MDR 2017/745 - New EU Regulation for Medical Devices: A Process Description for EHR Manufacturers on How to Fulfill the Regulation

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MDR 2017/745 - New EU Regulation for Medical Devices: A Process Description for EHR Manufacturers on How to Fulfill the Regulation.

MDR 2017/745 - Ny EU-förordning för medicintekniska produkter: En processbeskrivning för tillverkare av journalsystem om hur man uppfyller förordningen.

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Abstract

On the 26th of May 2021 the new regulation for medical devices, MDR 2017/745, will come into force. The underlying incentives to go from the medical device directive (MDD 93/42/EEC) to MDR are a series of adverse events involving medical devices. The main goal of MDR is to strengthen and improve the already existing legislation and thus will entail large changes for manufactures, one of them being manufacturers of Electronic Health Record (EHR) systems. For medical software, such as EHR systems, the new regulation will imply an upgrade in risk classification. This upgrade will bring additional requirements for EHR manufacturers. Furthermore, the released guidelines have been insufficient regarding the specific requirements for medical device software and thus EHR manufacturers are in need of tools and guidance to fulfill MDR.

This thesis examines the new regulation for medical devices and thus identifies main requirements for EHR manufacturers. A qualitative approach was conducted comprising a literature study as well as a document study of the medical device regulation along with interviews with experts within the field of medtech regulatory affairs and quality assurance. The information gathered was analyzed to create a process description on how EHR manufacturers are to fulfill MDR.

The process description is a general outline and presents the main steps on the route to be compliant with MDR in a recommended order of execution. The main steps are: divide the system into modules, qualify the modules, classify the modules, implement a quality management system, compile a technical documentation, compile the declaration of conformity, undergo a conformity assessment and finally, obtain the CE-mark. To each of the main steps additional documentation provides further information and clarification.

The process description functions as a useful tool for EHR manufacturers towards regulatory fulfillment. Even though the process description is created for EHR manufacturers, it can be useful for other medical device software manufacturers. The process description provides an overview of the path to a CE mark and functions as a guidance. It can be used in educational purposes as well as to serve as a checklist for the experienced manufacturer to make sure everything is covered. However, it is not sufficient to rely solely on the process description in order to be in full compliance with MDR. Moreover, there is still a need for further clarifications from the European Commission regarding specific requirements on medical device software.

Key words: MDR, regulation, process description, EHR system, CE mark, medical technology

Sammanfattning

Den 26:e Maj 2021 kommer det nya medicintekniska regelverket, MDR 2017/745, att träda i kraft. De bakomliggande incitamenten att gå från det medicintekniska direktivet, (MDD 93/42/EEG), till MDR är en serie av säkerhetsincidenser med medicintekniska produkter. Därmed är målet med MDR att stärka och förbättra det befintliga direktivet, vilket kommer medföra stora förändringar för medicintekniska tillverkare, däribland tillverkare av journalsystem. För medicinteknisk mjukvara, som journalsystem, kommer MDR innebära en högre riskklassificering. Höjningen av riskklass kommer innebära ytterligare krav för tillverkare av journalsystem. De riktlinjer som publicerats till förmån för tillverkare av medicinteknisk mjukvara har varit otillräckliga och därmed är tillverkare av journalsystem i behov av verktyg samt vägvisning för att uppfylla MDR.

Detta projekt undersöker MDR och identifierar de huvudsakliga kraven för tillverkare av journalsystem. Med ett kvalitativt tillvägagångssätt utfördes en litteraturstudie samt en dokumentstudie av förordningen tillsammans med intervjuer med experter inom medicintekniska regelfrågor och kvalitetssäkring. Informationen analyserades sedan för att skapa en processbeskrivning för hur tillverkare av journalsystem ska gå tillväga för att uppfylla MDR.

Processbeskrivningen är en övergripande disposition och presenterar de huvudsakliga stegen för att uppfylla MDR samt en rekommenderad utföringsordning. De huvudsakliga stegen är: dela upp systemet i moduler, kvalificera modulerna, klassificera modulerna, implementera ett kvalitetsledningssystem, sammanställa teknisk dokumentation, utarbeta försäkran om överensstämmelse, genomgå en bedömning av överensstämmelse och slutligen, erhålla CE-märkning. För varje steg finns tillhörande dokument med ytterligare information och förtydliganden.

Processbeskrivningen är ett användbart verktyg för tillverkare av journalsystem för att uppfylla MDR. Även om processbeskrivningen är skapad för tillverkare av journalsystem kan den även vara användbar för andra tillverkare av medicinteknisk mjukvara. Processbeskrivningen ger en överblick över vägen till CE-märkning och fungerar som vägledning. Processbeskrivningen kan användas i samband med utbildning men även fungera som en checklista för en erfaren tillverkare. Däremot är det inte tillräckligt att enbart förlita sig på processbeskrivningen för att uppfylla MDR. Detta då det fortfarande finns ett behov för ytterligare klargöranden från Europeiska Kommissionen gällande specifika krav för medicinteknisk mjukvara.

Nyckelord: MDR, förordning, processbeskrivning, journalsystem, CE-märkning, medicinsk teknik

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List of Abbreviations

AIMDD Active Implantable Medical Devices Directive

CDS Clinical Decision Support

CEN European Committee for Standardization

CENELEC European Committee for Electrotechnical Standardization

EC European Commission

EHR Electronic Health Record

ER Essential Requirements

EU European Union

ESMA European Security and Markets Authority

GSPR General Safety and Performance Requirements

IEC International Electrotechnical Commission

ISO International Organization for Standardization

MDCG Medical Device Coordination Group

MDD Medical Device Directive

MDR Medical Device Regulation

QMS Quality Management System

SaMD Software as a Medical Device

UDI Unique Device Identification

PIP Poly Implant Prothese

PMS Post Market Surveillance

PMCF Post Market Clinical Follow-Up

PRRC Person responsible for regulatory compliance

PSUR Periodic Safety Update Report

Introduction

Medical devices are an essential part of modern healthcare as they are used in every area of care such as diagnosis, treatment, prevention and rehabilitation [1]. The definition of a medical device spans over a large variety of products from a band-aid or an x-ray machine to an Electronic Health Record (EHR) system. In Europe, medical devices have since 1993 been regulated by the Medical Device Directive 93/42/EEC, MDD [2]. As of May 26th 2021, MDD will be fully replaced by Medical Device Regulatory 2017/745, MDR [3]. The cause of the change in regulation is a series of serious incidents of medical devices such as the PIP scandal [4].

The main goal of MDR is to strengthen and improve the already existing legislation [5]. MDR will have stricter requirements on quality and safety as well as more transparency and traceability of devices [3]. Another refinement of MDR is to strengthen the safety of software used in healthcare. In addition, going from a directive to a regulation means that each member state of the EU must directly apply the new regulation as law, instead of creating own laws to reach the directive [6].

The new regulation, MDR, will implicate many changes and additional requirements to several types of medical device manufacturers, one of them being manufacturers of EHR systems. The most comprehensive change for EHR systems is that they will be upgraded from a class I device, to minimum a class IIa device [7]. Except for the added requirements that MDR sets on software in healthcare, the upgrade in classification itself brings several additional requirements that the EHR manufacturer must fulfill as well. For EHR manufacturers to reach full compliance with MDR will entail a heavy workload and require a lot of resources. Above that, there is a gap in knowledge regarding some of the requirements set by MDR on EHR manufacturers that is making the process of being compliant even harder.

To face the challenge of implementing MDR 2017/745, EHR manufacturers and other medical device software manufacturers, need guidance that can simplify the road to compliance with MDR as well as clarifications on certain elements of the regulation [8].

1.1 Aim

The main goal of this master thesis project is to develop a model for how EHR manufacturers are to adapt their regulatory processes to fulfill MDR and receive their CE mark.

The central research question that this research project aims to answer is:

– How will MDR affect EHR manufacturers and what procedure is necessary to fulfill the requirements?

The central research question is supported by the following research sub-questions:

– How do the EHR manufacturers' current work processes align with MDD?

– What are the requirements on EHR software in MDR in contrast to MDD?

– According to MDR, how will EHR manufacturers classify their EHR systems?

1.2 Limitations

In order to conduct this project within the given time limit of 20 weeks the following limitations were adopted:

– This project covers the European market and its legislations on medical devices.

– This project is limited to only looking into EHR manufacturers.

– The interviews are based on Swedish EHR manufacturers.

– The project is limited to the released information regarding MDR available during the time period of the project.

During the development of this project the Coronavirus had its outbreak in Sweden. This limited the project as everything needed to be managed from home, on recommendation from the Public Health Agency of Sweden. All meetings, interviews and the evaluation had to be carried out via video link. In addition to that, the outbreak affected the development on the European medtech market. From a proposal given by the European Commission to the European Parliament and Council, the application date of MDR got officially delayed one year. The date of application is now the 26th of May 2021, instead of the previously decided date, 26th of May 2020.

Background

2.1 Medical Devices

Medical devices are an essential part of modern infrastructure and of deep importance to the health of the world's citizens [9]. Medical technology has become an underlying foundation of healthcare today and is fundamental in the process of delivering safe and efficient treatment as well as in preventing, diagnosing and monitoring illness [10, 11].

According to the current European legislation 93/42/EEC [2] concerning medical devices, collectively known as the Medical Device Directive (MDD), a medical device is defined as follows:

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

- *diagnosis, prevention, monitoring, treatment or alleviation of disease,*

- *diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,*

- *investigation, replacement or modification of the anatomy or of a physiological process,*

- *control of. conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;* EU directive MDD [2, p.3-4].

A medical device seeks to fulfill several parties' needs and demands. The patient expects a device that delivers safe and effective procedures. The operator desires a device that is efficient, making their time and effort well spent [12]. In society there is a great need for devices that can cut costs. When a device is ready to be released on the market the device aligns with country-specific regulations and legislation, whose sole purpose is to ensure patient safety and market efficiency [12].

Medical technology started to get introduced during the nineteenth century with one of the most important diagnosis innovations, the stethoscope [13]. However, it

was during the twentieth-century innovation of medical technology flourished with milestones such as the invention of electrocardiography (ECG/EKG), Electroencephalography (EEG), the pacemaker, the first commercial MRI scanner, CT scanner as well as the first commercial ultrasound and much more [14].

Software has grown to be a big integrated part of healthcare and is today an essential tool in a majority of tasks in a healthcare organization, such as administrating, logging a patients health, decision making, diagnosing, treatments etc. Whether a software should be classified as a medical device depends on its intended use and field of application. The field of application for software in today's modern healthcare is big, as is the value and risk it can bring when introducing it.

The continuous innovation of medical technology is the result of constant research and development within the industry as well as involvement with the end-users in the development process [15]. Medtech Europe [15] further states that medical technology products have a typical lifespan of 18-24 months before the product has been further developed, modified or replaced by new technology. Today there are 675 000 people employed in more than 27 000 medical technology companies in Europe [16]. The European medical technology market is the second largest medical technology market in the world covering 27% of the global market with over € 115 billion in sales [15]. In addition, the EU is a net exporter in this industry, making the European medtech industry an important part of the economy [11]. With a big market share and a constant flow of innovations, Europe is a world leader in medical device technology [17].

2.2 Regulation on Medical Devices

To protect public health and ensure safety for European citizens in the medical technology industry authorities set out legislations for the industry to follow, as well as guidelines and standards to facilitate regulatory processes. Thus, medical device suppliers, distributors and manufacturers etc. operating in the EU must meet several requirements in order to enter and stay on the market.

2.2.1 Responsible Surveillance Authorities

The precursor of the European Union, EU, was established after the Second World War. The purpose of the economic collaboration was to create a dependency between the countries with the aim of sustaining peace. In the beginning there were only six member countries and today, there are 22 additional European countries in collaboration. One of the main goals of the EU today is still to remain peace. However, additional goals are set that strive for providing freedom, security and justice within the EU such as development, economic growth, promote scientific, technical progress and equality as well as the welfare and values of the people of the EU [18]. There are internal institutions with various functions for the EU to reach its goals, one of them being the European Commission.

The role of the European Commission is to shape proposals for new European legislation as well as develop strategies for the EU [19]. Hence, the European Com-

mission has the function of being the EU's politically independent executive arm. The propositions made and put forward by the European Commission focus on the protection of the citizens and the interest of EU as well as utilizing experts from the public to receive high technical expertise [19]. The European Commission [19] further explains it is the European Parliament and the European Council that decides on the proposal, the European Commission is then responsible for implementing the legislation. In addition, the European Commission together with the Court of Justice assures that the laws are applied in an appropriate way by the member countries.

European Security and Markets Authority, ESMA, is an independent EU authority that strives for investor protection, orderly markets and financial stability within the union. Under ESMA's field of responsibility, each member state is bound to designate its own competent authorities for most EU directives [20].

To assure the correspondence of specific products before being released on the market, an organization assigned by the EU, a notified body, provides a conformity assessment [21]. The European Commission [21] states that manufacturers of such products are free to choose any of the assigned notified bodies to perform the conformity assessment. Thus, the notified bodies assigned by the EU must meet several principles, which are specified in Decision 768/2008/EC.

2.2.2 Legislative Acts

The actions and aims that are implemented by the European Commission can be of various legal forms, a legal act can either be regulations, directives, decisions, recommendations or opinions [6]. The current legislative act for medical devices, MDD, is a directive and the upcoming legislative acts, MDR, is a regulation. According to the European Commission [6], a directive is a goal that the countries of the EU must achieve, these goals are achieved by permitting every respective EU country to devise its own laws to achieve the goals. A regulation on the other hand, are a binding legislative act that directly becomes law in each member state. Therefore, a regulation must be fully applied in the same manner by all EU countries.

In order to assist and deliver guidelines to stakeholders regarding implementing new regulations for medical devices the European Commission provides guidance documents. These guidelines are non-legally binding, however, they assist the member states in a harmonized implementation of the current legislative. Under MDD the MEDDEV documents provided orientation in the implementation process and these will now be replaced by the medical device coordination group (MDCG) guidance documents under MDR. [22].

Medical devices in the EU are regulated by the European Commission, a National Competent Authority together with Notified Bodies. However, the European Commission does not interact directly with medical device manufacturers but coordinates with the other two institutions who do so [23]. Ramakrishna *et al.* [23] states that for a medical device to be released on the EU market, it must be CE marked and thereby prove that it meets the requirements of the European Commission. Depending on the classification of the medical device, it must be approved by a Notified

body before being released on the market. In the EU all severe adverse events associated with medical devices must be reported to the competent authority in the relevant member state. In Sweden, that competent authority is Swedish Medical Products Agency [24].

2.3 Certification Marks

A common certification mark is the CE mark. In order for any manufacturer to release a medical device on the market in Europe it has to be CE marked according to the current legislation on medical devices, which is now the directive MDD 93/42/EEC and has been since 1993 [25]. The Swedish Medical Products Agency [26] states that when a product is CE marked it implies that the manufacturer assures the product fulfills the regulations of documentation and construction of safety. In addition, the CE mark also requires proper risk assessment and management of products released on the market. Depending on the classification of the medical device, the process of receiving the CE mark will vary.

2.3.1 Classification

Primary, the device must correspond to the definition of a medical device according to the current legislation [26]. Further, the device will be classified based on field of application, routines and risk profile. Most EHR-systems in Sweden today are defined as medical devices, and must therefore undergo this CE process. Before may 26th 2021, a medical device will be classified as either class I, class Is, class Im, class IIa, class IIb or class III according to MDD [27]. Thus, depending on classification, the device has to undergo various routines to manifest the fulfillment of the requirements before labeling with the CE mark. The higher the class, the higher the requirements and the more difficult it gets to get the CE mark.

A manufacturer of a medical device class I has the least requirements to meet, before being able to CE label the device the manufacturer must register their device at the Swedish Medical Products Agency. However, for a sterile devices, class Is, and devices for measurement, Im, a notified body must inspect the manufacturing process. The certification process of devices belonging to class IIa or higher involves a notified body as well. The manufacturer of class IIa and higher has two options regarding the investigation and certification process. The two options are for the notified body to either examine the quality management system, QMS, or to test type products and production. It should be noted that devices belonging to class IIb and class III are of high risk and must therefore undergo more thorough investigation by a notified body as well as more frequent audits after the product has been released on the market [27].

2.4   Standards

A standard is compiled by one or several committees and establishes a solution for a repeated problem [23] [28]. There are various standards adapted for various businesses and purposes, but the the primary aim is to ensure reliability and to improve effectiveness [23] [29]. A standard is usually routines, technical specifications, guidelines, rules or definitions and can be used repeatedly. To follow a standard is not mandatory for an organization unless it is stated so in a law or regulation [23]. Standards are widely used within the field of medical technology to implement high quality systems and ensure that the organization is reliable with stable processes.

One type of standard is management systems. A management system describes the way an organization manage interrelated parts of their businesses in order to achieve their goals and meet the customer requirements [30]. The management system can have various focuses such as quality, environment, risk, service quality, health and safety or IT-security etc. The Swedish Standards Institute [30] further explains that management systems aid the top management to ensure that the business runs according to the set routines and policies. Depending on the size and complexity of the organization, it may be relevant to implement more than one management system. In addition, a management system can also support the employees in how to perform their daily job. The most widely used and known quality management system is ISO 9001, which focuses on customers, leadership, the commitment of the employees, processes, improvement, relationship management and decision making [31]. The standard is used by various industries and sectors and is sometimes even a requirement from customers in order to do business.

There are several standardization organizations in the world. The International Organization for Standardization (ISO) is a non-governmental organization that develops standards through its representative members from 164 countries [29]. International Electrotechnical Commission (IEC) is another international standardization organization with a primary focus on electronic and electrical technologies [32]. Furthermore, the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC) are also organizations that develop standards but based upon the interest of its members [33]. Similarly, the Swedish Institute for Standards (SIS) is a part of both CEN and ISO and thereby aid in developing standards [28].

Standards developed particularly for meeting laws and regulations are known as harmonized standards. The European harmonized standards are produced by CEN, European Committee for electrical standardization and the European Telecommunications Standards [34]. Organizations following harmonized standards can expect to meet EU regulations or directives that the standard is harmonized for. In addition, standardization aids interoperability, reduces costs and strengthens the European industries. When a standard is harmonized according to an European legislative, act it adds the prefix "EN" and adjust the year accordingly [34].

There are standards for various industries and since the medical device industry is larger than ever and includes a large span of various products, there are several

standards that can apply. There are several standards suitable for medical devices as well as standards specifically for medical devices, some more commonly used than others. Standards presented in the following chapter "Results och Literature Study" can aid manufacturers in several aspects such as safety, efficiency, production or management. Depending on the type of medical device, different standards can be more or less suitable.

Findings of Literature Study

3.1 Relevant Standards Regarding MDR

The most essential and most known standards for manufacturers of software and EHR systems are presented below with a description of what they provide to the manufacturer and their product.

3.1.1 ISO 13485

The most widely used standard for medical devices is ISO 13485 [35]. ISO 13485 is a quality management system based on the central requirements of ISO 9001. However, ISO 13485 is adapted to the regulation and quality requirements of medical devices. An important part of ISO 13485 is risk and safety, thus the standard has a systematic approach to ensure safety according to general legislation of medical devices [36]. When implementing ISO 13485 the organization can expect to improve several parts of their operations such as construction and manufacturing, distributing and storage, installation and service [37]. ISO 13485 is harmonized to MDD, however, there is no harmonized version of ISO 13485 to MDR.

Any actor in the medical device industry can apply ISO 13485 to their business, regardless of the size of the organization and in what stage they operate in the life cycle of a medical device. The standard constitutes a complement to the technical requirements for medical devices [37]. ISO 13485 covers the following areas;

– Quality management system

– Management responsibility

– Resource management

– Product realization

– Measurement, analysis and improvement [37].

There is a harmonized version of the standard, EN ISO 13485:2016, which is specifically harmonized to meet the EU Medical Device Directive 93/42/EEC, MDD [35]. Unfortunately, there is currently no harmonized version that meets the upcoming regulatory Medical Device Regulatory 2017/745, MDR.

3.1.2 IEC 62304

One standard relevant to software, and therefore EHR systems, is IEC 62304 Medical device software – Software life cycle processes. IEC 62304 can be applied both to a standalone software such as EHR systems as well as embedded parts of a device [38]. Furthermore, the standard defines the life cycle of a software by constituting a framework for processes, activities and tasks [38]. The main content of the standard consists of general requirements, software development process, software maintenance process, software risk management process, software configuration management process and software resolution process [39]. In order to decide on the necessary safety-processes, IEC 62304 defines three safety classes that the software should be defined by accordingly [40]. The three classes are, class A: No injury or damage to health is possible, Class B: Injury is possible but not serious, and Class C: Death or serious injury is possible [40]. Thus, by following IEC 62304, one can expect to cover safe design and maintenance of software by the processes and activities provided [40]. IEC 62304 is harmonized to MDD but not to MDR.

3.1.3 IEC 62366-1

IEC 62366-1 Application of usability engineering, is another standard relevant for EHR manufacturers. The purpose of the standard is to ensure usability by specifying processes to analyze, specify, develop and evaluate the medical device [41]. By applying human factors engineering to the device, it minimizes the probability for risks associated with faulty usage. The main content of ISO 62366-1 is the general requirements of usability engineering and the usability engineering process [42]. The general requirements consist of preparing usability engineering process, the risk control related to user interface design and information for safety related to the usability [42]. The usability engineering process covers the preparation of use specification and several other processes related to identification of hazardous events and establishment of user interface [42]. In addition, the standard also covers evaluation of the various processes. This standard is harmonized to MDD, but there is no harmonized version of this standard to MDR.

3.1.4 ISO 14971

ISO 14971 covers the application of risk management to medical devices. The standard describes processes that aims to aid manufacturers identifying risks associated with their device as well as estimation and evaluation of those risks [43]. This standard assists in how to monitor and minimize the identified risks. The main topics covered by ISO 14971 are general requirements for risk management, risk analysis, risk control, evaluation of overall residual risk and risk management review [44]. In addition, manufacturers can integrate the standard to be a part of their quality management system. ISO 14971 is harmonized to MDD, but not to MDR.

Since the regulation of medical devices requires high demands of safety and risk management, a standard that covers the topic is relevant for any manufacturer of medical devices [43]. Thus, ISO 14791 provides the manufacturer with the tools necessary in order to evaluate, control and monitor any risk with efficiency [43].

3.1.5 IEC 82304

IEC 82304 is specifically produced for medical device software without a hardware component and the focus of the standard is the general requirements for product safety [45]. The three main components of the standard are health process software requirements, health software validation and health software identification, marking and documents [46]. More specifically, the three areas of the standard cover maintenance, validation, development, design and installation and the life cycle of of health software [45]. IEC 82304 is not harmonized to MDD or MDR.

3.1.6 ISO 17791

ISO 17791 provides guidance on other standards regarding safety in health software [47]. The standard aims to provide a consistent suggestion of standards for medical device software to achieve safety in development, implementation and use [48]. The application of standards regarding the development of health software are aided by risk and quality management and life cycle aspects [48]. Other than guiding towards the appropriate implementation of standards, ISO 17791 also covers and addresses the gaps and overlaps of relevant standards [47]. ISO 17791 is not harmonized to MDD or MDR.

3.2 Medical Device Directive 93/42/EEC

Prior to 1990, each country in the EU regulated and approved medical devices according to their own evaluation [49]. The first regulation to be adopted in Europe was The Active Implantable Medical Devices Directives, AIMDD. AIMDD was established in 1990 followed by MDD in 1993 [50]. One of the main purposes of MDD was to permit and simplify manufacturers in Europe to trade their products without having to fulfill each individual country's legislation [51]. In addition, the intent was also to assure the member countries' safety and quality. MDD consists of 23 articles and 12 annexes over 60 pages [52]. G. Jiothy *et al.* [49] specifies the content of annexes:

> *"Annex I lists 14 essential requirements and 54 subsets, Annex II to Annex VII describe 6 different routes to acquiring the CE marking:*
>
> – *Annex VIII applies to custom-made devices*
>
> – *Annex IX outlines criteria for classifying medical devices*
>
> – *Annex X covers the clinical evaluation*
>
> – *Annex XI describes the designation of notified bodies*
>
> – *Annex XII illustrates how the CE marking should be applied"* [49, p.585]

Because MDD is a directive, each member state has written their own national laws based on the directives [53]. The competent authority of each state does not only approve clinical trials and assure the compliance with the medical devices to MDD, but is also responsible for post-market surveillance as well as acting on reports of

adverse events [53]. Jyothi *et al.* [53] further explains that the information and documentation available for competent authorities to rely on when verifying the compliance with MDD, is the harmonised standards. According to MEDCERT [54], a notified body based in Germany, there are currently 58 notified bodies under MDD.

For transparency and information exchange between the competent authorities and notified bodies, the databank EUDAMED is used to store relevant and important information of medical devices such as results of clinical trials, reports of post-market adverse events and information about the manufacturer [53]. However, according to MDD, EUDAMED is only available for authorities within the EU and not to the public.

Since 1993, there have been several updates and corrections of MDD [23]. One of the updates was published in 2007, which aided in declaring that software on its own should be defined as a medical device if it is produced for medical purposes [23] [51]. The amendment follows:

"It is necessary to clarify that software in its own right, when specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of a medical device, is a medical device. Software for general purposes when used in a healthcare setting is not a medical device" Taktak *et al.* [51, p.111].

In 2012, the Swedish Medical Products Agency released a guidance regarding medical device software to clarify the expectations, requirements and classification requirements [55]. In addition, the Swedish Medical Products Agency [55] states that the purpose of the guidance is also to aid the manufacturers and healthcare providers in their work and to harmonize interpretations of the regulations. The guidance is based upon the 93/42/EEG directive and the changes in the directive 2007/47/EG. According to the guidance, what determines whether an EHR system is a medical device or not is whether the purpose of the product falls under the definition of a medical device. Furthermore, the Swedish Medical Products Agency [55] explains that any software that executes and provides information as a foundation for diagnostization or treatment should be defined as a medical device. As an additional resource, the Swedish Medical Products Agency [55] provides a flowchart for qualification of software which the following flowchart, see Figure 3.1, is based upon.
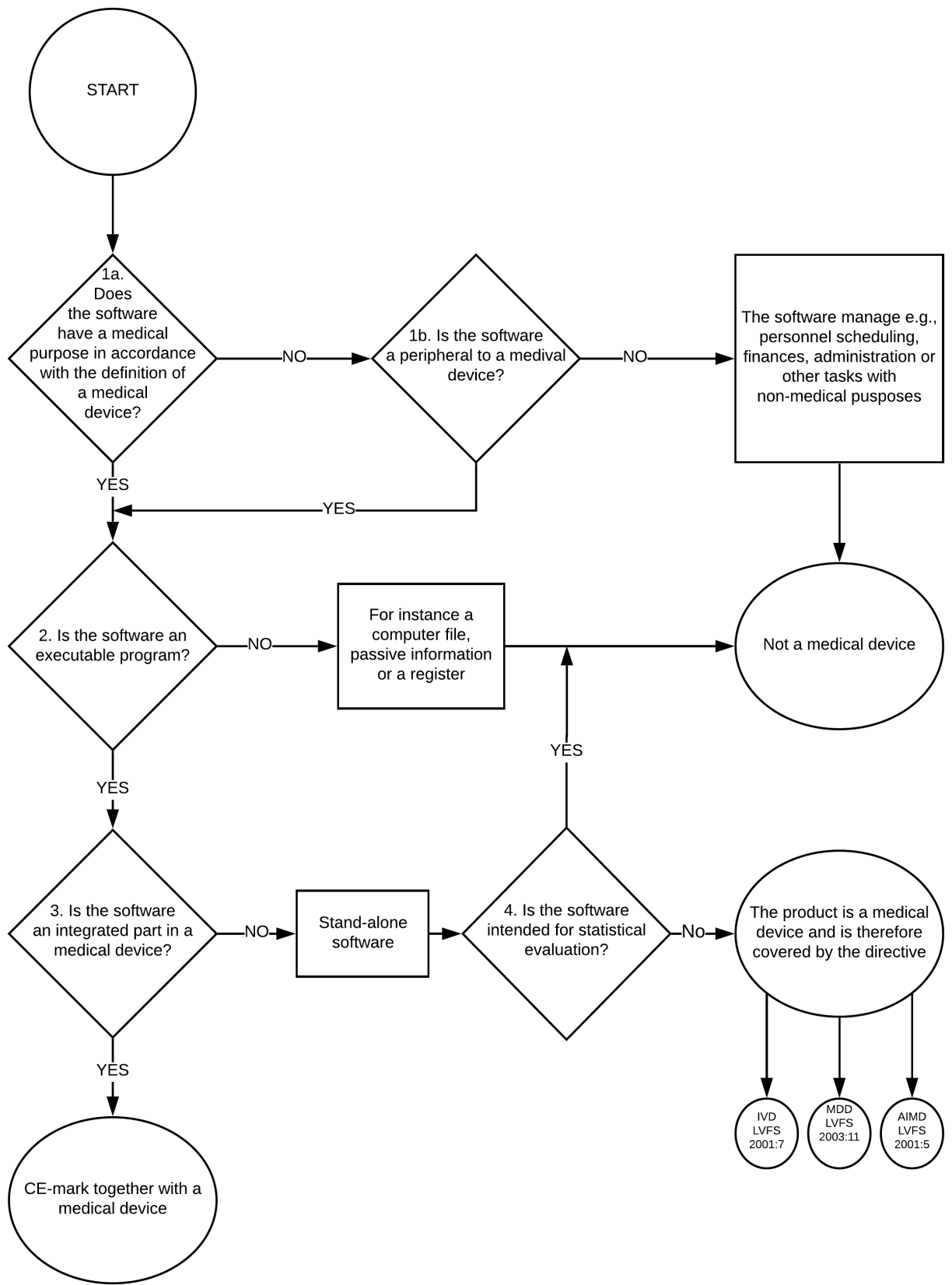
Figure 3.1: Flowchart for Qualification of Software under MDD, adapted from [55]

Regardless the classification of a medical device software, all medical devices must fulfill the essential requirements (MDD Annex I) of a medical device. The guidance by the Swedish Medical Products Agency states that an EHR is an active medical device that is partially used for diagnostication and should thus be classified as class I. Even software modules that function within a system such as modules for anesthesia, drugs and clinical information systems should be classified as class I. However, information systems such as Picture Archiving and Communication System (PACS) that are connected to medical imaging systems are classified as class IIa or class IIb [55].

3.3 Events Leading Up to the Development of a New Regulation, MDR

MDD needed to be updated for several reasons. MDD was established in 1993 and since then the medical technology market has grown, technology has advanced and there has been a rapid development of new innovation and inventions placed on the market.

When the current directive, MDD, became law in 1993 the term "Software as a Medical Device" (SaMD) was not yet written nor documented. Today, software is an essential tool and resource in modern healthcare. In addition, the demographics of Europe has changed since 1993 and the new regulation should be adapted accordingly, for instance in regards to transparency where information of medical devices should be available to the public to avert misuse. There were a few incidents around 2010 that shook the world and made an impact on the overall industry of medical devices. The incidents increased the need for a new stricter regulation with improved standards and processes, that could ensure higher safety for patients and higher quality on medical devices on the market.

One episode that indicated flaws in the current directive and made an impact globally was the PIP incident. Poly Implant Prothese (PIP) was a French company established in 1991 that made silicone breast implants. In 2001 the PIP company started to manufacture breast implants filled with an unapproved industrial grade silicone. Legal issues started to arise and surgeons started to notice an increase in the amount of ruptured breast implants, all linked to the same manufacturer PIP. Although, the review from an NHS Medical Doctor showed no evidence that the fillers were toxic or a threat to the public health, the high rupture rate and bad mechanical strength made it a deficient product [56]. Due to this scandal the company went bankrupt, liquidated and the founder, Jean-Claude Mas, was sent to prison and was fined 75 000 euros [57]. According to the European Parliament [4] it has been estimated that 50 000 women were affected by this catastrophic incident. The PIP scandal worked as a catalysator to initiate new regulation and made it clear that control and oversight of medical devices on the market needed to be improved. In addition, this incident indicated the importance of traceability for it was difficult to trace and reach out to everyone who had PIP implants [53].

There was another scandal regarding metal-on-metal (MoM) hip implants around the same time. The implants were found to have wear, where the metal ball and the metal cup rub against each other resulting in metal particles being released from the implant damaging surrounding bones and tissues. Other than implant failure, the release of metal in a patient's body leads to metal toxicity. Although this incident demonstrated the lack of post market surveillance within the Food and Drug Administration (FDA), it had a global effect and worked as a contributing factor for the initiation of an updated regulation [58].

Commercial use of medical products not included in the definition of a medical device according to MDD are now being reconsidered in the new regulation due to their possible risk. This concern has been addressed and has resulted in products, with a non-medical purpose, being covered by MDR [[3], Annex XVI]. These are products that are comparable to a medical device and possesses a similar risk-profile but has not been required by law under the directive MDD to be CE marked. The majority of products that will be affected by this change are today frequently used in beauty treatments and for other esthetic means such as fillers, radiation for hair removal and skin treatments as well as equipment for liposuction are also subject for this matter.

The common ground of the the initiative to update MDD that resulted in the development of MDR, was the need to ensure the public of higher safety in products and devices as well as better post market surveillance (PMS). These incidents and an increased usage of certain products have together contributed to a change in regulation.

3.4   Medical Device Regulatory 2017/745

On September the 26th of 2012 the proposal for the new regulation was published for the first time [59]. The proposal claims that the new regulation will capture the flaws in the previous directives as well as support innovation of medical devices [60]. The European Commission [60] states that patients, healthcare professionals and manufacturers will all benefit from the new regulation. MDR will apply to all member countries of EU as well as the countries that have entered international agreements with EU which is Norway, Liechtenstein and Iceland.

The new regulation will fully replace the previous legislation MDD and AIMDD on the 26th of May 2021 [3]. The main goal of MDR is to strengthen and improve the already existing legislation [5]. The EU explains that the new regulation is more robust due to higher standards on safety and quality as well as more transparency [3]. In addition, there has been improvements on the supervision of notified bodies and on the traceability of medical devices [3]. Products that have not previously been included by the previous directive, such as certain cosmetic and esthetic products are now included in MDR, specifically products with similar properties and risk profile as medical devices [5].

The European Commission has published "The new regulations in a nutshell" [61] that summarizes the main improvements of MDR. The European Commission [61]

explains that the new regulation will involve experts of high risk devices and thus implicate stricter control and an improved pre-market apparatus. In addition, the requirements of the notified bodies as well as for the requirements of post-market surveillance for manufacturers will be extended and made stricter. There will also be stricter and reinforced rules on clinical evidence and transparency within the EU. Thus, unique device identification (UDI) will have to be registered to the EU database EUDAMED. The database EDUAMED will be improved and widened under MDR. EUDAMED will be serve several purposes, and one of them being open to the public, not only to competent authorities. Furthermore, devices that were previously not covered by the medical device directives, such as certain esthetic products with certain risk profiles, will now be comprised by the new regulations. Finally, implants must introduce an implant card unique for every implant for improved safety and control [61].

When following a relevant harmonized standard revised by an European Standards Organization, one can expect to be compliant with the requirements of the regulation [3]. However, there are still no EN standards harmonized to assure conformity of MDR [34]. Other than being responsible for administrating harmonized standards, the European Commission provides guidance documents intended to aid manufacturers in applying the regulations [62]. The guidance documents are produced by the medical device coordination group (MDCG) with the aim of aiding a uniform application of the regulations.

After the transitional period from May 2017 until the 26th of May 2021, MDR 2017/745, will fully come into force. Thus, all medical devices on the market must fulfill the new regulation by May 26th 2021. However, during December 2019, the European Commission released corrigendum II [63]. Corrigendum II consists of corrections and amendments of 2017/745, one of them addressing some exceptions for certain manufacturers regarding when they need to fulfill the new regulations [64]. Corrigendum II states that medical devices that were classified as class I under MDD, and need to increase their classification under to the new regulation, will not have to be certified according to MDR by the set date 26th of May 2021, but by the 25th of May 2024 and can thus remain on the market with their MDD certification until then [63]. However, one important aspect of this is that even though the device must not be certified before the set date, many MDR requirements will still apply; such as implementation of QMS, PMS, risk management and clinical evaluation [64]. Another requirement of the devices covered by this corrigendum is the criteria of significant change, meaning that the device must not undergo any significant change during the extended period to 25th of May 2024 [63]. The latest version on the MDCG guidelines regarding significant change was released the 23rd of March 2020 [65]. Corrigendum II [64] states that changes that are considered as significant is a change of intended purpose, change in design or performance specification, change in software, change of material and change of sterilization or packing material.

3.4.1 The Structure of MDR

Similar to MDD, MDR comprises an introduction, several articles split in different chapters and multiple annexes at the end of the document. However, MDR is more comprehensive and detailed, making the document longer with additional articles and annexes. To get an overview of what MDR provides in the different articles and annexes, see Table 3.1 and Table 3.2. According to the British Standards Institute (BSI) group [66] MDD comprises 23 Articles and 12 annexes over 60 pages whereas MDR contain 123 articles and 17 annexes over 175 pages.

Table 3.1: The content of the articles in MDR

Chapter	Articles	
I	1-4	Scope and definitions
II	5-24	Making available on the market and putting into service of devices, obligations of economic operators, reprocessing, CE marking, free movement
III	25-34	Identification and traceability of devices, registration of devices and of economic operators, summary of safety and clinical performance, European database on medical devices
IV	35-50	Notified bodies
V	51-60	Classification and conformity assessment
VI	61-82	Clinical evaluation and clinical investigations
VII	83-100	Post-market surveillance, vigilance and market surveillance
VIII	101-108	Cooperation between Member States, Medical Device Coordination Group, expert laboratories, expert panels and device registrars
IX	109-103	Confidentiality, data protection, funding and penalties
X	104-123	Final Provisions

Table 3.2: The content of annexes in MDR

Annex	
I	General safety and performance requirements
II	Technical documentation
III	Technical documentation on post-market surveillance
IV	EU declaration of conformity
V	CE marking of conformity
VI	Registration of devices and economic operators; UDI
VII	Requirements to be met by notified bodies
VIII	Classification rules
IX	Conformity assessment based on a quality management system and on assessment of technical documentation
X	Conformity assessment based on type-examination
XI	Conformity assessment based on product conformity verification
XII	Certificates issued by a notified body
XIII	Procedure for custom-made devices
XIV	Clinical evaluation and post-market clinical follow-up
XV	Clinical investigations
XVI	List of groups of products without an intended medical purpose
XVII	Correlation table showing Council Directive 90/385/EEC, Council Directive 93/42/EEC and the MDR

What is presented below is a comparison made between the two legislation based on a comparison given by the BSI group [66] [67].

Comparison of the Articles

There are some main differences between MDD and MDR articles that contribute in making the MDR legislation more comprehensive and detailed. The key differences are by large in the areas of scope, declaration of conformity and CE marking, post-market surveillance and vigilance.

Regarding scope inclusions in Article 1, the MDR has a broader definition of what medical devices to cover and it includes far more devices than the scope of MDD. In addition to the scope of MDD, MDR also covers, among others, products intended for sterilization, cleaning and disinfection as well as medical devices for esthetic purposes rather than medical purposes.

Articles 11 and 17 in MDD concerning declaration of conformity and CE marking are now presented in articles 19 and 20 in MDR. The key changes in the new articles being the newly included detail on what the declaration of conformity should contain, and specifically for it to be up-to-date and available in the official language of where the device is supplied.

The topic of most changes and differences in MDR is the area of post-market surveillance (PMS). MDR emphasizes on the importance of device safety after the approved CE certification process through gathering of data when the medical device operates

on the market, and continuously doing so throughout the life cycle of the medical device. This is to be observant of risks that could occur in real-world clinical use of the device, such as when the device is used, stored, transported or cleaned. Following this, manufacturers can continuously update their risk assessment and take immediate action when necessary. MDR defines post-market surveillance as activities carried out in a proactive and systematic approach by the manufacturer, together with other economic operators, to gather, record and analyze data as well as to take corrective and preventive action. In addition to the PMS, there is the post-market clinical follow-up (PMCF). The PMCF is the continuous process that updates the clinical evaluation with clinical data.

MDD mentions the conduct of PMS system and PMCF but no further details. Requirements adjacent to an MDR expressed PMS is mentioned through different Annexes regarding conformity assessments in MDD, but there is no distinct definition nor requirements. However, in contrast to MDD, MDR focuses on giving detailed information and requirements regarding PMS system and PMCF in Articles 83-86. According to MDR [3] the PMS system should be based on a PMS plan, and the PMCF plan should work as an incorporating part of the PMS plan. MDR provides detailed necessities on what to include in the PMS plan, as well as the PMCF plan. In addition, MDR requires for the PMS system to be an integral part of the manufacturer's Quality Management System (QMS).

The last area containing main differences in articles between MDD and MDR is the topic of vigilance. Vigilance is one part of the post-market surveillance and has to do with the reporting of serious incidents and field safety corrective actions. The concept of vigilance in MDD is ambiguous and most of the information is found in the MDD guidance document MEDDEV 2.12-1: Guidelines on a medical device vigilance system. Therefore, the information in that document is now incorporated in the legal text of MDR and can now be found in articles 87-92. In addition, there is a change in terminology between the two legislations. MDD's "reportable events" is now called "serious incidents", as well as what was previously called "non-reportable events" are now considered as "incidents" and "non-serious incidents". Moreover, the deadlines of reporting considered serious public health threats and of reporting death or serious deterioration in health has been left unchanged, two and ten days respectively. However, the timeline of reporting all other serious events has been shortened from 30 days to 15 days.

Comparison of the Annexes

As well as differences in articles, there are some main differences between the two legislations regarding their Annexes. The following presents differences in Annexes between MDD and MDR in the areas of product requirements and declaration of conformity.

In order to establish conformity with the MDD the key element is to institute compliance with the given "Essential Requirements" (ERs) stated in Annex I. Correspondingly, to withhold conformity with the MDR, compliance with the given "General Safety and Performance Requirements" (GSPRs), stated in Annex I, needs to be established. While MDD sets out 13 ERs, MDR sets out 23 GSPR. The covered

topics are consistent between the two but the overall text and requirements are expressed more fully and in greater detail in MDR. Some areas have a more indicated importance in MDR than they had in MDD, such as embedded as well as stand alone software.

Declaration of conformity is the document in which the manufacturer announces and proclaims that its product is in conformity with the current medical device legislation and its requirements. This document is mentioned as a must for the manufacturer to draw up in the directive MDD, but never specified in detail on what to include. However, in MDR the content is stated and set out in detail.

3.4.2 For the Manufacturer of a Medical Device in MDR

The regulation addresses information for several parties that are a part of, and have obligations in, the process of placing a medical device on the market, such as manufacturers, distributors, importers, notified bodies etc.

In article 10 "General obligations of manufacturers" this regulation provides information on what requirements and obligations manufacturers need to fulfill in order to align with MDR. The article comprises a list of 16 subjects that a manufacturer needs to take into account and provide in the path of getting the CE mark for their product. As the article is written in a general manner and includes all the device classifications, every listed subject is not relevant to every medical device and manufacturer. What is of relevance and not depends on the assigned classification for every particular device. The majority of the 16 areas mentioned in Article 10 are further referring to annexes, chapters, and other articles where additional details for every possible classification the product could be assigned to are provided.

To properly and correctly follow Article 10 the manufacturer must first assign a proper class to its product, Annex VIII presents classification rules to help the manufacturer in this process. Article 10 directs certain information to specific classes, to decide if this information is relevant or not depends on the assigned class of the device. It is therefore crucial to, at an early stage, decide on the classification.

3.4.3 CE Mark and Classification

Just as in the current directive MDD, manufacturers of medical devices must CE mark their product in order to release it on the market according to MDR. As stated, the MDR requirements are more strict than the requirements in MDD and thus the process of CE marking the device according to MDR are more extensive. The risk classes, class I (or Im and Is), class IIa, class IIb and class III still remains [68]. Due to the change in requirements and that the definition of a medical device is broader, many of the devices have moved up to a higher risk classification making the route to CE mark more comprehensive. However, the route to CE mark for each risk classification is fairly similar between the two legisaltions [69]. The specific requirements on the route to CE mark for each risk class is specified in Table 3.3.

Table 3.3: Classification requirements [69, 68]

Class	Procedure						
	Register device to competent authority	Write and compile declaration of conformity assessed by a notified body	Write and compile technical documentation	Attach the CE mark	Notified body approves the total QMS or notified body performs type examination and controls the quality system of the production	Technical documentation assessed by a notified body	Notified body controls and approves the construction safety of the device
I	X	X (Assessment not needed)	X	X			
IIa		X	X	X	X	X	
IIb		X	X	X	X	X	
III		X	X	X	X	X	X

The following demands apply to each class:

– Meet the general safety and performance requirements.

– Implement QMS.

– Compile technical documentation

– Clinical evaluation.

– Register UDI for each device and register in EUDAMED.

– Determine a person responsible for regulatory compliance, PRRC [69].

One main difference between the classifications is also the amount and frequency of audits by notified bodies after the release on the market [70].

Depending on the classification of the device the route to achieve certification will differ. In MDR, Annexes IX, X and XI presents three options regarding the assessment made by a notified body to receive CE mark [3]. Annex IX presents conformity assessment based on the quality management system and assessment on technical documentation, Annex X presents conformity assessment based on type-examination and Annex XI presents conformity assessment based on product conformity verification.

3.5 Software

Software in healthcare is an important element in the Healthcare IT Industry, *i.e* the IT services that are relevant to healthcare. This software refers to systems helping healthcare personnel to manage and record patients' information, coordinate care as well as offering support in the management of information among healthcare

providers, insurance, billing, prescription of drugs, etc. Other than that, software is an important part of several medical devices in modern healthcare. Software systems in healthcare can also help to detect diseases and assist doctors in the decision making process of diagnosing a patient through the use of data. The consequences of not having proper functioning software that operate medical technology can be devastating and fatal.

There is an increased interest in a knowledge-based integrated systems among healthcare providers and decision-makers that provides immediate assistance, guidance and feedback [71]. According to Snyder and Paulson [71] these kinds of systems facilitate the process of giving a well-informed decision about treatments, providers, institutions and health plans.

3.5.1 Electronic Health Records Systems

A widely used software in healthcare is Electronic Health Record (EHR) systems. In this system, medical information about patients can be created, managed, evaluated and stored in a digital format. By having it stored electronically it can easily be shared by authorized parties in one healthcare organization . Moreover, handwritten notes and records can be poorly legible and have a higher risk of causing medical errors than when using EHR systems. In that way, by using EHR systems higher quality of care can be ensured.

European citizens have a right to healthcare while being abroad in the EU. In addition, they have a right to be reimbursed for healthcare across borders by their home country. Directive 2011/24/EU [72] on patients' rights in cross-border healthcare states conditions to ensure quality care across the EU and to encourage cooperation regarding healthcare between member states. To make healthcare cross borders in the EU easy to access and manage one concern is regarding EHR systems.

To facilitate quality care across the EU, initiatives from the EU regarding interoperability of medical records systems have been made [73]. The recommendation [74] presents a framework that provides development of an European Electronic Health Record exchange format that can ensure EU citizens of interoperability of systems and access of health data across borders. By making health records in a format compatible for exchange, access to and sharing of health data across the EU is supported. This is made to ensure the citizens of the EU that they can get high-quality healthcare when needed wherever they are in the EU without the exchange of data being an obstacle for proper care.

Above the given directives from the EU, member states have national laws regarding their own electronic health records. In Sweden there is no central EHR system and the medical records are kept regionally. There is no centralized Swedish authority responsible for the purchasing of the regions' medical record system, that processed is managed and driven solely by the County councils and regions themselves. Therefore, there are a variety of IT-systems that are used in different parts of Sweden.

The four largest EHR systems on the Swedish market during 2018 were Cosmic (by Cambio), Take Care (by CompuGroup), Melior (by Cerner) and NCS Cross (by Evry) [75]. However, many of the Swedish regions are currently negotiating who will be their future supplier of EHR system. Therefore, it is not known exactly what the market will look like after 2020. Even though the regions in Sweden have various manufacturers of EHR systems they can still share patient information and other relevant data from the patient journals through NPÖ, national patient summary [76]. The purpose of NPÖ is to strengthen patient safety, create a more efficient flow of care as well as high-quality care [76].

An EHR system is not a one time purchase. Once a hospital or other healthcare facilities implement an EHR system there will be continuous updates and improvements of the system, and thus it operates as a continuous service. Furthermore, the users of the EHR system can add additional modules or functions to the system after the initial implementation if needed.

Today, many EHR systems are very sophisticated and holds many additional functions other than storing patient data. EHR systems are nowadays developed to assist in all the steps of the care chain by providing function for evaluation, planning, implementation, results and even enabling the integration of other healthcare applications [77][78]. Storing and providing of health information and data is the first and most fundamental function of an EHR system. According to Sinha *et al.* [78] an EHR system should hold the patients' medical history, current medication, diagnostics, laboratory results, and other relevant information. It is also important that the function provides clear identification and contact information of the patient as well as identification of the healthcare professional in charge of each input in the journal, the sensitivity of certain medications, time and date of previous healthcare contact, the patient's preferences in regard of treatment, etc [77].

According to Sinha *et al.* [79], one can divide the functionalities of an EHR system into three different categories. The first category is direct care, which includes functionalities such as clinical decision support (CDS) and care management. The second category is supportive, which consists of functionalities that includes analysis, research, measurements and reports as well as clinical support. The third category includes business rule management as well as security and health record information and management, and is therefore referred to as information infrastructure [79]. An EHR system is thus built up by modules providing unique functionalities.

A function of EHR systems that has become more common is CDS. The purpose of such a function is to provide assistance and knowledge with help of data stored in the EHR system. The CDS can thus aid healthcare professionals in their work in diagnostics, preventive practices and other decision-making in the clinical workflow [78]. It is also common that EHR systems hold administrative and economical functionalities, business rules and workflow management [79].

3.5.2 Software as a Medical Device (SaMD)

The term "SaMD", short for "Software as a Medical Device", was outlined and introduced by the Medical Device Regulators Forum (IMDRF) in a final document that was released in december 2013, with the title "Software as a Medical Device (SaMD): Key Definitions"[80]. The current legislation, MDD, addresses software when embedded in a physical device. However MDD does not cover and can be accurately applied to stand-alone software that is not part of a hardware medical device, and the risk that type of software may pose to the public health. The purpose of releasing this document was to provide a common framework and definition for when software is, by itself, considered a medical device. This document presents guidelines on how to identify these types of software, SaMD, as well as to give some information on the associated risks that can come with a SaMD. IMDRF defines the term SaMD as a *"software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device* [80, p.6]*."* The term SaMD covers, for instance, applications scanning patient images to detect cancer or algorithms that are to detect diseases. Software that is already integrated in monitoring equipment and simply controls the device is not defined as a SaMD.

In MDR, classification rules regarding specifically SaMD are addressed. Rule 11, under Annex VIII Classification rules in MDR, addresses stand-alone software that is a medical device. If the software has a diagnostic or a therapeutic purpose, it will fall under Rule 11 [7]. The presented classification rules in Rule 11 are strict and can come to effect a multitude of software in healthcare today. The following conditions is stated in Rule 11 in Annex VIII "Classification rules" in MDR [3]:

"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*

- *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. All other software are classified as class I EU Regulation MDR [3, p.145].*"*

When combining the terms and conditions in Rule 11 with the definition of a medical device presented in MDR, the outcome is that a great amount of software that is used in healthcare today will be classified as class IIa or higher. This, due to the fact that software that serves the purposes of diagnosis, monitoring, prediction, prognosis or treatment (and thereby is defined as a medical device according to MDR) is also providing information that is used to make decisions with diagnosis or therapeutic purposes (and thereby falls under rule 11). There will be a vast minority of stand-alone software that will belong to class I [7].

The consequences of Rule 11 instituting new classification rules that will affect a numerous amount of software, is that a majority of them have to move up in classification. Many of them being the applications going from class I under MDD to a higher class under MDR, see Table 3.4. As soon as a device is no longer included in class I and changes to a higher classification, the manufacturer needs to make some alterations. The main alterations being to involve a notified body in order to get their software CE marked and in general, establish a certified quality management system. This will entail large costs and high expenses for manufactures and small to medium sized software companies will be highly affected [7].

Table 3.4: Software will be classified in higher classes according to MDR, adapted from [7]

Product	Class according to MDD	Class according to MDR
App supporting the selection and dose calculation of cytostatic drugs	I	III
Software suggesting diagnoses based on test results	I	IIb (or higher)
App to diagnose sleep apnoea	I	IIa (or higher)
General EHR systems	I	IIa (or higher)

In 2018 the EU considered making Rule 11 in MDR 2017/745 applicable to not only stand-alone software, but applicable for software in medical devices as well. As of December 2019, 32 MDCG endorsed guidance documents have been released to ensure harmonized and uniform application of the provisions of MDR 2017/745 [81]. In one of these documents, MDCG 2019-11, it was presented that rule 11 will be applicable to stand-alone software as well as for software in medical devices. That meaning, software embedded in a physical device that does more than just controlling it, should be assigned its own class. There are ongoing developments of further guideline documents that are still to be introduced [82].

In the MDCG 2019-11 documents decision trees are provided in order to clarify what software MDR 2017/745 will cover, see Figure 3.2. The purpose of this flowchart is to help manufacturers of both stand-alone and embedded software in their process of understanding if their product will be covered by the regulation or not.
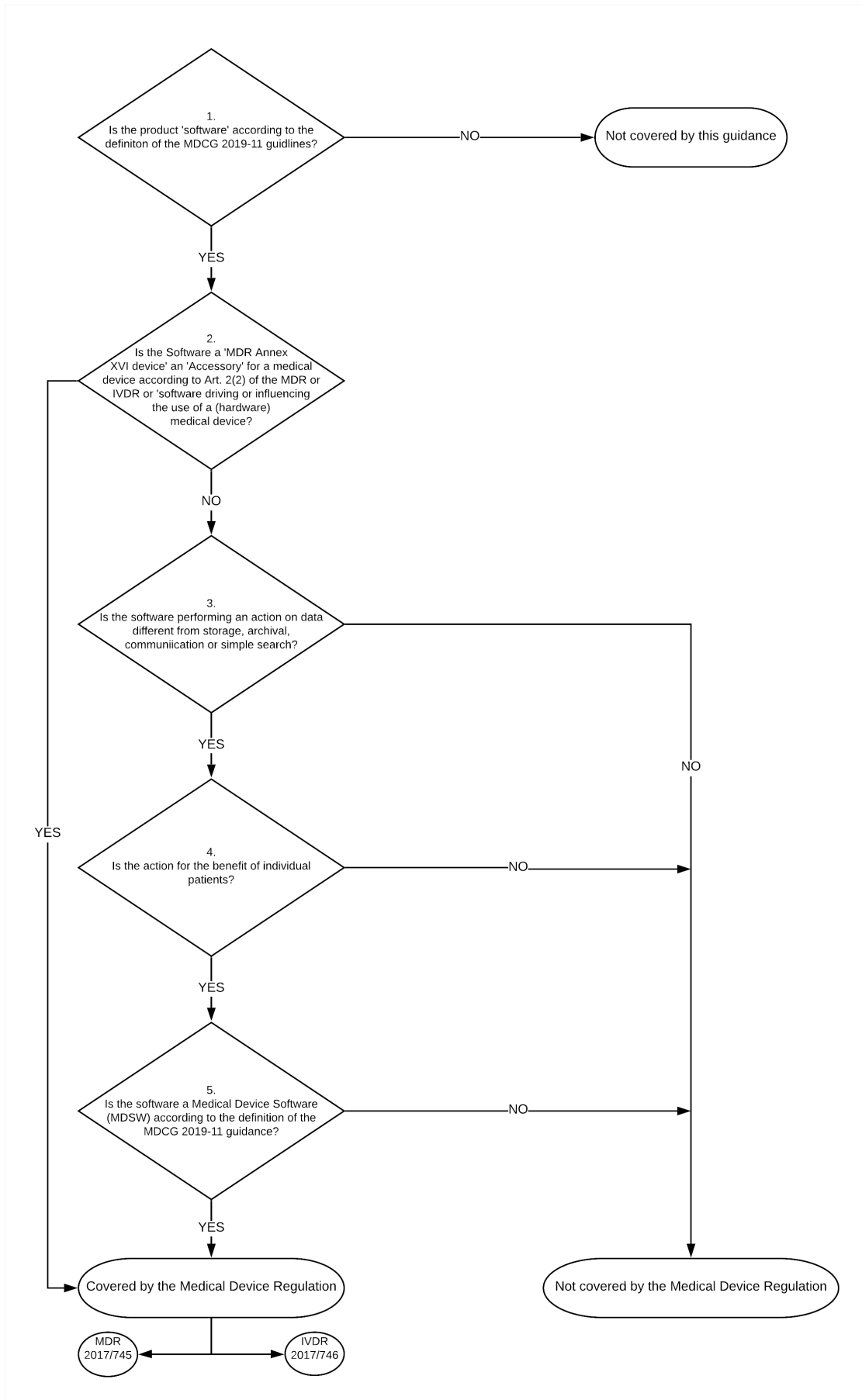
Figure 3.2: Flowchart for qualification of software under MDR, adapted from [83]

As previously mentioned, the corrigendum II states that a device that needs to move up in classification from class I does not have to be MDR certified by 26th of May 2021, but by the 25th of May 2024 and can thus remain on the market with their MDD certification until then. This amendment is applicable to this issue and can cover the great number of software that must not belong to class I anymore in MDR but rather class II or higher.

However, even though the corrigendum II simplifies the time frame for EHR manufacturers for getting their CE mark, there are concerns regarding the meaning of significant change. Corrigendum II states that the devices that can make use of this extended period must not undergo any significant change in design or a significant change in the intended purpose under this extended period. If it does undergo a change that is considered as significant, authorities and notified bodies need to be informed and the product has to be reapproved. In the document "MDCG 2020-3 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" [65] it is presented, in the form of flowcharts, what is considered a significant change. Unfortunately, a lot of software changes are considered as significant changes, leaving EHR manufacturers still very confused. Software manufacturers work mostly agile and update their software continuously resulting in around one new release every quarter to their clients. This to keep their clients in the forefront and to always deliver an up-to-date and accurate version of their product. However, the amendment on significant change can come to change that.

To make an EHR-system MDR-approved is a process that requires an exceptional expertise within the regulatory field as well as top knowledge of the product in every detail possible. Going from MDD to MDR, manufacturers are experiencing a lack of guidance regarding the implementation of the new regulation. Manufacturers argue that meeting MDR is a challenge. In a study from 2019, only 27% of 230 manufacturers expected to be compliant with MDR by May 2020 [8]. The new classification rules for medical device software manufacturers will imply large changes as almost every medical device software will be upgraded from class I to a higher classification. In addition, the requirements of rule 11 will entail a heavy workload, especially for smaller companies manufacturing medical device software. Thus, EHR manufacturers, as well as other medical device software manufacturers, are in need of tools and guidance to simplify and provide coherent path to compliance with MDR as well as clarification on certain elements of the regulation [7][8].

Methods

4.1 Design of Data Collection

The fundamental idea of this project was to study MDR more closely. After a discussion with the supervisors, the suggestion of limiting the study to scrutinize MDR in regards to EHR manufacturers evolved. As the discussion continued the research questions were formulated.

Due to the nature of this project where the understanding and scrutinizing of a large quantity of complex information were the main work task, a qualitative research methodology was applied [84]. Thus, the design of the data collection was developed according to appropriate qualitative approach with an extensive literature study, conducting two interviews with experts within the field of quality assurance and regulatory affairs in medical software as well as attending seminars.

4.1.1 Literature Study

The strategy of the literature study was to start by building an understanding of the scope of the problem. This required knowledge about the structure of the European Union, the European Commission, various authorities and how legislative acts are composed. Thus, the start of the project implicated research from the website of the European Commission, the Swedish Medical Products Agency, the International Organization for Standardization, the Swedish Institute for Standards and other authorities.

The next step of the literature study was to find more information about the directive and the regulation itself and thus examine guidelines and studies of MDR. While conducting the literature study, the research was carried out based upon the research question and the sub-questions of this thesis. The literature research was mainly done through data-bases KTH Primo and Google Scholar for additional guidance on the subject. Key-words during the literature search included: MDR, MDD, technical documentation, QMS, software regulation, CE mark, software as a medical device, EHR system and guidance. Since the project and the problem description is based on the medical device regulatory 2017/745 it also required an extensive study of that documentation. The retrieval from the literature study came to create the chapter "Results of Literature Study".

Document Study

Studies on the medical device regulatory 2017/745 were essential for developing the results of this thesis. To create the process description required thorough investigation and deep understanding of the MDR document. In order to gain knowledge and understanding of the structure and content of the regulation, summaries and compilations of the relevant articles and annexes were created. Moreover, the regulation was decomposed in a qualitative manner by gathering the most relevant information and sorting it accordingly.

Interview Study

Literature studies on how to conduct a proper qualitative interview were also made. The interviews were held to gain knowledge regarding the interviewees understanding of MDR as well as to gather information on their regulatory work processes to fulfill MDR. Thus, an interview protocol was developed containing open-ended interview questions. The questions were compiled based on the research question and the sub-questions of this thesis.

4.1.2 Seminars

The medical device regulatory 2017/74 has been of high importance to the whole medical device industry. Consequently, there have been several seminars regarding the understanding and implementation of the new regulation from various perspectives such as QMS, technical documentation and main changes. In the scope of this project to gain knowledge from experts in the field, following seminars was attended:

- "Introducing QMS According to MDR" - Plant Vision (2020-01-30).

- "What happens if the medical device does not fulfill MDR by May 26th" - Ciro Law firm (2020-02-05).

- "Regulatory Summit" - Swedish Medtech (2020-02-20).

- "Technical file writing" - Swedish Medtech (2020-03-24).

During the seminar "Introducing QMS According to MDR" given by Plant Vision the requirements on QMS according to MDR were presented. The seminar also explained the content of ISO 13485 and introduced suggestions on how to implement the standard by a given method.

Ciro law firm conducted a thorough review of the legal consequences if MDR is not fulfilled. During the breakfast seminar the processes of surveillance and inspections was explained as well as the new concept introduced in MDR of having a person responsible of regulatory compliance.

The regulatory summit given by Swedish Medtech presented the published guidelines and other acts released as a compliment to the new regulation, information to manufacturers regarding article 10 as well as relevant information to other actors such as suppliers and distributors. Management according to MDR was also

discussed and presented. The seminar was attended by Cecilia Fornstedt, the supervisor of this project from PwC, who passed on the information and content to aid this project.

The "Technical file writing" seminar given by Swedish Medtech presented the essentials regarding technical file writing. The seminar included explanations and review of Annex II and Annex III of MDR and the prerequisites of technical documentation. In addition, the seminar highlighted common mistakes as well as recommendations regarding technical file writing.

4.1.3 Interviews

To get an understanding of how current EHR manufacturers have been working to align their work and their product so far, interviews with two experts within that field were conducted. Interviews were used as a method of data collection partly to enable participants to provide historical information in a context where the line of questioning could be easily controlled [84]. The purpose of doing these interviews was to look into these two cases and study their individual path to a CE mark, to uncover similarities and differences, and hopefully help in the assessment of creating a general process description. The interviewees that were selected currently work with quality management at companies that develop EHR systems for the public sector. They are experts in the field of quality management in general and highly knowledgeable regarding MDD and MDR, and therefore chosen to be participants in this study.

Initially, in-person meetings were scheduled where the interviewees were to be met individually in their offices with access to tools such as whiteboard and digital means to present slides and images. However, due to the current circumstances regarding the Coronavirus, Covid-19, the interviews were rescheduled to digital meetings with short notice.

The interviewees were met with two times, the first meeting being an initial one and the second one being the full interview.

Initial Meetings

The two initial meetings were set individually with the two interviewees at the companies respectively, other than the interviewee the project's supervisor from PwC were present. The purpose of the meeting was to discuss where the companies were in their MDR CE marking process, what they will be able to share in a potential interview and their initial thoughts and ideas about the study.

Interviews

The interviews were conducted via video link. The interviews were held at two different occasions separately with the interviewees. A sketch of a preliminary suggestion for a process description as well as the interview questions were sent to the interviewees a few days before the interview were to be conducted in order for them to be prepared.

Part one of the interview was spent discussing the preliminary sketch of the process description. The interviewees presented feedback and areas of improvement for the process description to be as correct as possible and with the right order presenting accurate information.

Part two of the interview had a focus on the interview questions. The questions were asked in the pre-decided order, as in the document given to the interviewees beforehand. Throughout the interviewing the answers given by the interviewee were written down. Part three of the interview were spent on wrapping up the interview and making sure the interviewee were satisfied with their answers.

Interview Questions

The interview questions was formulated to help answering the research questions as stated in section 1.1. The majority of the interview questions were open-ended to encourage further conversation, not limiting the interviewees way of answering as well as to avoid bias. The interview questions resulted in qualitative data. The interview questions are to be found in Appendix A.1.

4.2   Data Analysis

4.2.1   Analysis of Data From Literature Study

The analysis consisted of going through all of the findings, reviewing the data and extract what would contribute to a meaningful process description for the intended user.

4.2.2   Analysis of the Data From the Interviews

The feedback given in part one of the interview were for the purpose of enhancing and improving the process description. The data given in part two of the interview were analysed for the purpose of making the document to the process description complete. The interviewees answers were comparable due to using the same set of questions.

The interview data was compared with the data from the literature study. What was seen as relevant data, above the data given from the literature study, were extracted. This extracted data complemented the already given literature study data and therefor enhanced and improved the project description further.

4.3   Development of Process Description

In order to develop the process description the main requirements and steps of becoming MDR compliant were identified through document study as well as literature study. A preliminary sketch of a process description was developed from the findings. The sketch was then reviewed during the interviews by the interviewees who

provided feedback and additional relevant information. With further document and literature study in combination with the input from the interviews, the final process description and the attached documents were developed.

4.4   Evaluation

After the process of gathering and analysing the data, the data was used to create the process description. The process description was then evaluated by a panel of experts in the regulatory medtech field. The participants of the evaluation were given the final process description one week in advance in order to have time to analyze it.

The evaluation took place via video link with a panel of experts. After an introduction round, the course of the project as well as the result was presented orally. The panel then individually presented their input, their view of the result as well their feedback.

Results

Results presents a process description for an EHR manufacturer to make their EHR system fulfill the necessary regulatory requirements and be MDR compliant, pursuant to the laid out conformity assessment in Annex IX. There are several ways to be compliant with MDR and this result is a suggestion for medical software manufacturers. The process description is a general outline and presents the recommended order of the main steps on the route to be compliant. Each main step is referring to a document that provides detailed information, requirements and guidelines.

During the interviews unresolved issues and concerns regarding MDR and the implementation of its requirements were addressed by the interviewees. To optimize the implementation of the presented process description these concerns needs further clarification:

Checklist of unresolved issues and concerns

☐ Significant change

☐ The difficulty working according to a directive compared to a regulation

☐ Contradictory guidelines between MDR and MDCG documents

☐ Inhibit medtech innovation
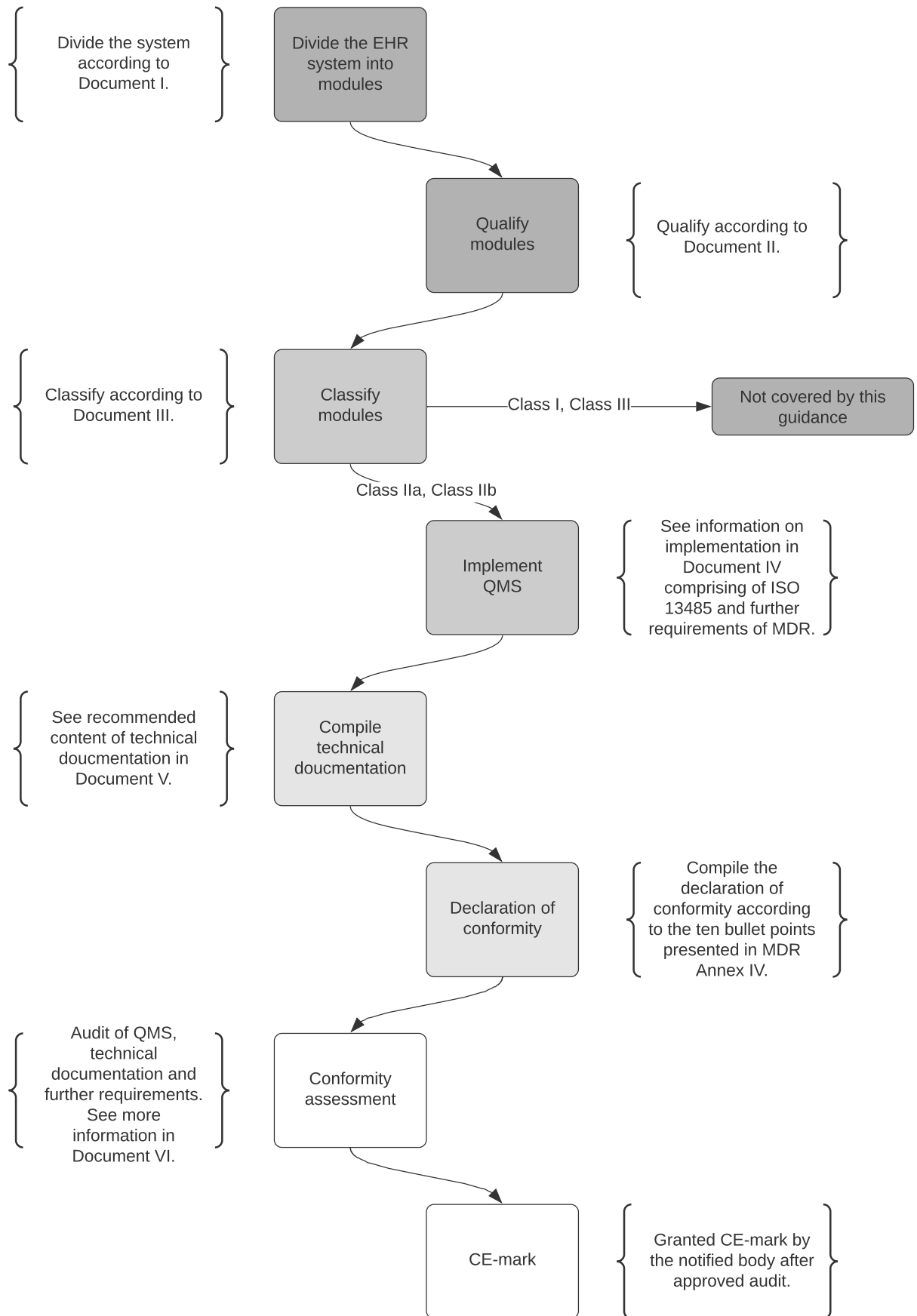
Figure 5.1: Process description for an EHR-system to be MDR compliant

Document I: Divide the EHR system into modules

An EHR system consists of several modules holding various functions, the first step in the process of fulfilling the regulation is to divide the system into modules and define them. To qualify and classify the modules correctly, the manufacturer must provide information on how the different modules affect each other. It is therefore valuable to clarify which of the features are at a system level and what are at a module level. When classifying the different modules separately in different classes the manufacturer must ensure they do not affect each other in a way that could tamper with the given classification.

The division enables the possibility to identify whether a module is qualified as a medical device or not. The modules qualified as a medical device can then be classified.

The manufacturer can decide whether to classify the whole system as the highest classified module, as stated in Annex VIII Chapter 3 clause 3.5, or whether to hold each module as its own medical device. Be aware of that the two choices will imply different amount of necessary documents and ways of compiling them. It is however unclear what specific differences the two choices will imply.

Document II: Qualification

Identify those modules of the software that qualify as a medical device and are therefore covered by MDR. Qualify the modules with the help of and according to previous demonstrated flowchart Figure 3.2 that is also presented below.
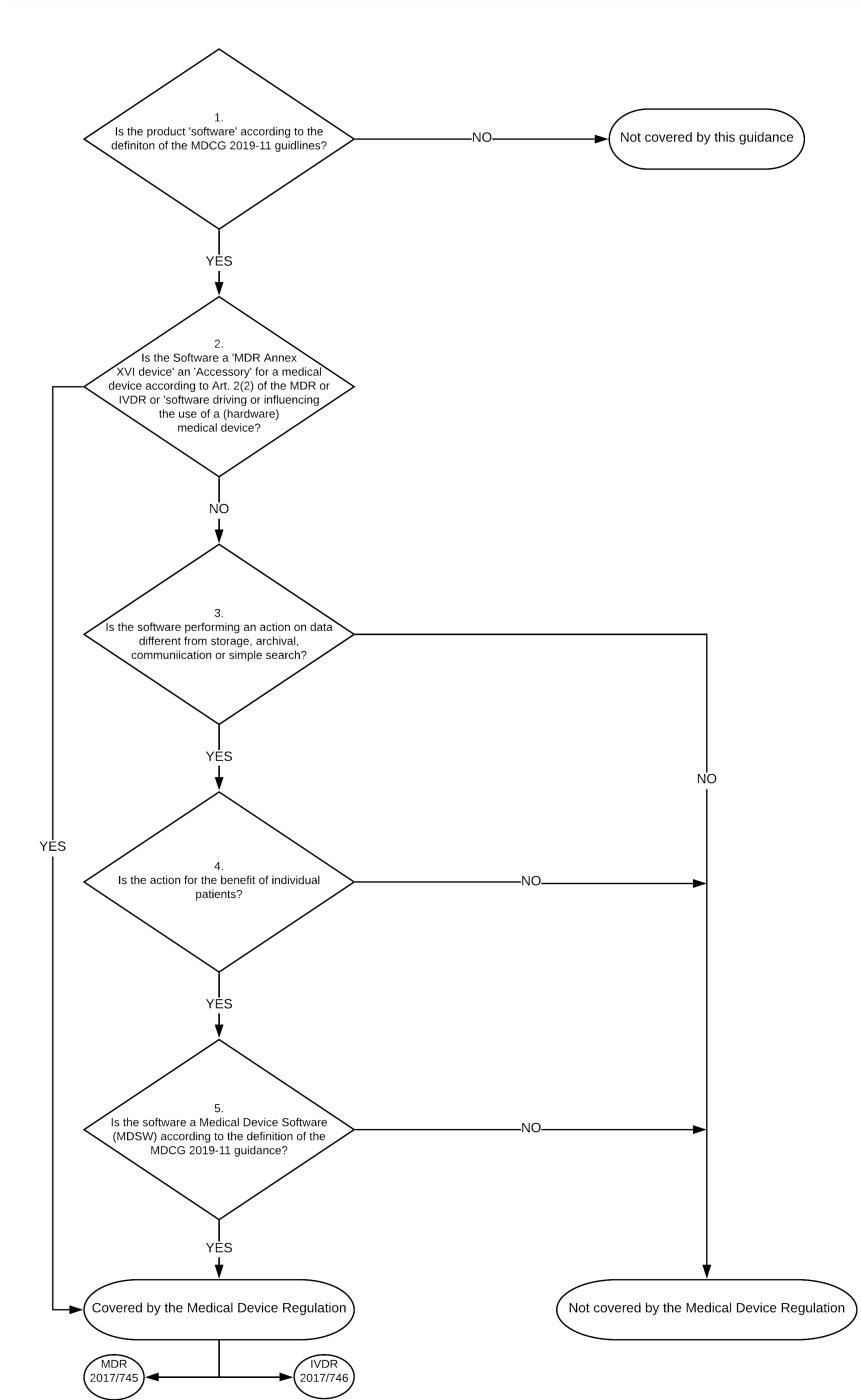
Figure 5.2: Flowchart for qualification of software under MDR, adapted from [83]

Document III: Classification

Classify the identified and qualified modules. The classification is based on the risk profile of each module. Perform the classification process according to the following presented passages of MDR 2017/745 as well as guidance documents with further details provided by the MDCG:

- MDR 2017/745, Annex VIII:

    - Chapter 1 "Definitions specific to classification rules"
        - Clause 2.5
    - Chapter 2 "Implementing rules"
        - Clause 3.3, 3.5
    - Chapter 3 "Classification rules"
        - Rule 11

- MDCG 2019-11 "Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR"

Document IV: Implement QMS

Implement ISO 13485

In order to implement ISO 13485 and be compliant, one must purchase and follow the actual standard. To successfully fulfill ISO 13485 it must be done according to the standard itself. The results and information presented below in this section provides guidelines, clarifications and concrete tips on how to implement ISO 13485.

When implementing ISO 13485, follow a plan- do- check- and act-approach (PDCA). PDCA is an iterative process allowing continuous improvement of the QMS:

– The first phase of PDCA is plan, which includes planning and analyzing. MDR sets high requirements on planning phases, specifically risk management plans. Sections in ISO 13485 applicable with the plan-phase are 5.4.1 and 5.4.2, regarding the quality objectives and quality system. Section 5.1, 5.5.2 and 5.3, regarding responsibilities is also a part of the plan-phase as well as 6.1, 6.2 and 6.3, regarding resources.

– Do, is the second phase of PDCA which is the phase where the implementation of the plan-phase is made. In this phase, the requirements and design of the product, which are covered in sections 7.2.1 and 7.3, are set. Processes regarding controls such as purchasing and production are covered in section 7.4.1 and 7.5.1.

– The third phase, check, includes processes and controls that ensure that the implemented plans and processes are operating as planned and intended. One important control is the effectiveness of the QMS, covered in section 8.5.1. Additional sections suited in the check-phase are complaint handling, 8.2.2, and analysis of data, 8.4.

– The final phase of PDCA is act, where the main factor is improvement. Thus, sections relevant to the act-phase are 8.5.2 and 8.5.3 about corrective and preventive actions.

Keep in mind that what sections should be included in various phases can vary from organization to organization. Thus, always evaluate how the organization operates and perform PDCA specifically for the organization. Preferably, use the PDCA in as many of the processes in the QMS as possible.

To simplify several of the plans and processes of ISO 13485 and to fulfill several requirements regarding life cycle process, usability and safety it is recommended to apply additional standards. IEC 62304 - Medical device software lifecycle process, IEC 82304 - General requirements for product safety on health software and IEC 62366-1 - Application of usability engineering to medical devices are all relevant to EHR manufacturers and should be applied in the operations of the organization. ISO 17791 can be applied for additional guidance on the previously mentioned standards and how to implement them.

All the mentioned processes and plans in the QMS must be documented. All the processes in ISO 13485 are governing documents that are generating the resulting documents, used in the technical file.

Quality management system

Section 4 in ISO 13485 regarding the quality management system holds the main requirements and principles of the QMS and thus operating as the foundation of the entire standard. Terms and definitions are set, as well as processes for documentation.

– Define the EHR system's and the organization's task, purpose and significance, section 4.1.1.

– Define the role of the organization.

– Define the internal and external context of the organization in which it operates. Examples of the context are market size, competition, technological changes and size of the organization.

– Identify tools to maintain the effectiveness of the QMS.

– Implement a process for validation of the software tool used for the QMS.

– Decide on how to control and document processes and documentation.

– Implement quality manual, section 4.2.1. The quality manual is based on the quality policy and quality objectives set in section 5. All the procedures as well as the structure of the QMS is to be documented in the quality manual.

Factors to keep in mind:

– The employees, as well as the management and board, must be aware of the organization's task, purpose and significance and thus work accordingly.

– The effectiveness of a QMS depends much on the ability of an organization to achieve planned results.

Management responsibility

In section 5 of ISO 13485 the responsibilities and organizational roles are to be set. This section is of large importance since the success of a QMS if often dependent on the commitment of the top management, thus the top management must administer evidence of their commitment. The main responsibilities of top management are:

– Assign a QMS representative from the top management.

– To implement a quality policy and quality objectives.

  – Define the quality policy, which is the commitment by the organization, the requirements from the regulations as well as requirements from the customers. The quality policy should be written in a way that spans over the goals of the entire organization.

- The key areas of quality policies include customer attention and relationship, leadership, continuous improvement, and creating and spreading the awareness of the QMS within the organization. Before it is possible to implement the quality policy, the organization must define the quality objectives, i.e the method of translating the quality policy into plans. Examples of quality objectives can be schedules, defined time frames for responses or results of processes. This is to be documented in the quality manual.

- To be responsible that the set quality objectives and quality policies are in accordance with the QMS to assure the effectiveness of the standard.

- To ensure that the customers' needs are met and maintained by making sure there is a process in place for this need.

- To ensure that there is a process to meet regulations.

- That roles and responsibilities are assigned and understood by all employees.

- To meet and handle the needs for resources.

- To holding accountability of the effectiveness of the QMS.

- To assess communication processes within the organization.

- To document continuous improvement.

Factors to keep in mind:

- The quality objectives should be specific, measurable, agreed, realistic and time-based, also known as S.M.A.R.T.

- The employees, as well as the management and board, must be aware of the quality objectives and thus work accordingly.

- Normative requirements according to the the relevant member state must also be met.

Resource management

In section 6, the resource management refers to three different types of resources, human, infrastructure and work environment. The work environment of a software company developing EHR systems is less complex, since it does not involve e.g sterile conditions or production lines. Instead, the work environment is more linked to the hardware available to produce software such as good PCs or good working spaces. The main requirements of section 6 are:

- Identify resources and competences.

- Provide training for personnel.

- Plan the resources.

Section 6.4.2 cannot be ignored even though it might not be relevant for the organization. Then justification on why it does not apply to the organization needs to be presented.

Product realization

Developing a software is an iterative process including the following steps: specification, design, coding, tests, delivery and validation. Section 7 covers planning of product realization, customer-related processes, design and development, purchasing, production and service provision and control of monitoring and measuring equipment. In the scope of section 7, several plans and processes are needed:

- Risk management plan. The regulatory requirements of risk management are specified in MDR, Annex I, chapter 1 in the general safety and performance requirements.

    - When implementing risk management, apply the standard ISO 14971 - Application of risk management to medical devices.

- Project management plan.

- Software development tool validation plan.

- Software design and development plan.

- Software design and development process.

    - Including design inputs, outputs, reviews, verification and validation.

- Software test plan.

- Product realization process.

- A plan for training of EHR system.

- A process for training and education of the EHR system.

- Software requirements specification.

- A plan for cyber security.

- A process for cyber security.

- Have a quality contract when outsourcing or using suppliers or subcontractors.

Not applicable for EHR systems: Section 7.5.2, 7.5.5, 7.5.7 and 7.6. Keep in mind that the topics in the standard that is not applicable to the device must be be justified in the documentation.

Section 7.4 regarding purchasing products is generally not relevant to EHR manufacturers. This section emphasize on evaluating the suppliers and keeping a high quality on components in order to work well with the device in question. There are generally no supplier products and purchases necessary in order to develop and create the software product, other than computers and other hardware tools to create and store code. However, purchase control is a mandatory part of the standard and needs to be dealt with and commented on. If the manufacturer believes the section is inapplicable to EHR-system in question, the reason(s) needs to be presented here.

Nevertheless, if the manufacturer uses consultants this can be considered as a purchased supplier product as well for the reason that the job from the consultant can affect the end result of the system. Therefore, It is important to evaluate everything that can affect the quality of the EHR system, both physical products as well as the competence of people involved.

Section 7.5 covers the production and service provision. Keep in mind that the production process of software is very different from a hardware device and does not include a typical production line.

Measurement, analysis and improvement

To succeed with the standard the processes for evaluation, improvement and control is important. Considering a software is continually improved, the maintenance of the software is fundamental. Following processes must be implemented:

- Complaint handling.

- Internal and external feedback.

- Demonstrate conformity.

- Communication and report to authorities.

- Corrective and preventive action.

    - The corrective action process can be dealt with in seven steps. The first step is to define the problem and describe it concretely. Second, define the scope of the problem and the magnitude of it. The third step is containment actions, which is the method to stop the problem. Fourth, find the root cause of the problem. Finding the root cause can be done by using several methods such as fish-bone diagrams. The fifth step is the corrective action plan, once the root problem is discovered it needs to be eliminated with this plan. Furthermore, implementing the corrective plan is the sixth step. Finally, the seventh step is to follow up on the entire corrective process and evaluate its effectiveness.

- Analysis of data.

- Internal audits.

- Monitoring and measurement of the quality management system.

Additional QMS requirements in MDR

Clinical evaluation, including PMCF

Where to find this in MDR:

- Article 61

- Annex XIV

Part A - Clinical Evaluation

Clinical evaluation is done to evaluate the safety of the device as well as to assure it performs as intended. The evaluation is done by generating, collecting, analyzing and assessing clinical data to determine the risk and benefit ratio associated with the use of the device. Clinical data is *"information concerning safety or performance that is generated from the use of a device* [3, p.18] *"*. Clinical data can be gathered from:

– Clinical investigations of the device or of an equivalent, i.e investigations involving one or more human subjects.

– Clinical experience of the device or of an equivalent

– From PMS, primarily in the PMCF.

To demonstrate proper equivalence see Annex XIV Part A clause 3.

Main steps to plan, continuously conduct and document a clinical evaluation (Annex XIV):

1) Establish and update a clinical evaluation plan, detailed plan in Annex XIV Part A clause 1.

2) Clinical Data:

    a) Identify available clinical data.

    b) Assess all relevant clinical data.

    c) Generate additional clinical data necessary.

    d) Analyse all relevant clinical data.

Table 5.1: How to generally approach a clinical evaluation of a software in three steps, adapted from [85]

	Valid Clinical Association	**Analytical Validation**	**Clinical Validation**
Objective	To examine that the output of the software has a valid clinical association to the clinical condition.	To provide evidence that demonstrates the software is faultless and constructed correctly, i.e generate accurate, reliable and precise output data from the input data.	To establish that the output of the software is clinically meaningful and achieve the intended purpose.

When performing a clinical evaluation on EHR-system modules where there is no direct impact on the patient, it is more about providing evidence that the system is not unbeneficial and to present its availability. Benefits can be found and presented through:

- Literature studies and usability research.

- Information given by clients regarding the system.

- Assessment of safety, look into vigilance-cases.

Part B - Post-Market Clinical Follow-up, PMCF

PMCF is a continuous process that updates the clinical evaluation and is done by proactively collecting clinical data from the use of the system and then asses that data. The objective is to affirm safety and performance of the system from the beginning to the end of the system's life-cycle.

The methods and procedures of the PMCF is documented in a PMCF plan, detailed plan on what to include at least in Annex XIV Part B clause 6.2.

Important documentation:

- Clinical Evaluation Plan (CEP), Annex XIV Part A clause 1(a).

- Clinical Evaluation Report (CER), Article 61 clause 12. Presenting the result of the clinical evaluation.

- PMCF plan, Annex XIV Part B. Presenting the method of the PMCF process.

- PMCF evaluation report. Presents the results from the PMCF. Article 61.

Setting-up, implementation and maintenance of a post-market surveillance system

Where to find this in MDR:

- Chapter VII Section 1 Article 83, 84 and 86.

Post-market surveillance system is activities carried out in a proactive and systematic approach to gather, record and analyze data regarding the quality, performance and safety of the software, as well as to take corrective and preventive action. The data gathered should be used:

- To update:

    - The risk management.
    - Design and manufacturing information, usability.
    - Clinical evaluation.
    - Summary of safety and clinical performance, Article 32.

    - Needs of corrective action.
    - Where safety, usability and performance can be enhanced.
    - Reportable trends.

Important documents:

– Post-Market Surveillance Plan (PMS plan), Article 84 in accordance with Annex III clause 1.1. For which the PMS system is based on.

– Periodic Safety Update Report (PSUR), Article 86. Presents the results and conclusions from analyses of the post-market surveillance data gathered based on the post-market surveillance plan.

Processes for reporting of serious incidents and field safety corrective actions in the context of vigilance

Where to find this in MDR:

– Chapter VIII Section 2 Article 87

The manufacturer shall report serious incidents involving the software and any safety corrective action, Article 87. The reports of these incidents and actions shall be submitted through an electronic system set up by the Commission, Article 92.

The time frames on reporting these events for the manufacturer are:

– For a serious incident: no later than 15 days after awareness of the incident.

– For a serious public health threat: no later than 2 days after awareness.

– In the event for death or unanticipated serious deterioration: no later than 10 days after awareness.

In addition, in the context of vigilance, the manufacturer shall conduct trend reporting when there is a significant increase in non-serious incidents and unwanted side-effects as this could impact risk-benefit analysis, Article 88. The trend report is submitted via the electronic system, Article 92.

Immediately after a reporting of a serious incident the manufacturer must initiate an investigation to analyse the incident, compromising a risk assessment of the incident and safety corrective action, Article 89.

Important documents:

– PMS plan, presents methodology on how to manage the incidents in the trend report.

Verification of the UDI assignments to all relevant devices and ensuring consistency and validity of information provided

Where to fins this in MDR:

– Article 27

– Article 29

– Annex VI Part C

UDI stands for "Unique Device Identifier" and is a series of characters that is used to identify devices. To have a UDI system allows for traceability of devices on the market as well as better monitoring by competent authorities. For further details on the UDI system, see Annex VI Part C.

The manufacturer shall assign an UDI at the system level of the EHR-software, in accordance to Article 27 clause 2 and Annex VI Part C clause 6.5. The UDI comprises an UDI device identifier (UDI-DI) and the UDI production identifier (UDI-PI). Whenever a modification changes in the EHR-system a new UDI-DI shall be established, see details in Annex VI Part C clause 6.5.2, whereas minor alterations require a new UDI-PI and not a new UDI-DI, see details in Annex VI Part C clause 6.5.3. In addition, information presented in Annex VI Part B shall be submitted as well as transferred into the UDI database, when established.

The manufacturer of the software shall place the UDI according to Annex VI Part C clause 6.5.4.

The Commission shall establish an UDI database that is made public where information regarding devices on the market is collected, stored and validated.

Identification of applicable general safety and performance requirements and exploration of options to address those requirements

Where to find this in MDR:

– Annex I

In order to establish compliance with the regulatory, compliance with the 23 General Safety and Performance Requirements is the keystone, they are found and set out in Annex I.

Be aware that some of the clauses in each GSPR will be non-applicable to EHR-systems, such as requirements regarding sterilization and implantable devices.

Risk management

Where to find this in MDR:

– Annex I clause 3

To keep in mind while implementing a risk management system for software is the cause and consequences of hazardous events. When the device in question is a hardware the parts of the device might get worn out over time and break, this is fixed by using replacement parts. The cause of an event lies, for the most part, in the design of the software, and the only way to mitigate the risks is to change the design of the software. Therefore, it is recommended to develop the risk management in parallel with the software development.

ISO 14971 is a standard that sets out a risk management that manufacturers can apply. It is also recommended to look through and see over additional concepts and activities mentioned in IEC 62304 that target software.

Document V: Technical Documentation

The technical documentation needed in order to be compliant with MDR with the route IX process are documents generated from the governing documentation of the QMS. Keep in mind that the technical documentation must be updated continuously. The documents mentioned in this result is a recommendation on documents relevant in the technical file to EHR manufacturers.

The technical documentation is based on Annex II and Annex III. Annex II consists of six sections covering the following areas. After each area mentioned and explained, a set of recommended documents in that area is presented. See Appendix A.2 for full recommended table of content for the technical documentation.

1. Device description and specification, including variants and accessories.
   This section is about introducing the device and providing an understanding of the EHR system and its use in healthcare.

   1. **Device description and specification, including variants and accessories**

      1.1. Device description and specification
         1.1.1. Product name, full description of the device and intended users
         1.1.2. UDI
         1.1.3. Intended use and patients
         1.1.4. Principle of operation
         1.1.5. Product qualification and classification
         1.1.6. Novel features
         1.1.7. Accessory devices description
         1.1.8. List of configurations of the device
         1.1.9. Description of key functionalities and modules of the software
         1.1.10. Products photos and usage photos
         1.1.11. Technical specification
      1.2. Reference to previous and comparable products
         1.2.1. Previous generations of the device
         1.2.2. Similar devices on the EU market

Figure 5.3: Recommended table of content: Chapter 1 in technical documentation

2. Information to be supplied by the manufacture.
   This section covers the labeling, packaging and instructions of use. Note that the labeling and the user requirements shall be available in the languages accepted in the Member States where the device is envisaged to be sold.

2. **Information to be supplied by the manufacturer**

    2.1. Labeling of the device

    2.2. Legend of symbols

    2.3. Instructions for use

    2.4. User requirements, including contraindications, use environment, operate of use manual, warning, indication.

    2.5. Training materials for the user

    2.6. Installation and service instructions

    2.7. Marketing materials

Figure 5.4: Recommended table of content: Chapter 2 in technical documentation

3. Design and manufacturing information.
    This section provides information on how the EHR system is built by providing the design and architecture of the software.

    3. **Design and manufacturing information**

        3.1. Software development plan and process

        3.2. Software architecture and detailed design

        3.3. UML diagram

        3.4. Spec sheet including component specification

        3.5. Software requirements specification

        3.6. Software validation and test plan

        3.7. Final product testing

        3.8. User interface specification

        3.9. Suppliers and sub-contractors

Figure 5.5: Recommended table of content: Chapter 3 in technical documentation

4. General safety and performance requirements.
    This section constitutes the information and documentation to demonstrate the fulfillment of the 23 GSPR. Furthermore, one must also explain why some GSPRs might not apply. For EHR systems, the following GSPR are not applicable: Section7, Section 10-13 section 14.2 a, c, e, section 14.3, section 16, section 18.2, section 18.3, section 18.4-18.7, section 19-21, section 23.2 e, l, n, o, r, s, section 23.3, section 23.4 l, m, n, p, r, t, u and aa.

    4. **General safety and performance requirements**

        4.1. Applicable General Safety and Performance Requirements

        4.2. Methods to demonstrate conformity

        4.3. Declaration of conformity

        4.4. Applied standards

        4.5. Evidence of conformity with harmonised standards

Figure 5.6: Recommended table of content: Chapter 4 in technical documentation

5. Benefit-risk analysis and risk management.
This section provides the necessary benefit-risk analysis as well as the results and solutions of the risk management.

> 5. **Benefit-risk analysis and risk management**
>> 5.1. Risk management plan
>> 5.2. Benefit-risk analysis
>> 5.3. Risk solutions, controls, measures and verification
>> 5.4. Risk management report
>> 5.5. Risk acceptance matrix, pre and post risk mitigation

Figure 5.7: Recommended table of content: Chapter 5 in technical documentation

6. Product verification and validation.
This section covers the results of the validation and verification processes such as software validation or integration tests. These validation and verification tests shall demonstrate the conformity of the EHR system.

> 6. **Product verification and validation**
>> 6.1. Pre-clinical and clinical data
>>> 6.1.1. Usability file
>>> 6.1.2. Formative User Interface Evaluation Report
>>> 6.1.3. Summative User Interface Evaluation Report
>>> 6.1.4. Results from static code analysis, code reviews and unit tests
>>> 6.1.5. Integration tests
>>> 6.1.6. Software system tests
>>> 6.1.7. List of unknown anomalies in software
>>> 6.1.8. Results from design calculations
>>> 6.1.9. Stability and duration tests
>>> 6.1.10. Performance over volume and load
>>> 6.1.11. Software verification and validation
>>> 6.1.12. Clinical evaluation plan
>>> 6.1.13. Clinical evaluation report
>>> 6.1.14. PMCF plan
>>> 6.1.15. PMCF report
>>> 6.1.16. Software release protocol
>> 6.2. Additional information required in specific cases
>>> 6.2.1. Proof of compatibility with other devices

Figure 5.8: Recommended table of content: Chapter 6 in technical documentation

Annex III on technical documentation declares the requirements on post-market surveillance and consists of one section covering the PMS plan and the PSUR.

Not applicable requirements

Several requirements featured in Technical Documentation Annex II are not applicable when CE marking a software. The items presented below are recommended to exclude from the final technical documentation due to being non-relevant for software.

- **Device description and specification, including variants and accessories**

    - Device description and specification

        - A description of raw materials

- **Product verification and validation**

    - Additional information required in specific cases

        - Device incorporating substance, as an integral part
        - Device utilising tissues or cells of human or animal origin
        - Devices that are composed of substances or combinations of substances
        - Devices containing CMR or endocrine-disrupting substances
        - Sterile Devices or with a defined microbiological condition
        - Devices with a measuring function

Document VI: Conformity assessment

The conformity assessment is performed by a notified body and is based on the Quality Management System and the Technical Documentation that is compiled. It is up to the organization to chose a notified body within the EU. Keep in mind that the waiting period before the notified body is available can be long, thus it is recommended to contact the notified body of choice months prior to the assessment.

In the scope of MDR, there are new requirements incorporated in the QMS and technical documentation that are important to meet.

– There must be an assigned person responsible for regulatory compliance, PRRC, within the organization. The PRRC must either have relevant education such as a university degree in a relevant area combined with at least a year of working within the subject, or professional background and competence in regulatory affairs for at least four years. Further requirements are specified in article 15. If the organization is classed as a micro or small enterprise according to Commission Recommendation 2003/361/EC, there are other requirements (Article 15, section 2).

– The organization must register the device in EUDAMED (once available). The registration in EUDAMED must contain the information specified in Annex VI, part A, section 2. The following requirements are not applicable:

– 2.6, 2.7, 2.8, 2.9, 2.10, 2.12, and 2.14.

Once the EHR system is CE marked there will be continuous audits to ensure compliance with the regulation. There will at least be one planned audit every 12 months of the QMS, PMS and technical documentation performed by the notified body. The notified body will also perform at least one unannounced audit every five years.

Keep in mind that if the EHR system undergoes a significant change the organization must contact a notified body which must perform an assessment again to evaluate the change.

Discussion

6.1 Discussion of Results

The aim of this project was develop a model for how EHR manufacturers are to adapt their regulatory processes to fulfill MDR. The resulting process description, Figure 5.1, provides information for EHR manufacturers to be compliant with MDR, the main requirements a recommended order of execution. Since software is not a physical device the process description is based on the assessment presented in Annex IX (route IX) where the software is evaluated according to the implemented QMS and the compiled technical documentation. Since the scope of this project is broad and complex, the process description is not developed for a certain type or size of EHR manufacturer. The approach that the process description is providing is rather generic. Thus, the results can be of use as a first guidance for a small startup as well as for a large organization that is currently compliant with MDD.

The main findings of this project are the steps in the process of an EHR manufacturer to achieve the CE mark, the order of them and the content of the documents attached to each of the steps. This section of the report will first present a further discussion on each of the steps in the process description as well as the intention of use. Then, an analysis and further discussion on the mentioned areas of unresolved issues and concerns in the presented checklist are layed out.

The results is within the area of interest to all SaMD manufacturers as still a lot of uncertainty remains regarding the implementation of MDR. Even though the results can be used for various medical software organizations, it is specifically useful for small and medium sized companies, as large companies generally have various competences within the company as well as more resources to spend on expert consultants when needed to fulfill MDR. Therefore, since the new regulations, specifically the upgrade in risk classification from class I, will imply an increase in costs it will especially have a large impact on small and medium sized EHR companies.

While the information provided in the process description is considered by experts to be reliable there is no warranty to its completeness and full accuracy for every EHR manufacturer. It is not sufficient for EHR manufacturer to only rely on the results of this thesis to ensure complete compliance with the new regulation. As stated in the process description, compliance with the QMS, ISO 13485, can only be guaranteed when following the standard itself. The same applies for MDR as a whole, therefore, to ensure complete compliance with MDR and be fully guaranteed

that all requirements set on the manufacturer by MDR achieved, it is recommended that one must control compliance with the regulation itself before undergoing the assessment for the CE mark.

The process description is a new guidance that has not previously existed on the market. It provides an overview of the path to a CE mark for an EHR manufacturer that has not previously been clearly mapped out and illustrated. By proposing practical processes the process description concretize the complex process towards MDR fulfillment for an EHR manufacturer and thus makes it accessible for anyone operating in the regulatory field of EHR systems to use.

6.1.1 Discussion of Process Description

Division and definition of modules

One of the main findings was that there are two ways to proceed with the certification process for an EHR system. One way is to CE mark the entire system as a whole, the other is to CE mark each qualified module separately, as stated in Document I. The differences between the two options will impact the process of receiving the CE mark. If the manufacturer chooses to certify each module separately, it will probably imply heavier technical documentation as each module must be documented as its own medical device. On the other hand, if the manufacturer chooses to certify the system as a whole there might be modules that are not qualified as a medical device that then needs to be documented, as they are a part of the whole system. However, it is still not clear what the main differences between the two paths are. Since EHR systems often are composed of modules there is a need for more information and clarification regarding this from the European Commission.

In addition, if the manufacturer chooses to certify the system module by module, it is crucial, according to MDR, to prove that the modules are not dependent on or affected by each other in a way that could alter the classification set on each module. Critique regarding this is made due to the near impossibility of each module being a complete stand-alone software module, not influenced or affected by the system or other modules. An EHR system is a complex network of systems and must have modules interacting with each other to some extent.

As for now, it is only the company itself that can decide whether to certify each module, or the system as a whole, depending on what suits the organization best. However, the manufacturers of EHR systems are seeking clarifications and guidance regarding this.

Qualification and Classification

The results suggest to first qualify the defined modules and then classify them as presented in Document II and III. The decision of where to place these two steps unfolded organically as the qualification needs to be set and investigated, in order to then classify what has been qualified.

Though the MDCG 2019-11 guidance was released in October in 2019, presenting qualification and classification guidelines for software, there is still a need for further clarifications for medical software companies in Europe. The release of the document created a confusion in the medtech software field, as it does not limit Rule 11 in MDR to standalone software bur rather expanding it to cover integrated software as well. Releasing a guideline that leads to further confusion can be perceived counter intuitive rather than accomplishing its sole purpose that is to deliver more clarity.

The qualification tool, Figure 5.2, is adapted from the MDCG 2019-11 guidance and therefore reliable for the manufacturer to use, as is the provided classification process. However, it most certainly will be more documents and guidelines released in the near future regarding qualification as well as classification for software. This creates a risk for uncertainty and confusion. There is a responsibility laid on the manufacturer to be aware of the current state and to be up to date with the recent released recommendation on how to qualify software with a more or less medical purpose. By only reading the original MDR 2017/745 the scope might seem incomplete with a lack of details.

The critique of MDR 2017/745 as well as the MDCG guidance documents regarding software lacking consistency, clarification, and that the documents leaves room for interpretations, points at the fact that this can lead to safety hazards. The ambiguity that current EHR-manufacturers are experiencing while working towards being MDR compliant needs to be acknowledged. Concerns have been raised that this ambiguity might even make smaller companies more prone to miss important requirements as these might not have the time, competency or money to ensure complete regulatory fulfillment.

QMS

The only way to be compliant with a standard is to follow the standard itself and implement all the mentioned documents and processes. Thus, to not repeat ISO 13485 in the process description, Document IV presents suggestions on the content and implementation of a QMS specifically for EHR manufacturers. The suggestion is fairly general and gives an overview of what is important in each section of the QMS. The PDCA approach which is mentioned as an appropriate way of working with the QMS is not a requirement of MDR. However, one of the requirements of a QMS is continuous improvement and thus PDCA is a good way of working.

Although Document IV aims to simplify the implementation and fulfillment of QMS for EHR manufacturers, implementing an entire QMS is a complex process that requires broad knowledge and experience. The complexity of implementing a QMS, especially since ISO 13485 is not harmonized, will require a heavy workload and a lot of resources from the organization. EHR manufacturers will require more than the information presented in this report in order to fully implement ISO 13485. However, the structure and overview that Document IV presents makes it suitable for educational purposes when learning about QMS, or as a checklist to assure that all the main areas and requirements are covered.

For the reason that there still is no harmonized version of ISO 13485 according to MDR, it is crucial to be extra careful when implementing ISO 13485 to make sure that the requirements of MDR are met. Considering this, the idea of adding the document "Additional QMS requirements in MDR" arose. The idea is to highlight procedures important for an MDR approved QMS. Thus, the second part of Document IV refers to these complementing requirements of MDR that are not met by only implementing ISO 13485. For instance, the requirements on PMS and clinical evaluation are not fully met by only implementing QMS according to ISO 13485. To implement and perform clinical evaluation on a software is not as straight forward as a typical hardware medical device, as presented in Table 5.1. Since a software can not be tested in direct contact with a human, it requires more creative ways of working. Thus, clinical evaluation of a software focuses on substantiating that the software is clinically meaningful and accurately constructed, which can be hard to demonstrate properly.

However, the ultimate helping tool to implement a fully covered and perfect QMS according to MDR will be the ever so wished for MDR harmonized QMS standard. But that, is yet to come.

Technical Documentation

The technical documentation, Document V, contains a suggestion of all relevant subjects regarding documentation for EHR manufacturers. Figure 5.3, Figure 5.4, Figure 5.5, Figure 5.6, Figure 5.7 and Figure 5.8 display a table of content for each chapter for the documentation. To compile and implement the documentation will require knowledge and competence in the area to comprehend the content in every document. Since the documents holds a variety of information, from information regarding the company to detailed description of the architecture of the software, it might even require competent personnel from various areas of the company to compile the documentation properly. However, it is important to compare the technical documentation compiled to the requirements of MDR to assure fulfillment.

Even though it requires high competence and knowledge within the area to implement the technical documentation, the technical documentation presented in Appendix A.2 can be used as guidance and objective before going in to the specific details.

To simplify the work of compiling the technical documentation, it is important for the company to write and compile documents along with the development of the product and to compile the resulting documents of the QMS. If one does not write and compile along the way, it will be very hard and time consuming to do so all at once.

Declaration of Conformity

During the literature study the apprehension was that the information given in MDR about what to include in the declaration of conformity was straightforward and therefore no further explanation or clarification was needed in the process description. This apprehension was confirmed and shared by the panel of experts

during the evaluation of the process description, thus no document was attached to the declaration of conformity step.

Conformity Assessment

Shortage of Notified Bodies
One main finding during the literature study was the extreme shortage of notified bodies in combination of the increasing demand for notified bodies. The organization releasing the device can choose freely which certified notified body that will perform the assessment. However, due to the new regulations there has been very few notified bodies certified to perform the assessments under MDR which has lead to a shortage of notified bodies.

The reason for this shortage is partially due to a higher demand of notified bodies and a "survival of the fittest"-mentality where only companies with access to great finacial means can survive and become MDR certified notified bodies. To become a MDR certified notified body is financially demanding which forces notified bodies to shut down. In addition, the strict MDR classification rules, first and foremost for medical software, are making the majority of software on the medtech market to move from class I, where no notified body is necessary, to class II where the involvement of a notified body is a must. This is increasing the demand of MDR certified notified bodies.

As of March 2020, there where only 11 certified notified bodies in Europe that could perform assessments under MDR. Thus, the shortage of notified bodies relevant to all medtech companies in Europe that will need to undergo an assessment will lead to long waiting periods for assessments. The waiting periods are said to be several months which means that the companies must contact a notified body prior to being ready to undergo an assessment. This means that the companies must plan and estimate how long time they will need to be compliant with MDR and undergo the assessment. Still, many companies will likely have to wait months before being able to undergo an assessment and CE mark their device.

This unwanted, however for now inevitable, waiting period might inhibit new players on the medtech market to enter as well as putting existing companies on the market on hold as they wait for a MDR CE mark. If the waiting period is too long, devices with only a MDD CE mark need to be withdrawn from the market which could lead to severe and catastrophic healthcare consequences.

PRRC
One of the new requirements presented in MDR is a person responsible for regulatory compliance, PRRC. The PRRC will thus hold heavy responsibility making sure that the EHR system is fulfilling the regulation. Not only is the PRRC responsible, but the PRRC will also receive eventual consequences of not fulfilling the regulation, which in worst case scenario can imply prison. Even though the case of prison is very unlikely, being at risk for that type of consequence might implicate that it will be hard to find a person that is both qualified and willing to take on that position. Furthermore, being the sole responsible person for regulatory compliance is a large responsibility.

Prior to MDR, the responsibility of regulatory compliance was not assigned to a single person but to the organization itself. Due to the change in responsibility there might be a risk that organisations, or the top management, starts to give regulations and quality less priority since the main responsibility will lie with the PRRC.

Even though it could be problematic leaving the regulatory responsibility with one person, it could also have some advantages. To delegate responsibilities within a group is an effective method to get things done. Now that a person is assigned the responsibility of regulatory compliance it can no longer be overlooked. Thus, the quality of the regulatory work might increase when introducing the concept of a PRRC, leading to safer products for patients.

Usage of Process Description

The strength of this process description is that it targets a broad spectrum of possible users. The difficulty lies in the balance of giving enough information and details to make the process description helpful and relevant to an EHR manufacturer, but still keeping it sufficiently general in order to target small, middle sized and big companies within EHR manufacturing wherever they are in their CE marking process. To find this desired balance required en extensive amount of literary research as well as carefully prepared questions to the interviews. However, to make the process description even more suitable for all types of EHR manufacturers more interviews must be done with all the different sizes that are in different stages of their CE mark certification process. A more in depth analysis on how a better balanced process description could be achieved using a more extended methodology is presented under Discussion of Methodology. Moreover, the perception of EHR systems differs within Europe. The process description is now based on interviews conducted with Swedish EHR manufacturers. The result might have been different if the interviews had been held with manufacturers in Southern Europe where the perception of EHR systems as a medical device differs. Swedish EHR manufacturers qualify their EHR systems as medical devices, whereas In Southern Europe there is a tendency to not qualify EHR systems as medical devices.

Part of the feedback given during the evaluation was that this process description is very suitable education material for beginners in the field of not only EHR manufacturing, but medical software companies in general. In addition to that, the process description will also be helpful in giving an overview of the process for everyone in the organization. This would be of benefit when the issue of engaging everyone at management level of an organization in the regulatory process. The regulation of a medtech company is a fundamental building block, and should therefore engage the management. However, due to its complexity this is a hard task. By using this process description and making the process more hands-on by visualizing it in a flowchart and writing the documents more reader-friendly, this can be achieved.

6.1.2 Discussion of Checklist

Significant Change

As stated in corrigendum II, the delay to fulfill MDR for devices being upgraded from class I to a higher classification is beneficial for manufacturers of EHR systems. The upgrading from class I involves an increase in work, money and resources for the manufacturers since there will be additional requirements. However, one of the prerequisites of being enclosed by corrigendum II is that the device can not undergo a significant change. Like any software, an EHR system is never completely finished. EHR systems will always undergo updates to eliminate bugs, make the system more efficient, make the system safer, or improve the system. The iterative way of working with an EHR system is problematic in regards to the concept of not being allowed to undergo any significant changes since there is no clear rule on what a significant change is and what updates are allowed to make.

The statements in the latest guideline, released in March 2020, will allow EHR manufacturers to eliminate bugs and improve safety such as cyber security. However, it is not allowed to change any interface or data presentation, even though that might be a way to minimize risks associated with faulty usage of the software. In addition, it is not allowed to change any algorithms, even though that could also be a safety precaution. Thus, the complexity and unclarity of significant change is problematic for EHR manufacturers and it can be hard for the manufacturers to live up to the prerequisites. To have to undergo a new certification process every time the EHR system is updated, usually about four times per year, would cost the companie a large amount of money and resources that could lead to bankruptcy.

The issue of requirements regarding systems evolving over time will become more important with the increased usage of CDS systems within healthcare that rely on machine learning. It will be difficult to decide whether a system is different enough to require reassessment as well as how to judge this. This raises questions regarding how regulation will handle systems that are improved by machine learning. Continuously learning systems will oppose the concept of being re-certified for every significant change as it will be too time consuming and financially stressful.

The Pros and Cons of Following a Directive Compared to a Regulation

The European medtech market is transforming from following a directive to following a regulation. The change of law type per se affects the implementation of it and the response towards it.

The directive is transposed into national law by each member state, how this is to be done is up to each member state. The freedom of choosing the method will benefit the adaptedness of the law. Each member state will choose an appropriate way to implement the directive that will benefit the state itself and their way of working. By making competent authorities, in each member state decide on how to achieve the goals of the directive, the implementing method will be customized and give the manufacturer a feeling of that the decision-making is "closer to home". This way the competent authority is freer in releasing clarifying documents and guidance

on the decided processes, since they are the originator of that national law. If confusion and a feeling of ambiguity arise among manufacturers, the competent authority can, hopefully, easily clear this up without having to raise the issue in the European Commission, causing time delays.

However, making the medical device law into a regulation has its advantages as well. To create a unified European medtech market, a unified law controlled by the EU is to prefer. By making the law a binding act directly in each member state and applied in the same manner, strengthens the affiliation in the EU.

The issue of the transition from a directive to a regulation arises when looking at, for example, software used in medical environments, such as EHR systems. Software has not been covered to the same extent in MDD as it is now in MDR, which has made room for national notions of whether EHR systems should be classified as a medical device or not. These different opinions are now colliding when trying to stand under the exact same laws.

A unionized law strengthens the EU market. However, considering the ambiguity manufacturers have experienced by trying to apply the regulation and the critique of national competent authorities in each member state being absent and not participating as expected, the change of law has not yet been effective. The lack of effectiveness could also be shown in the need for the released corrigendum, making room for a longer transformation period for companies increasing in classification. The lack of notified bodies, companies falling behind in their regulatory processes and the substantial confusion among manufacturers, suppliers, importers, distributors and other stake holders indicates that a better implementation process would have been needed.

Inhibition of Medtech Innovation

The new requirements on medical device software under MDR are much stricter and complicated than the previous legislative. The way that MDR is compiled is appropriate for hardware devices that are created under much more typical production manner. When creating a software, it is an iterative process and an agile way of working which means that the software is never completely finished. Thus, the rule of significant change will inhibit development and improvement of the software since it only allows minor changes. Hospitals manage and control a multitude of systems and devices while caring for patients, which makes hospitals a complex environment. Due to restrictions on significant change, the EHR manufacturers are limited in making adjustments on the software to make it more efficient in the hospital environment, and even changes to reduce identified risks. The new regulation might affect patients in a negative way in the long run since appropriate and even crucial changes can not be made after it has been CE marked. This implies that MDR inhibits improvements that could enhance the EHR system and make the healthcare better, safer and more efficient for patients as well as healthcare workers.

The upgrade in classification for medical device software will lead to large adjustments in the organizations due to the additional requirements. These adjustments will require time, new competences and financial resources. It is financially exhaust-

ing to undergo the necessary assessments and the work prior to the assessments will be time consuming and require expertise within quality and regulatory area to fulfill the new requirements of MDR. All these efforts needed can result in less resources to spend on innovation and thus lead to slower innovation rate. In addition, the new requirements of MDR might seem to large for startups to take on and can thus lead to fewer startup companies within medical device software industry. Moreover, it could lead to inhibition of the innovation and the future of medical technology.

Even though the rigidity of MDR might inhibit medtech innovation, the purpose of having strict requirements is to strengthen the safety of devices and thereby ensuring safety for patients and healthcare personnel. Since the use of software within healthcare is increasing, it is important that the legislation address this and is adapted to the current development of medical devices to ensure safety for the patients exposed to the devices. The demands of MDR such as more transparency and stricter requirements on software used in healthcare, will lead to safer care for patients.

6.2 Discussion of Methodology

A qualitative method was chosen due to the large quantity of complex information that needed to be closely reviewed and understood. The approach was to first create a foundation of knowledge within the field as well as to get get an understanding of the state of the art. This was done through extensive literature studies. It was a significant task to create this understanding and the basics in the regulatory field as well as to grasp the issue at hand. The complexity of the information and the formality in the released documents made the literature study heavy. Due to the recency of this topic there was a lack of material, other than the official documents released form the European Commission, blog posts and chat rooms. Therefore, it might have been beneficial to have had an initial meeting with an expert generalist in the field of medtech regulation in the beginning of the study. This meeting would have helped in giving some basic knowledge of the area and thus facilitated the first stages of the literature study.

The next step was to understand what the EHR manufacturers wanted out of the process description, and what information they were missing from what was provided by authorities. This was done by going to seminars, conducting the initial meetings with the interviewees as well as the following interviews. This study conducted two interviews with two different EHR manufacturers. Even though both interviews had the same set of questions, the line of the interviews and the main focus differed from each other. The first interview had a tendency towards quality management system and the second towards the technical documentation. The direction of tendency was initiated and motivated by the interviewees, but fairly controlled and supervised by the interviewers. The trend of the interviews was welcomed as the interviewee had more to say within the areas of interest. This way, the interviews complemented each other very well. This shows that event though both companies are going through the same journey of certifying their EHR system under MDR, their competencies in different fields varied, as well as the perception of what is most important in terms of fulfilling the new regulation.

For the process description to have been more applicable to a broad range of EHR manufacturers additional interviews should have been held. These additional interviews should preferably have been carried out with different types of manufacturers in regards to size, experience, competence and financial means to get different inputs. It would also have been beneficial to let the interviewees be manufacturers in different stages of the CE marking process. By doing this the interviewees could therefore have contributed to what they are missing at their stage in their CE marking journey.

Furthermore, additional interviews should have included participants with various regulatory experience to try and make the process description usable for a broad range of users with various knowledge and experience. This will be even more important if the process description were to be used in educational purposes at EHR companies where persons new in the field will learn from it.

Even though the first stages of the approach were heavy and time consuming the amount of information gained was necessary and beneficial in the later stages. Without the heavy literature study the interviews would not have given as much information. This due to the level of expertise among the interviewees. Without proper basic knowledge within the area, details and other specifics that were wanted from the interviewees would have been difficult to get. The entry level of even beginning to understand the area of medtech regulation is high, which makes it hard to undertake and therefore required the extensive literature study beforehand.

The coronavirus outbreak affected the approach of the study. The interviews had to be held via video link instead of meeting in person. This might cause the interview to feel less personal with less freedom of expression. A person's way of expressing themselves can get limited, misunderstandings are more likely as well as distractions that can affect the quality in the interviewees' answers. However, the initial meeting with the interviewees had been made in person and thereby already established a personal connection with the interviewees. By that means, to hold the second meeting with the interviewees, the interview, via video link did not feel as distanced. To handle the increased risk of misunderstandings and distractions there was always the opportunity to lengthen the interview as well as to schedule an additional meeting to continue the interview if needed. The first interview stuck to the initial time plan, a two hour interview. However, the second interview did not manage to fit into the scheduled two hour interview. Therefore two additional interview sessions, one hour each, were conducted.

6.3 How to deal with the unresolved issues

As stated in the checklist, there are some unresolved issues regarding requirements set on software manufacturers by MDR that needs further clarification. These issues are responsibilities for the European Commission to solve and clarify. According to the interviewees of this thesis, there is nothing that the EHR manufacturers can do to deal with these issues. EHR manufacturers continue to work agile and continuously improving the software, even though significant change is a big concern.

The prospect of the EHR manufacturers is for the European Commission, and other competent authorities, to deal with these issues and resolve the concerns as time goes on and complaints cannot longer be overlooked.

Regarding the issue of going from a directive to a regulation, the competent authorities of each country, such as the Swedish Medical Products Agency, should do more in order to aid the companies in their countries. Competent authorities should communicate with the European Commission in order to release guidelines However, it is up to the EHR manufacturers and other medical software companies to remember and focus on the purpose of their businesses and therefore always strive for continuous improvement in order to not inhibit medtech innovation.

6.4   Future Work

In order to improve the process description and thereby facilitate the process of CE marking for EHR manufacturers three areas needs further work.

The first area is further work with the process description in terms of additional interviews. By increasing the amount of interviews from various types of EHR manufacturers that are in different stages of their CE marking process the process description can be improved. More information and details can be added. Additional interviews could also benefit a broader variety of end-users.

The second area is the awaited documents that are to be released from the EU. There have been several documents, clarifications, guidance and corrigenda that have been released, and there is more to come that can affect the market. The most anticipated is the upcoming harmonized standards that can facilitate the CE marking process and ensure compliance with MDR.

Finally, the third area is to acknowledge, accept and meet the demand for further clarifications from medical software manufacturers. Clarifications regarding previous released corrigenda and guidance such as the restriction of significant change must be made. Moreover, clarifications on how to continue an agile work approach even under MDR as well as how a clinical evaluation should proceed for a software is requested. Additional guidelines from authorities such as the Swedish Medical Products Agency or the European Commission itself must be provided to EHR manufacturers in order facilitate software development within medical technology.

Conclusions

The new medical device regulation, MDR, will imply large changes for many medical device manufacturers, especially for medical software manufacturers. Today EHR manufacturers work with harmonized standards to ensure conformity with the current legislation MDD where most software are classified as a class 1. However, there are no harmonized standards pursuant to MDR and the regulation presents strict requirements on embedded and stand alone software within healthcare, resulting in a higher classification. Therefore, EHR manufacturers must classify their systems modules as class IIa, IIb and some modules as class III according to MDR. Due to the upgrade in classification EHR manufacturers must undergo a more complex route in order to receive the CE mark. EHR-manufacturers need guidance that can simplify the road to compliance with MDR.

As the project has demonstrated, EHR manufacturers may use a step-by-step process description tool as a basis to develop a process for regulatory fulfillment. The process description presented in this project functions as a helpful tool towards regulatory fulfillment. Other than the purpose of providing an overview of a step-by-step CE marking process, the process description can serve as a checklist for the experienced to make sure everything is covered as well as to educate beginners in the regulatory field. By solely using the process description for regulatory fulfillment for EHR systems according to MDR, complete compliance with MDR cannot be guaranteed.

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Appendix

A.1 Interview Questions

A.1.1 Part One - Process Description Flow Chart

1. Do you agree with the process description in general? Have we forgotten something or should some of the steps switch order?

2. Did you design any kind of process description in order to fulfill MDR? In that case, how did you frame it and how did you proceed?

3. What other guidance have you used?

4. Did you start with article 10 to assure fulfillment of MDR?

A.1.2 Part Two - QMS and Technical Documentation

QMS

1. How have you proceeded to implement 13485? Did it only require you to make updates from 9001 or did you have to start over?

    1.1. How do you implement 13485 from the beginning?

2. Have you identified anything in 13485 that does not live up to MDR? Or is there something missing?

3. Are there parts in the QMS and the technical documentation that overlaps? Does the documentation requirements of the QMS refer to the content of the technical documentation?

4. Are there any guides or other resources available in order to implement all the processes needed in a QMS? For example, how does one know how to document processes of internal communication or work environment?

5. What parts of the QMS are the hardest ones to implement? Why?

6. Is it harder to implement a QMS for a software?

7. What parts of the QMS can be disregarded since an EHR system is not a physical product?

8. What is the main factor in order to succeed to work according to the QMS (or other standards) and not just document processes due to the audit?

9. How does one perform clinical evaluation on an EHR system? How are you intending to do the clinical evaluation? Is the clinical evaluation done for each module?

10. How will you perform PMS and PMCF? What are the challenges to perform the PMS and PMCF since the product is an EHR system?

Other Standards

1. What standards have you/will you implement? Why?

2. Is there any standard that has simplified you work? Which ones?

3. What is the hardest part regarding the implementation of standards?

4. Is there something that the risk management standard does not cover regarding EHR systems?

5. What is the difference of the medical device file needed in 13485 and the technical documentation? Can it be the same document?

Technical Documentation

1. Have you chosen to categorize your technical documentation, how?

2. What technical documentation do you this is necessary to have in place before proceeding with other?

3. Is there any specific technical documentation you believe is of more importance regarding EHR systems that is not specified anywhere?

4. How do you ensure that you have all the required technical documentation? And how do you assure that the documentation is performed in a correct manner?

5. What do you believe are the largest challenges with the technical documentation?

6. How does one UDI-mark an EHR system? Does every module have its own UDI? Does the UDI change for every update in the software?

Final Overall Questions

1. What guidance or service would you have liked regarding MDR?

2. What are the largest changes your organization will have to undergo in connection to the transition from MDD to MDR?

A.2 Technical Documentation

1. **Device description and specification, including variants and accessories**

   1.1. Device description and specification

      1.1.1. Product name, full description of the device and intended users

      1.1.2. UDI

      1.1.3. Intended use and patients

      1.1.4. Principle of operation

      1.1.5. Product qualification and classification

      1.1.6. Novel features

      1.1.7. Accessory devices description

      1.1.8. List of configurations of the device

      1.1.9. Description of key functionalities and modules of the software

      1.1.10. Products photos and usage photos

      1.1.11. Technical specification

   1.2. Reference to previous and comparable products

      1.2.1. Previous generations of the device

      1.2.2. Similar devices on the EU market

2. **Information to be supplied by the manufacturer**

   2.1. Labeling of the device

   2.2. Legend of symbols

   2.3. Instructions for use

   2.4. User requirements, including contraindications, use environment, operate of use manual, warning, indication.

   2.5. Training materials for the user

   2.6. Installation and service instructions

   2.7. Marketing materials

3. **Design and manufacturing information**

   3.1. Software development plan and process

   3.2. Software architecture and detailed design

   3.3. UML diagram

   3.4. Spec sheet including component specification

   3.5. Software requirements specification

   3.6. Software validation and test plan

   3.7. Final product testing

   3.8. User interface specification