note, that if the device in question is intended to be used in combination with another device, the classification rules shall apply separately to each of the devices.

Accessories for a medical device are in the scope of MDR and shall be classified in their own right separately from the device with which they are used (art 1 (4) MDR and Annex VIII art 3.2.). [7]

5 Discussion

This chapter discusses the results through applicable norms (MDR) and current guidelines. The author tries to answer the research questions, brings out the main limitations of the study and provides suggestions for the future studies on this topic.

5.1. Patient facing mobile medical applications

According to the MDR art 51 (1) and EU guidelines it is the obligation for the manufacturer to determine the intended purpose of the device and this will determine the risk classification of the device. [8] It is relevant for the discussion to highlight again the actual Rule 11, Annex VIII, MDR: The text of Rule 11, Annex VIII, MDR can be divided into what are essentially three sub-rules that are applied depending on the intended use/purpose of the mHealth SaMD: 11a: (3 first paragraphs of Rule 11) *intended to provide information which is used to take decisions with diagnostic or therapeutic purposes* (and the rule includes also factors that increase the potential risk and therefore also risk class); 11b: (Paragraph 4 of Rule 11) *intended to monitor physiological processes or parameters*; 11c: (Paragraph 5 of Rule 11) *all other uses*. [24]

Author is highlighting that sub-rule of 11a states that "Software intended to provide information which is used *to take decisions* with diagnosis or therapeutic purposes is classified as class IIa." The question may raise that, who should be the decision maker here? Both the IMDRF guideline [48] and the corresponding EU Commission guideline [9] refer to the criterion "relevance to significance of the information provided by the software to the healthcare decision and the healthcare situation or patient's condition" only in the context of the decisions of a medical professional, not the patient itself. Also, the exceptions in sub-rule 11a, which increase the risk class of the device (to the risk class IIb in case the decision may cause serious deterioration of a person's state of health or a surgical intervention or to the highest risk class III in case it may cause death or an irreversible deterioration of a person's state of health), are regulating the classification of the devices aimed at the health care professional. So, the rule is directed only to such devices that are aimed at healthcare professionals, as only these encompass clinical decision-making competence and authority. So, this leads the author to conclude that the intended user of the device is utmost relevant in determining the risk class.

This is different however with the wording of rule 11b, as it states: "*Software intended to monitor* physiological processes is classified as class IIa, except if *it is intended for monitoring* of vital physiological processes, where the nature of variations of those parameters is such that it could result in immediate danger to the patient, in which case it is classified as class IIb." The rule does not include decision making element in the wording of the norm. So, the question is whether this rule applies to both: patient facing mobile medical apps and health-care professional facing devices or only the last one? EU guidelines narrow here the scope of the regulation, and states that: SaMD that is intended to monitor physiological processes will, under most circumstances, provide "information which is used to take decisions with diagnosis or therapeutic purposes and hence fall under sub-rule 11a. Sub-rule 11b) should therefore be considered as a specific rule for SaMDs intended only for monitoring purposes. Sub-rule 11b) was introduced to ensure that SaMD, which has the same intended purpose as (hardware) devices which would fall under rule 10 MDR, would be in the same risk class. [9] This leads to confusion whether solely patients facing medical apps (where self-monitoring is part of functionality) would fall also under 11b or is 11c here applicable, as the monitoring does not bring along clinical decisions.

Last sub-rule 11c) states that *all other software* (not depending on the intended user of the device), *is classified into class I.* Hence, this leads to the conclusion that patients facing mHealth SaMDs (patient facing mobile medical apps), should be usually classified into class I, as there is no health care professional that would use the information provided by the SaMD for clinical decision making.

Study showed that majority of class I devices are solely patient facing and most of the devices had medical purpose as the alleviation of the disease in the form of digitalized cognitive behavioral therapy sessions, and at the same time functionalities of the device did not usually include monitoring of physiological processes or vital signs (or it was only a supporting functionality for adjusting the behavior not making treatment decisions by the professional). Also, it was recognized that such devices usually do not contain automated data transfer functionality from application to the health care professional (however it is often possible to export data for the user itself in pdf or CSV format and send by the request of the user the same export data also via e-mail to the health care professional).

The intended purpose statements of such devices include sometimes also "self-monitoring" or "self-management of the disease" statements, some of the devices aimed for mental health, neurological and behavioural theraupeutic areas included also "treatment of the disease" or "prevention of symptoms", but eventually, the prominent medical purpose of these devices is to help patients to manage their disease effectively and improve the quality of life. The study results mirror recent market analysis conducted by Deloitte, concluding that majority of the digital therapeutics places on the market aim at self-management of the disease.

So, these devices are directed to self-care, and they predominantly include therapeutic function in the form of digitalized cognitive behavioral therapy sessions (like all devices developed by GET.ON Institut für Online Gesundheitstrainings GmbH: HelloBetter Depression Prävention, HelloBetter ratiopharm chronic pain, HelloBetter Stress and Burnout, HelloBetter Diabetes and Depression, HelloBetter Sleep, but also Mamly by QuickBird GmbH, Polish UpBalance by Prosoma sp. z o. o., MindDoc by MindDoc Health GmbH, Kalmeda by Mynoise GmbH, Meine Tinnitus App by Sonormed GmbH, Memodio App by memodio GmbH) or digitalized physiotherapeutic exercises (like HerzBegleiter Smart Care Assistant by HerzBegleiter GmbH & Co. KG, Kontina by Aidhere GmbH, Kranus Edera by Kranus Health GmbH, French Emy by Fizimed SAS). Interestingly, even though their core function was "digitalized cognitive behavioral therapy sessions", then their intended purpose statement usually did not claim the "treatment of disease", but was narrowed to the "alleviation of the disease". For example, "*HelloBetter Depression Prevention is an online psychological prevention and reduction program of depressive symptoms and to improve the health-related quality of life of people with no or subclinical depressive symptoms*." Such a choice of intended purpose statement is understandable, as intended purpose defines the level of clinical evidence needed for application. Mobile medical devices that are claiming "treatment of disease" have higher clinical validation burden compared to the devices that merely claim, "alleviation of the condition or disease."

Study revealed that mobile medical applications usually encompass many additional non-medical functions that support the fulfillment of the special medical purpose, there might be some that are supporting the fulfillment of special medical purpose, but there might be also some that are contributing to the user experience of the device and service provided by the same entity who is device manufacturer. For example, they provide education or information about general wellness

or specific disease states, consist of alarms and notifications for better adherence with the program, self-assistance therapy sessions etc., digitalized diaries, or logbooks with analytical element for the continuous self-monitoring and reflection. Some devices also contain self-monitoring of health status based on the connected CE certified medical device (e.g. blood pressure) or wellness devices (wearables) (Heartfish by Heartfish GmbH). Some guide the patient step-by-step to take specific actions for addressing their own health, like program of therapeutic exercises based on the clinical guidelines (Memodio app by Memodio GmbH, Kranus Edera by Kranus Health GmbH). Some devices require the user to set their health goals, followed by numerous continuous sessions of exercising, physical activity and/or digitalized cognitive behavioral therapy sessions and success in achieving the set health goals is measured by continuous self-monitoring (Mebix by Vision2B GmbH). Some also have teleconsultation or chat functions incorporated to the device (Mamly by QuickBird GmbH, Mebix by Vision2B GmbH).

Another type of device the author wants to highlight was Danish Symptomtjekker by Oda ApS. This is a patient facing mobile medical device, that had according to the MDR art 2 (1) special medical purpose "prediction". This solution also did not share the data with the health care professional (so nobody making decision based on the information provided by the device, nor did the solution monitor any physiological processes or vital signs, so last sub-rule of Rule 11 could be applicable leading the device into lowest risk class. When analyzing the functioning of the solution it was detected however, that the solution operates based on simple search function: the user enters some pre-defined information (symptoms), the symptom checker provides a reference (the relationship between symptoms and various diseases) based on the information entered by the user. The results denoted by Symptom Checker, refers to an external source that contains comprehensive information about diseases (www.sundhed.dk). Therefore, it is questionable whether this specific solution should be qualified as medical device at all, as it´s functionality is based on the simple search function. "Simple search", which refers to the retrieval of records by matching record metadata against record search criteria or to the retrieval of information does not qualify as medical device software (e.g. library functions). [9]

If to elaborate the possibility of such mobile medical application and its classification to lowest risk class, then solely patient oriented prediction software (which do not monitor physiological processes or vital signs), for example risk scoring for chronical illnesses based on EHR data for

motivating preventative activities, could be classified in author´s opinion into class I according to the Rule 11c. In case a device is aimed at the health care professional (for example identifying patients with potentially higher risk to some disease for preventative (personalized screening program), then there are different interpretation possibilities. Prevention is in timeline placed prior diagnosing and treatment (the person is not ill yet and prediction scoring only leads to the subsequent preventative steps), then actually sub-rule of Rule 11a should not apply. Hence such device would be in class I. If, however, we consider that Rule 11a applies to any medical decision-making based on the SaMD output information, then such device would classify into risk class IIa. EU guidelines currently do not provide a clear classification indication for such devices.

Third type of special medical purpose that was detected in the intended purpose statements of the mHealth SaMDs referred to the "app intended to support conception" (Clue Concieve by Biowink GmbH). Such device is even provided as an example of class I device in the EU guidelines [8]. Here however risk classification interpretation problems should be highlighted. The menstrual cycle is also one of the characteristics of physiological processes of the female body. The Clue Concieve app functionality digitalizes the symptothermal method, including also monitoring of the body basal temperature (BBT), so it could be according to Rule 11b, considered also as "*Software intended to monitor physiological processes*", provided this rule applies also to only patient facing mobile medical devices. Rule 11b does not contain any special norm for the fertility tracking software, so it should be applicable (placing the device to risk class IIa). To make the topic even more confusing, there is also special Rule 15, which states that "All devices used for contraception or prevention of the transmission of sexually transmitted diseases are classified as class IIb, unless they are implantable or long-term invasive devices, in which case they are classified as class III." And another EU guideline states that: "*Rule 15 applies to devices used for contraception or prevention of the transmission of sexually transmitted diseases. Software used for contraception will be classified as class IIb."* This case is a good example of the ambiguity of MDR and EU guidelines. Hence, when solution is intended for the supporting of the pregnancy according to the EU guideline it could be classified into class I on the basis of sub-rule 11c (despite the fact that actually rule 11b could be applicable – leading to class IIa), but when the software is aimed for preventing the pregnancy, then it is classified into class IIb, according to the Rule 15.

5.2. Hybrid (multi-user) devices

The study identified numerous mHealth SaMDs classified into class I, that users were patients and health care professionals (incl here also nursing specialties) at the same time. In most of the cases such solution´s intended purpose statement included notion "monitoring" (either specifying self-monitoring, or simply monitoring). According to their intended purpose statements and functionalities it is possible to divide them into: 1) hybrid patient monitoring and self-management devices (example part of Diabetes-M functionality, as the user manual includes also references to the analytics and insights for the health care professional, then it may exceed this category); 2) devices connected to sensors and wearables that transfer the data "as is" to the EHR or other system (or to other medical device) (example MedCor4U); 3) devices connected to sensors and wearables that include also analytical element that use input data to provide information (insights) to the health care professionals (Neptune Care). The author thinks that such division is important also for classification purposes.

5.2.1. Hybrid patient monitoring and self-management devices

Multi-user patient monitoring and self-management devices that transmit the data also to the health care professional, but which intended purpose statement does not include information provision to the health care professional to diagnostic and therapeutic purposes and which intended purpose statement also does not claim for clinical monitoring, could be still in considered as patient-facing mobile medical application, provided that the data transmission to the health care professional is solely limited to the function of facilitating data exchange that usually patient would provide himself (orally, showing notes, history of some medical device readings etc) during clinical interview. Hence, the clinical aim of such functionality is to facilitate information collection for patient anamnesis nor provision of the additional (analytical information) that would already provide insight for diagnosis or therapeutic decision. Author acknowledges, that here is a thin line, where the information transmitted through the mobile medical app could qualify as patient self-declared information, and where it already transforms to the information provided by the software as a medical device. Although there is no interpretation assistance in this matter in the EU guidelines, in US FDA has stated in the guidance document of "Policy for Device Software Functions and Mobile Medical Applications" in context of documenting or transmitting pictures (e.g., photos of a patient's skin lesions or wounds), that such mobile medical applications that

include functions specifically marketed to help patients to communicate with health care professionals by supplementing or augmenting the data or information that would otherwise be a verbal description in a consultation between health care professionals or between health care professionals and patients/caregivers are low risk. [21] So, even if they fulfill the medical device definition, they are low risk devices and FDA applies enforcement discretion. Hence, it could be argued also in EU, that mere data transfer functionality from patient to health care professional does not automatically increase the risk class. The manufacturers should be cautious however, that the functionalities of the device would be limited to the facilitation of transfer of the patient generated data (as would be provided in the clinical interview) and not the provision of analytical information for the clinical decision-making purposes in the HPC component.

5.2.2. Devices connected to sensors and wearables that transfer the data "as is"

Here actually two different types of legal qualifications exist, depending on the functionality of the software. The software may be: 1) as an accessory to a medical device, or 2) the software could be component of the medical device driving or influencing the use of other medical device, then it must be considered as part of that device. This qualification step determines the conformity and validation route: 1) an accessory shall be qualified in combination with the parent device but classified independently; 2) component shall be qualified inside the parent device and classified within the same class as the parent device.

MDR art 2(2) provides that 'accessory for a medical device' means an article which, whilst not being itself a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable the parent medical device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the parent medical device(s) in terms of its/their intended purpose(s). In study we found example of MedCor4U solution, which the manufacturer has clearly stated that it supports the following devices: Omron EVOLV: SYS, DIA and Pulse**,** Omron BP M4 Intelli IT HEM-7155T**,** Omron VIVA: Body weight and BMI**,** Omron Scale HN-300T2**,** Beurer FT95 contactless thermometer: Body temperature**,** Beurer PO60 Oxygen Saturation: SpO2 and Pulse**,** Beurer AS99 activity tracker: Steps count. The MedCor4U platform comprises a Mobile App on both Android and iOS platform, and a cloud for securely storing users' data. The app allows the measuring equipment to connect wirelessly to the app via Bluetooth protocol and to transfer the readings "as

is" directly to Electronic Health Records (EHR). As the parent devices function also independently (and they are not influenced by the application), but the application merely assists the functionality and fulfillment of intended use (to use the device for home-monitoring purposes), then it can be considered as "accessory to a device" and should be classified independently (art 3.2. implementing rules Annex VIII). Rule 11c) applies here – all other software is classified as class I (as the software itself does not provide the information for diagnostic, therapeutic or monitoring purposes), but it is the accessory to such parent device. Also, UK Medicines and Healthcare products Regulatory Agency guidance document qualifies similar devices as accessories. [46]

Annex VIII MDR implementing rule 3.3. states that software which "*drives a device or influences the use of a device"*, shall fall within the same class as the device. In such a case parent device cannot be used without this additional software, or software influences when and how the parent device is used. EU guideline issued on the basis of MDD makes an example here of the patient monitoring platform that function includes also patient specific "filtering rules" based on alarm severity and alarm type. These alarm rules support the ability to suppress specific alarms, delay specific alarms and separate rules for visual, audio, and paging of alarms. It states that the alarm functioning of the platform could be influencing the use of the bedside devices and therefore it should be classified also as software influencing the use of the device (in current example in highest risk class, as the monitoring solution was aimed at used in the intensive care wards with ventilators, pulse oximeters and other devices applying additional "filtering rules" for independent devices alarms). In our study we did not detect such devices, although it is impossible to fully identify the functionalities of the devices without investigating their technical documentation (which are not usually disclosed to public). On the other hand the results of the study reflects that usually such devices are not class I devices.

5.2.3. Devices connected to sensors and wearables that include on the HCP side also analytical element

Software systems (solution, platform) may consist of different modules inheriting different functionalities. It is the obligation of the manufacturer to identify which parts of the system are qualifying as medical devices, and which ones are not. Engage platform solution identified in the research is a good example here. It consists of numerous modules (administrative component: appointment booking, pre-admission administrative paper-work management, kiosk and ticketing,

online payment; medical component: connected tracking, PROMs and PREMs, teleconsultation, reports; and some general information portal for both patients and health care professionals), but of course not all of them do not qualify as SaMD. Connected tracking module and analytical PROMs and PREMs are the ones that might have a special medical purpose, as they include functionality to connect to the platform different home-monitoring devices, analysis of patient results (received via digital PROMs and PREMs) is made, score per patient is provided and alerts when needed triggered in case patient's condition deteriorates and person needs hospitalization. Hence, these system modules (connected tracking together with analytics based on PROMs and PREMs) have functionalities that fulfil the special medical purpose: patient home-monitoring, and should be classified by Rule 11a or 11b (home-monitoring of physiological processes), and therefore classified in minimum to risk class IIa (reference also to vital signs monitoring is made on the website, so this might even lead to IIb). As seen, the intended use statement together with functionalities that the device has is relevant for the correct classification of the device, then manufacturers should not exaggerate with the list functionalities and device´s intended purpose. Rather, one should take a conservative approach to the medical claims related to the device.

Based on the results of the research and applying literal and systematical legal interpretation methods to MDR Annex VII, Rule 11, the author created an indicative risk classification guidance for mobile medical applications (mHealth SaMDs), that is provided in Table 7.

It should be noted that implementing rules for classification (as provided in MDR Annex VIII chapter II) apply.

The results of this thesis are useful for mobile medical apps manufactures for better understanding of Rule 11, Annex VIII, MDR application.

Table 7: Indicative mHealth SaMD risk classification chart, source: author

SaMD is aimed to fulfil the following medical purpose according to art 2 (1) MDR	**SaMD is intended solely to patient**	**The patient and health care professional are SaMD users at same time (multi-component device)**
Prevention	Class I Rule 11c	Class I Rule 11c
Prediction	Class I Rule 11c	Class I Rule 11c (Not diagnosis assistance, not triage, not clinical prognosis, for example inclusion to preventive screening program)
Prognosis	Not applicable (or shall be considered as prediction)	Class IIa or higher Rule 11a
Diagnosing	Not applicable	Class IIa or higher Rule 11a
Alleviation of the disease (self-management, self-care)	Class I Rule 11c	Class I, if only transfers patient generated data as would be during clinical interview. Class I Rule 11c, if accessory to medical device and transfers "as is" data without any analytical component (if not component of SaMD). Rule 11a - Class IIa or higher if intended purpose is aiming for the provision of information (insights) for diagnosing or therapeutic purposes.
Monitoring (incl self-monitoring, home-monitoring of physiological processes or vital signs)	Class I Rule 11c *Note however that Rule 11b does not require clinical decision making and therefore Class IIa might be applicable also.* When term "monitoring" is used for some other data than providing information for	Class IIa Rule 11b Class IIb Rule 11b, in case vital signs

	physiological processes, then class I Rule 11c (as could be considered as alleviation of the disease)	
Treatment	Class I Rule 11c (Decision for diagnosis and treatment is made, software functionality itself has treatment effect, ie. Digital CBT)	Class I (Decision for diagnosis and treatment is made, software functionality itself has treatment effect, i.e. Digital CBT) Rule 11c Class IIa or higher (if device includes analytical component providing immediate information relevant for treatment decisions) Rule 11a
Supporting pregnancy	Class I Rule 11c	Not applicable
Contraception	Class IIb (Rule 15)	Not applicable

5.2 Limitations

The methodology used for this research is comprehensive, however, it clearly has some limitations. EUDAMED is not yet fully functional and class I medical devices registration there is currently voluntary, so therefore the study does not include all class I mHealth SaMDs placed on the EU market. The outcome of the research shows that German manufactures have been the most active in also registering class I devices in EUDAMED, but this cannot confirm that actually in other country national registries such devices do not exist. Also, the intended purpose statements and functionalities revision could be made only basis of the public sources, not including technical documentations of the devices, therefore it is impossible to check whether the functionalities disclosed in the documentation are the ones implemented in the devices.

5.3 Further research

The study included only manufactures perspective (how manufactures have been classifying the class I devices placed on the EU market). For more comprehensive results the interpretation of the national competent authorities for the proposed classification decision chart could be obtained. Also, research could be elaborated by including class I mobile medical applications registered in the national medical devices databases based on MDR (so not legacy devices).

6 Conclusions

The present master thesis is a practice-oriented study. The main aim of which was to analyze the risk classifying practice in EU of mobile medical apps to the lowest (I) risk class from the manufacturer´s perspective. To do so, the author of this thesis determined which are the common criteria in the intended purpose statements and functionalities of the class I mobile medical devices placed on the EU market and registered in the EUDAMED. Intended purpose statements and functionalities of I class SaMDs in EUDAMED (N=38) were identified, out of these 27 were qualifying to be Class I mobile medical applications, which intended purpose statements and functionalities were further analyzed in applying MDR Rule 11 using literal and systematical legal interpretation method.

Findings of the thesis show that majority of class I devices were solely patient facing mobile medical applications and most of the devices had medical purpose "the alleviation of the disease" in the form of digitalized cognitive behavioral therapy sessions and/ or digitalized therapeutic exercises (implemented to software pursuant to clinical guidelines), supported with multiple additional functionalities (education, wellness, goal setting, digital diary and outcome reporting), and at the same time the functionalities of such devices did not include monitoring of physiological processes or vital signs (or it was only a supporting functionality for adjusting the behavior of the patient, and not for diagnosing or treatment decisions taking purposes by the professional).

There were some multi-user solutions identified that claim to be class I device. Author can agree with class I classification in case the device is actually an accessory to a medical device connecting to sensors and wearables that transfers the data "as is" to the EHR, to the patient facing mobile application or other system (or to another medical device) (system-to-system devices) (example MedCor4U), but when the device is influencing or driving the other medical device then it should be considered as component of the device, and should be classified to the same risk class as parent device (usually IIa or higher). Also multi-user, multi-component devices that are aimed for providing the information for diagnostic or therapeutic purposes or clinical monitoring purposes (monitoring physiological processes or vital signs) are highly likely to be classified into higher risk class, exception might be a device which health care provider side includes only telehealth

functionality (then this part of solution is not device at all), or simple patient generated data transmission (data that patient would provide during clinical interview).

The contribution of the present thesis is to clarify Rule 11, Annex VIII, MDR application. The author compiled an indicative risk classification chart that may assist the manufacturers of mobile medical applications to conduct a risk classification assessment. Summing up, it is necessary to state that the research conducted within the framework of this master thesis helped to gain a deeper understanding of problematics of risk classification.

7 References

[1] Alaiad A, “The Determinants of M-Health Adoption in Developing Countries: An Empirical Investigation,” *Appl Clin Inform,* pp. 820-840, 2019.

[2] BCC Research , “Mobile Health (mHealth) Technologies and Global Markets,” BCC Publishing, Boston, June 2022.

[3] European Commission, “Green Paper on mobile Health ("mHealth"),” 2014. [Online]. Available: https://digital-strategy.ec.europa.eu/en/library/green-paper-mobile-health-mhealth. [Accessed 03 03 2023].

[4] Svempe, L., “Regulation and Its Impact on Innovation in Healthcare: SAMD Case,” *Electronic Scientific Journal of Law Socrates,,* vol. (3) 21, p. 43–52, 2022.

[5] European Commission, “Press Release: Safer, more effective and innovative medical devices,” 12 09 2012. [Online]. Available: https://ec.europa.eu/commission/presscorner/detail/en/IP_12_1011. [Accessed 03 03 2023].

[6] Martindale, V. “The PIP scandal: an analysis of the process of quality control that failed to safeguard women from the health risks,” *J R Soc Med,* vol. 106(5), no. May, p. 173–177, 2013 .

[7] “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/EE,” [Online]. Available: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32017R0745. [Accessed 09 03 2023].

[8] MDCG Document, “MDCG 2021-24 Guidance on classification of medical devices,” 10 2021. [Online]. Available: https://health.ec.europa.eu/system/files/2021-10/mdcg_2021-24_en_0.pdf. [Accessed 05 04 2023].

[9] European Commission, “Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR,” 10 2019. [Online]. Available: https://health.ec.europa.eu/system/files/2020-09/md_mdcg_2019_11_guidance_qualification_classification_software_en_0.pdf. [Accessed 25 02 2023].

[10] Borderline and Classification Working Group (BCWG), “Manual on borderline and classification for medical devices under Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnostic medical devices, version 1,” 09 2022. [Online]. Available: https://health.ec.europa.eu/system/files/2022-09/md_borderline_manual_09-2022_en.pdf. [Accessed 25 02 2023].

[11] Herz, J. “How does MDR Rule 11 impact Software as a Medical Device (SaMD) Classification?,” 21 05 2021. [Online]. Available: https://www.generaldigital.com/blog/how-does-mdr-rule-11-impact-software-as-a-medical-device-classification/. [Accessed 01 04 2023].

[12] Johner Institute, “MDR Classification Rule 11 for Medical Device Software,” 22 07 2017. [Online]. Available: https://www.johner-institute.com/articles/regulatory-affairs/and-more/mdr-rule-11-software/. [Accessed 20 04 2023].

[13] Mantra Systems, “Software as a Medical Device (SaMD),” 13 10 2022. [Online]. Available: https://www.mantrasystems.co.uk/eu-mdr-compliance/software-as-a-medical-device-samd. [Accessed 20 04 2023].

[14] Eitan, T. “How the new MDR may hurt patients in the short term.,” 2020. [Online]. Available: https://healthcare-in-europe.com/en/news/how-the-new-mdr-may-hurt-patients-in-the-short-term.html. [Accessed 04 04 2023].

[15] Pashkov, V. “Challanges of Classification of Stand-Alone Software as a Medical Device,” 02 2021. [Online]. Available: https://www.researchgate.net/publication/350706740_CHALLENGES_OF_CLASSIFICATION_OF_STAND-ALONE_SOFTWARE_AS_A_MEDICAL_DEVICE. [Accessed 01 03 2023].

[16] Lenaerts, J. “To Say What the Law of the EU Is: Methods of Interpretation and the European Court of,” *Academy of European Law,* vol. 9, 2013.

[17] WHO Global Observatory for eHealth, “mHealth – New horizons for health through mobile technologies: second global survey on eHealth.,” vol. 3, p. 6, 2011.

[18] Fürstenau, D, et al “Digital Therapeutics (DTx),” *Bus Inf Syst Eng,* 2023.

[19] European Council, “Council Directive 93/42/EEC of 14 June 1993 concerning medical devices,” [Online]. Available: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A31993L0042. [Accessed 03 03 2023].

[20] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, p. p. 1–43 .

[21] FDA. Department of Health and Human Services, “Policy for Device Software Functions and Mobile Medical Applications,” 28 09 2022. [Online]. Available: https://www.fda.gov/media/80958/download. [Accessed 04 04 2023].

[22] Wagner, T. “Challenges of Medical Device Regulation for Small and Medium sized Enterprises,” *Current Directions in Biomedical Engineering,* vol. 4, no. 1, pp. 653-656, 2018.

[23] Maresova P et al, “Do Regulatory Changes Seriously Affect the Medical Devices Industry? Evidence From the Czech Republic,” *Frontiers in Public Health,* vol. 9, 2021.

[24] European Commission, “Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices,” 06 01 2023. [Online]. Available: https://health.ec.europa.eu/system/files/2023-01/mdr_proposal.pdf. [Accessed 03 03 2023].

[25] Bianchini, E. “Medical Device Regulation: Should We Care About It?,” *Artery Res. ,* vol. 28(2), pp. 55-60, 2022.

[26] Bertram, D. “New regulations on medical devices in Europe: what to expect?,” *Expert Review of Medical Devices,* vol. 11:4, pp. 351-359, 2014.

[27] Clinipower, “Software in the medical device field – definition and risk classification according to the MDR,” 03 03 2022. [Online]. Available:

https://www.clinipower.fi/en/software-in-the-medical-device-field-definition-and-risk-classification-according-to-the-mdr/. [Accessed 06 03 2023].

[28] Martin Dræbye Gantzhorn, “When is software regulated as medical devices?,” 22 06 2021. [Online]. Available: https://www.bechbruun.com/en/news/2021/when-is-software-regulated-as-medical-devices. [Accessed 06 03 2023].

[29] Maak, D. “Medical Device Regulation: A Comparison of the United States and the European Union,” 05 2016. [Online]. Available: https://www.researchgate.net/publication/303354890_Medical_Device_Regulation_A_Comparison_of_the_United_States_and_the_European_Union. [Accessed 03 03 2023].

[30] Keutzer, L. “Medical Device Apps: An Introduction to Regulatory Affairs for Developers,” 26 06 2020. [Online]. Available: https://pubmed.ncbi.nlm.nih.gov/32589154/. [Accessed 25 02 2023].

[31] Terry, -N. “Mobile Health. Assessing the Barriers,” *CHEST,* vol. 147, no. 5, pp. 1429-1434, 2015.

[32] Knöppler K, “Digital-Health-Anwendungen für Bürger. Kontext, Typologie und Relevanz aus Public-Health-Perspektive. Entwicklung und Erprobung eines Klassifikationsverfahrens,” 02 2016. [Online]. Available: https://www.bertelsmann-stiftung.de/fileadmin/files/BSt/Publikationen/GrauePublikationen/Studie_VV_Digital-Health-Anwendungen_2016.pdf. [Accessed 03 03 2023].

[33] Albrecht, U. “Kapitel 1. Einführung und Begriffsbestimmungen, in: Chancen und Risiken von Gesundheits-Apps (CHARISMHA),” 2016. [Online]. Available: https://leopard.tu-braunschweig.de/receive/dbbs_mods_60005. [Accessed 03 03 2023].

[34] Migliore, A. “On the new regulation of medical devices in Europe,” *Expert Review of Medical Devices,* vol. 14, no. 12, pp. 921-923, 2017.

[35] Wagner, S. “Challenges of Medical Device Regulation for Small and Medium sized Enterprises,” *Current Directions in Biomedical Engineering,* vol. 4, no. 1, pp. 653-656, 22 09 2018.

[36] Kaule, S. “Medical Device Regulation and current challenges for the implementation of new technologies,” *Current Directions in Biomedical Engineering,* vol. 6, no. 3, pp. 334-337, 2020.

[37] Maxwell, A.“33-Country Single Market For MDR And IVDR, And Bigger Reach Beyond,” 15 11 2018. [Online]. Available: https://medtech.pharmaintelligence.informa.com/MT124250/33Country-Single-Market-For-MDR-And-IVDR-And-Bigger-Reach-Beyond. [Accessed 05 05 2023].

[38] CJEU, “Case C-329/16 - Snitem and Philips France,” 07 12 2017. [Online]. Available: https://curia.europa.eu/juris/liste.jsf?language=en&num=C-329/16. [Accessed 06 03 2023].

[39] Grell, A-S. “MDR impact on MDSW: what has changed from MDD?,” 15 09 2021. [Online]. Available: https://qbdgroup.com/en/blog/mdr-impact-on-mdsw/. [Accessed 04 04 2023].

[40] Dragotti, G. “Mobile Health: Radical change in fitness and wellness is on its way in Italy,” 05 07 2020. [Online]. Available:

https://www.dlapiper.com/en/insights/publications/2020/07/mobile-health-radical-change-in-fitness-and-wellness. [Accessed 25 02 2023].

[41] European Commission, “Overview EUDAMED,” [Online]. Available: https://health.ec.europa.eu/medical-devices-eudamed/overview_en. [Accessed 03 03 2023].

[42] European Commission, “EUDAMED Time line - The European Commission planning,” 06 2022. [Online]. Available: https://health.ec.europa.eu/system/files/2023-01/md_eudamed_timeline_en.pdf. [Accessed 03 03 2023].

[43] FIMEA, “Device registration,” 2021. [Online]. Available: https://www.fimea.fi/web/en/medical-devices/registrations. [Accessed 04 04 2023].

[44] European Commission, “Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD,” 03 2020. [Online]. Available: https://health.ec.europa.eu/system/files/2020-09/md_mdcg_guidance_significant_changes_annexes_en_0.pdf. [Accessed 01 03 2023].

[45] MedicalDeviceHQ, “What is a medical device according to the MDR,” 8 12 2021. [Online]. Available: https://medicaldevicehq.com/articles/what-is-a-medical-device-according-to-the-mdr/. [Accessed 94 04 2023].

[46] MHRA, “Guidance: Medical device stand-alone software including apps (including IVDMDs),” 2021. [Online]. Available: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1105233/Medical_device_stand-alone_software_including_apps.pdf. [Accessed 01 05 2023].

[47] Court of Justice of the European Union (CJEU), “C-219/11 - Brain Products,” [Online]. Available: https://curia.europa.eu/juris/liste.jsf?num=C-219/11&language=EN. [Accessed 03 03 2023].

[48] IMDRF, “"Software as a Medical Device": Possible Framework for Risk Categorization and Corresponding Considerations,” 18 09 2014. [Online]. Available: https://www.imdrf.org/sites/default/files/docs/imdrf/final/technical/imdrf-tech-140918-samd-framework-risk-categorization-141013.pdf. [Accessed 10 04 2023].

[49] Saunders, M et al “Understanding research philosophies and approaches,” Jan 2009. [Online]. Available: https://www.researchgate.net/publication/309102603_Understanding_research_philosophies_and_approaches/stats. [Accessed 01 05 2023].

[50] MDCA Authorities, “Helsinki Procedure 2021: Exchange of information between medical device competent authorities on borderline and classification cases,” 23 06 2021. [Online]. Available: https://health.ec.europa.eu/system/files/2021-09/md_border-class_helsinki-proc-mdr-ivdr_en_0.pdf. [Accessed 20 04 2023].

[51] Bowen, G. A. “Document Analysis as a Qualitative Research Method,” *Qualitative Research Journal,* vol. 9, no. 2, pp. 27-40, 2009.

[52] Salehijam, M. “The Value of Systematic Content Analysis in Legal Research,” *Tilburg Law Review,* vol. 23, no. 1, pp. 34-42, 2018.

[53] Miller, A. “The Myth of Objectivity in Legal Research and Writing,” *Catholic University Law Review,* vol. 18, no. 3, pp. 290-307, 1969.

[54] Roberts, “Attempting rigour and replicability in thematic analysis of qualitative research data; a case study of codebook development,” *BMC Med Res Methodol,* vol. 19, no. 66, 2019.

[55] DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 1998 on in vitro diagnostic medical devices, vol. 1.

[56] European Union, “Types of Legislation,” [Online]. Available: https://european-union.europa.eu/institutions-law-budget/law/types-legislation_en. [Accessed 06 03 2023].

[57] Kirsh, D. “PIP breast implant scandal: A story that triggered change,” 13 11 2017. [Online]. Available: https://www.massdevice.com/pip-breast-implant-scandal-story-triggered-change/. [Accessed 06 03 2023].

[58] Dutch Ministry of Health, Welfare and Sport (VWS), “MDR Guide for Medical Device Software version 1.0,” 16 07 2021. [Online]. Available: https://www.fme.nl/system/files/publicaties/2021-09/MDR%20Guide.pdf. [Accessed 03 03 2023].

[59] Tupy, M.L. “The European Union: A Critical Assessment,” 22 06 2016. [Online]. Available: https://www.cato.org/economic-development-bulletin/european-union-critical-assessment. [Accessed 03 03 2023].

[60] Minevich, M. “European AI needs strategic leadership, not overregulation,” 15 05 2021. [Online]. Available: https://techcrunch.com/2021/05/15/european-ai-needs-strategic-leadership-not-overregulation/?guccounter=1&guce_referrer=aHR0cHM6Ly93d3cuZ29vZ2xlLmNvbS8&guce_referrer_sig=AQAAABGJ43YRCyVEsOkLTIrEpjgsVbs_KA1diueqmpmwahtzQlKO7Gi1_26e6e0QCOgPRqs1NosdDCCp6njbj. [Accessed 03 03 2023].

[61] Adam J. Prince, “The Impact of the Medical Device Directive to Medical Device Regulation Transition on Early Clinical Testing of Cardiovascular Devices,” *Journal of the Society for Cardiovascular Angiography & Interventions,* vol. 1, no. 5, 2022 Sept-Oct.

[62] Zhong D, “Regulatory barriers blocking standardization of interoperability,” *JMIR Mhealth Uhealth,* Vols. Jul-Dec, 2013.

[63] H. Arksey and L. O’Malley, “Scoping studies: Towards a methodological framework,” *Int. J. Soc. Res. Methodol,* vol. 8, p. 19–32, 2005.

[64] H. Morgan, “Conducting a Qualitative Document Analysis,” *The Qualitative Report (TQR),* vol. 27, no. 1, pp. 64-77, 2022.

[65] Braun V, “Reflecting on reflexive thematic analysis,” *Qualitative Research in Sport, Exercise and Health,* vol. 11, no. 4, pp. 589-597, 2019.

[66] Klapper L, “The Impact of Business Environment Reforms on New Firm Registration,” *Available at: SSRN Electronic Journal,* 2011.

[67] Manu M, “A review of medical device regulations in India, comparison with European Union and way-ahead.,” 07 2021. [Online]. Available: https://pubmed.ncbi.nlm.nih.gov/35198422/. [Accessed 25 02 2023].

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