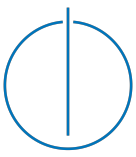
DEPARTMENT OF INFORMATICS

TECHNISCHE UNIVERSITÄT MÜNCHEN

Bachelor's Thesis in Information Systems

Challenges of software certification for startups in the medical technology industry

Ilian Boyadjiev



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Challenges of software certification for startups in the medical technology industry

Herausforderungen der Softwarezertifizierung für Startups in der Medizintechnik

Author:	Ilian Boyadjiev
Supervisor:	Prof. Dr. Florian Matthes
Advisor:	Dian Balta
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I confirm that this bachelor's thesis in information systems is my own work and I have documented all sources and material used.

Munich, 15.07.2022 Ilian Boyadjiev

Abstract

The intent of the Medical Devices Regulation (MDR) is to ensure a high standard of safety and quality for medical devices. The use of such devices saves lives and extends the life expectancy of some patients; on the other hand, failures can sometimes be fatal. For that reason it is important to build trust in medical technology through standards and certificates. Despite all the positives, in practice it turns out that the certification of software according to the MDR is a complex process that requires a lot of prior knowledge, activities and resources.

The goal of this thesis is to give the reader an overview of the certification process for medical software in Germany. We summarize and analyze the main challenges for manufacturers, as well as the involved stakeholders in the certification process. We look into the internal processes of companies that meet the requirements of the regulation to discover approaches to overcome these challenges. The result serves to describe a continuous approach to MDR compliance.

Keywords: Medical Device Regulation (EU) 2017/745; Medical Software; MDR Compliance; certification process; start-up; procedures; stakeholders

Abstrakt

Ziel der MDR ist es, einen hohen Sicherheits- und Qualitätsstandard für Medizinprodukte zu gewährleisten. Der Einsatz solcher Geräte rettet Leben und verlängert die Lebenserwartung mancher Patienten; andererseits können Ausfälle manchmal lebensgefährlich sein. Aus diesem Grund ist es wichtig, durch Standards und Zertifikate Vertrauen in die Medizintechnik zu schaffen. Trotz aller positiven Aspekte zeigt sich in der Praxis, dass die Zertifizierung von Software nach der MDR ein komplexer Prozess ist, der viel Vorwissen, Aktivitäten und Ressourcen erfordert.

Das Ziel dieser Arbeit ist es, dem Leser einen Überblick über den Zertifizierungsprozess für medizinische Software in Deutschland zu geben. Wir fassen die wichtigsten Herausforderungen für Hersteller und die am Zertifizierungsprozess beteiligten Akteure zusammen und analysieren sie. Wir untersuchen die internen Prozesse von Unternehmen, die die Anforderungen der Regulation erfüllen, um Ansätze zur Bewältigung dieser Herausforderungen zu entdecken. Das Ergebnis dient dazu, einen kontinuierlichen Prozess zur Einhaltung der MDR zu beschreiben.

Schlüsselwörter: Medizinprodukteverordnung (EU) 2017/745; Medizinische Software; MDR Compliance; Zertifizierungsprozess; Start-up; Prozeduren; Stakeholder

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List of Acronyms

MDR Medical Devices Regulation iii

MDR EU MDR (EU) 2017/745

MDD Medical Devices Directive 1

EU European Union 2

EC European Commission 10

EEA European Economic Area 1

QMS Quality Management System 7

RMS Risk Management System 7

UDI Unique Device Identification 7

PRRC Person Responsible for Regulatory Compliance 7

MDKU Medical Device Knowledge Units 7

SMEs small and medium-sized enterprises 15

CEP Clinical Evaluation Plan 26

PMS Post-market surveillance

PMCF Post-market clinical follow-ups

CAMD Competent Authorities for Medical Devices 32

Contents

1 Introduction

1.1 Situation

Medical devices are a fundamental component of modern healthcare systems. All devices, software, materials or other objects used for diagnostic and/or therapeutic purposes are considered medical devices. They range from surgical masks through hearing aids, x-ray machines to implantable pacemaker pulse-generators. Medical devices are considered a fundamental component of healthcare systems. The benefits of such devices keep growing every year as technologies evolve over time. They are essential for the prevention, diagnosis, treatment and rehabilitation of diseases.

To ensure that they work in a safe and effective way, and are compatible with the settings in which they are used, governments introduce legal regulations such as the Medical Devices Regulation (MDR). The MDR is replacing the Medical Devices Directive (MDD) that has been active for the past 25 years. Unlike directives, regulations do not need to be transposed into national law. The latest changes became effective as of 26 May 2021 [7]. Compliance with this regulation is mandatory for medical device companies that want to market or sell their products in the European Economic Area (EEA) [34]. Due to some key differences, discussed in detail in Chapter 2, between the Directive and the Regulation, there is an urgent need for a fundamental transformation of business processes for both large and small manufacturers.

The definition for medical devices is stated in MDR and manufacturers must comply with it. The manufacturer bears responsibility for the correct classification [11]. The classification is always determined for a concrete, individual product [11]. The state authorities (in Germany "Landesbehörden") bear responsibilities to supervise the production, placement and usage of medical products. Manufacturers have to be more transparent and structured, they also have to take into account the increased administrative burden of registering the products with the authorities. Companies are forced to hire additional staff and invest a lot of time and money in paperwork. Thus, manufacturing costs are increasing, but at the same time product specifications have not changed.

Being unfamiliar with the requirements can be a barrier to deploying new technology to researchers and early–stage innovators. Innovation can happen within small companies, where regulatory support is usually limited.

1.2 Problem Statement

This thesis aims to increase transparency by identifying and analysing key challenges to manufacturers of medical products. From a startup perspective, we research how obligations of the Regulation need to be fulfilled in order to place compliant devices on the market. Further, we take a look at the processes of large and small companies and see how their products are certified and how compliance with the MDR is ensured. With the results of our research, we introduce a framework to streamline the medical software certification process.
The following section presents the guiding research questions, the used research design, and expected results.

- Research Question 1: What are the main challenges of MDR compliance?
  To answer this question we conduct a qualitative literature review [23], as described further in Chapter 3. The review of published articles helps us to lay the foundation to further analyze the current situation in Germany and the European Union (EU). The most demanding obligations of manufacturers are outlined together with pain-points for the companies. We explore why challenges have arisen. In addition, we analyze the short-term consequences from a startup perspective.

- Research Question 2: What processes are already in place to deal with the challenges? Given the complexity of MDR compliance, many companies have defined a process to find an effective and efficient method for delivering all requirements. In addition, large-scale manufacturing requires an approach to continuously review and ensure MDR compliance. We capture the processes by conducting semi-structured interviews with companies from the medical device industry. The findings are described and analyzed in terms of the problems they solve, the roles involved in the process, the responsibilities shared between the roles and the software tools used. The conclusions then serve as the basis for answering research question 3.

- Research Question 3: How can a startup bring a new product onto the Market? With the outcome of the previous research questions, we propose a framework for decision making during the certification process. The framework provides a clear overview of the necessary process steps to people who are not familiar with the details of MDR. It leads us to a solution area when applied to a specific company's situation.

The outcome of the research questions is presented visually in a research poster [25]. It contains a summarized overview of the main research topics, challenges and involved

parties in the certification process according to MDR. It outlines the necessary process steps, measures and documents to successfully and efficiently develop a new compliant medical device from scratch.

1.3 Thesis Outline

Further, in Chapter 2, we address the theoretical background that provides the context for this work. Chapter 3 shows and verifies the research methods used for this research. In chapter 4 identify challenges for manufacturers of medical software and approaches to continuously ensure MDR conformity. In chapter 5 we get an insight into the certification processes by presenting results from semi-structured interviews conducted with companies in the sector. We conduct stakeholder analysis and identify interrelations between the challenges and the involved parties. Building on all the information gathered, chapter 5 also presents a framework that can be used as a roadmap to help manufacturers organize and streamline the medical software certification process. In chapter 6 we apply the research results using an example device and follow the steps of the certification process for this device. Finally, we present conclusions, limitations of this work and possibilities for future work.

2 Theoretical Foundations

This chapter details on the theoretical foundations of the underlying research questions. It aims on building the necessary knowledge base for understanding the contribution of this thesis. Here we present an overview of the MDR requirements and the current certification approach in Germany. In this paper we will refer to MDR (EU) 2017/745 also as simply MDR. In this context, all devices, software, materials or other objects that serve diagnostic and/or therapeutic purposes are referred to as medical devices.

2.1 Outline of MDR Requirements

This section explains how directives differentiate from regulations. We look at the new MDR changes compared to MDD. We also trace the chronological order of events, when was the MDR conceptualized and when it came into effect. This section draws on informative pages and factsheets from the European Commission.

The first question to answer is why was there a need for change, the Medical Devices Directive has been active for 25 years before it was replaced by the Medical Devices Regulation. The main driver for change was that there was no unified interpretation of the laws between the different EU member states. Post-marketing methods for monitoring devices sold on an international level were also limited. The MDD was replaced with the new regulation to ensure compliance with standardized medical device regulations throughout Europe. The new regulatory requirements aim to improve the safety and performance of medical devices in Europe and ensure a high level of protection for the health of patients and users of these medical devices [34]. They have the goal of ensuring quality and safety of all medical devices and software.

One major change is most notable, as it effects existing products that must be re-certified in accordance with the new classification rules of MDR [6, 29]. The definition of medical devices and active implantable medical devices was be significantly expanded to include devices that do not have a medical intended purpose. Since all types of medical software aim to fulfil the purpose of diagnosis and therapy, there are practically no class I software products currently on the market, according to MDR's definition [24]. As a result of the changes, almost all medical software products are classified at least as class IIa or higher. Class I devices do not need to be registered with a Notified Body, while Class II devices and above require certification. This affected many companies

that previously only produced Class I certified software. They either had to develop a process to ensure compliance with the MDR or withdraw their product from the market.

According to a March 2020 MedTech Summit report [16, 29], only 17% of manufacturers felt fully prepared for the MDR. It was 15% that reported being not at all prepared or slightly better. 65% of respondents were intending to use the full validity period of MDD certificates to get prepared for the MDR.

2.1.1 Classification of Medical Devices

Here we are going through the details of the classification rules for medical devices. The risk-based system for classification is explained, also a description of the main classes is provided, with examples in tabular form. Finally, we elaborate on the involved parties and who bears which responsibilities for the correct classification. The main questions to answer here are:

- What is the role of a manufacturer in the classification process?
- What are the various risks associated with incorrect or inaccurate classification?

The correct classification is a responsibility of the manufacturer and is later audited by a Notified Body. It is done according to the classification rules of Annex VIII of MDR. Depending on the potential risk associated with the device and it's intended purpose, products are classified according to a 'risk-based' system. There are four main medical device classes - I, IIa, IIb and III - ranging from lowest to highest associated risk. To clarify and to distinguish the different classes, Table 2.1 contains a few examples of medical software and devices with their respective classification. A short description is provided in the third column to explain the reasoning behind the respective classification.

Class I devices are low-risk devices, and as such are subject to the least amount of regulatory control. Manufacturers can declare conformity for class I products without informing a notified body. However, their intended purpose cannot be to make decisions or diagnoses.

Class II devices are intermediate-risk devices. The class is divided into two main subclasses – IIa (low to medium risk) and IIb (medium to high risk). A good rule of thumb is to ask if the device is monitoring vital physiological processes. If so, then the device is class IIb, otherwise class IIa.

Class III devices medical devices are those devices that have a high risk to the user. These devices usually sustain or support life, are implanted, or present potential unreasonable risk of illness or injury. Examples include implantable pacemakers and breast implants.

It is of utmost importance for the classification that the manufacturer states the

intended use of their software. Software for general purposes when used in a healthcare setting is not a medical device. For example, a smartwatch used to monitor the wearer's heart rate during cardio exercise could fall outside the scope of the MDR rules. On the one hand, the smartwatch is used for the monitoring of a physiological process - therefore it should fall under class II. On the other hand, if the heart rate monitoring does not serve any medical purpose — but is intended for the user's own information during exercise — it may not be subject to the medical devices rules. If a manufacturer is unsure how to classify the product or if there is a disagreement with the notified body, the competent authority to which the notified body is subject should be contacted [7, 8]. It is actually the Notified Body's responsibility to check that the manufacturer has correctly declared the intended use in order to avoid misleading descriptions.

Examples of medical devices and software			
Software/Intended Use	Class	Risk Level	Comment
Remote control for surgery table	I	low	Class of surgery table
BMI calculator	I	low	If result is not used to take decisions
Patient Data Management System	IIb	medium to high	Stores data for Intensive Care Unit patients
Insulin dose calculation	III	high	Wrong drug or dose may kill patients
Hospital information system	None	None	Not a medical device (just documentation)

Table 2.1: Examples of medical devices and software
Based on source: Johner Institute [24]

2.1.2 Obligations for Manufacturers

The regulation urges companies to adopt stricter quality assurance measures so that individual devices can be quickly tracked and retrieved in emergencies. The new changes do not only apply to classification, but also require the manufacturers to fulfil

other obligations [6], such as:

- to appoint a Person Responsible for Regulatory Compliance (PRRC)
- to conduct clinical evaluations
- implement a Quality Management System (QMS) as well as a Risk Management System (RMS)
- implementation a Unique Device Identification (UDI) mechanism
- compile technical documentation
- apply a conformity assessment procedure
- to conduct post-market surveillance
- draw up a liability plan for defective devices
- draw up a declaration of conformity
- apply CE marking to their devices

The manufacturers are responsible for the implementation of all requirements and must prove their authenticity to the authorities. A representative of the authorities examines the conformity of the manufacturer through audits. In Section 5.2 the process is described and analyzed in details. After the audits are passed, the manufacturer is granted permission to place the medical product on the market. After product launch, the manufacturer is obliged to collect and review experience gained from their devices, with the goal of identifying risk, malfunctions and potential harm, as well as continuously updating the benefit-risk assessment.

Through these requirements, the MDR aims to introduce control over the production of medical products, followed by mitigation of the risk for patients and standardization of the quality of devices and software in the healthcare industry.

2.2 Related Work

The work of one of the companies we discovered during the literature review process, Avasis Solutions GmbH, specifically addresses challenges in certification of medical product under MDR. The company has background in compliance and product management matters in the MedTech industry. The company proposes an innovative data model that is used to digitalize the process of compiling and managing technical documentation, called the Medical Device Knowledge Units (MDKU) [1]. The data

gathered during the certification process from various sources, e.g. Risk Management System, clinical reports, usability compatibility, is compiled into "Knowledge Units" [1]. This improves the re-usability of the collected data. According to Avasis, 37% of the collected information is re-used in at least one other process of the manufacturer. The goal of the MDKU project is to eliminate inefficiencies in the creation, maintenance and modification of technical documentation content by reducing redundancies and inconsistencies throughout the documents [1]. Furthermore, the maintenance effort for the manufacturer is reduced in the long term [1].

As the MDR has recently entered into force, the industry still lacks an effective tool to guide less experienced companies in the medical device market. Innovation is the main obstacle for start-up companies when it comes to preparing a certification plan, because their products have no analogue and it is difficult to determine the necessary obligations for compliance with the regulation. The MDKU is especially applicable for small and young companies. They can use the knowledge units and adapt them to their product for the best efficiency. The official documentation of the MDKU concept highlights four main objectives [1] to achieve efficiency. First, the digital data model must be compliant with the requirements of the MDR. Second, it is possible to implement the data model independently of the product being developed as well as the manufacturer's internal processes. Thirdly, the knowledge units must be useful for both the manufacturer as well as the verifying authorities (auditors and Notified Bodies) during verification and validation of the technical documentation. Finally, the MDKU should serve to reduce the effort to create and maintain documentation rather than increase it in size - thus allowing for the easy addition of new information, the reuse of data, and continuous updates. The project stands out as significantly useful for our study because it offers a solution to the challenges we address later in the thesis. The proposed solution is innovative as there is no alternative in the industry, and offers the possibility to be adapted to innovative medical products of any nature.

3 Methodology

This chapter describes the research design and methods of this work. A qualitative mixed-method approach was used to answer the research questions given in Chapter 1. A systematic literature review served to gain insights into challenging concepts in the certification process according to MDR. Manufacturers' business processes were discovered and analyzed through a series of semi-structured interviews with experts from the MedTech industry. From this research, a framework for streamlining the certification process is derived and applied using a case study.

3.1 Literature Review Process

To familiarize ourselves with the foundations, we conducted a qualitative systematic review [23, 33] of the published literature on the subject, as we wanted to use narrative and more subjective (rather than statistical) methods to bring together the findings of the included studies. The literature review helps us to answer the first research question in particular. The goal is to get an overview of the current situation in the medical software industry. By studying the literature, it is possible to identify the actors involved, the MDR requirements they need to meet and their respective obligations, as well as potential challenges and obstacles to the certification process under MDR.

The literature review was conducted using Zotero Connector 5.0.92, a software tool to organize all references, in combination with Mozilla Firefox 98.0.1. All of the references were administered in a BibTeX format.

Since the MDR was developed in 2017 and came into force in 2021, the scope of the literature search is limited to findings that only appeared after 2017. The search engine Google Scholar allows us to narrow the result by filtering by the year of publication. The languages are limited to German and English references. An additional limitation is that the countries examined in the publications should be a part of the European Union. For the initial gathering of data, the following keywords are used: "MDR Compliance AND (software OR startup OR startups OR process OR certification)". The search results in 41 publications (as of March 2022). After reading the Abstract section of each finding, the list of relevant sources is narrowed down to around 10 publications based on their content. References addressing risks for manufacturers and difficulties in ensuring MDR compliance are included, while scientific or disease-specific papers

on medical topics are eliminated. We notice that a few of the materials found were referenced in a conference paper[1] published in March 2022.

A simple Google search for the keywords "MDR Requirements AND manufacturers" is enough to come across several publications by the European Commission (EC) and informative pages on the MDR official website [2]. To contribute to the first research question of this thesis, we have selected three factsheets published by the EC relating to I) obligations to manufacturers, II) class I devices and III) transition processes from MDD to MDR. While it would be too cumbersome to read through all the legal texts, the factsheets provide a first-hand overview of all requirements and obligations from a manufacturer's point of view.

In this work we will also use the findings of a research conducted by the company Avasis, a service company that has established itself in recent years as a leading provider of digitalization solutions for small, medium and large companies. Their research team has developed an innovative data model [3] for the medical device industry, whereby content of the technical documentation of medical devices can be efficiently mapped in digital form. The Medical Device Knowledge Units pinpoint specific obstacles to the certification process of products under MDR, which will be further analyzed later on in this thesis.

We got an interesting insight into the practical aspects of the medical device industry through an online blog and podcast, Easy Medical Device[4], created and maintained by Monir El Azzouzi, a medical device compliance expert. As part of this blog, guests from the MedTech industry, including manufacturers and representatives of notified bodies, are invited to discuss the details of relevant processes in the form of semi-structured interviews.

3.2 Case Studies via Semi-structured Interviews

This section reports on the chosen approach for conducting semi-structured interviews.

3.2.1 Preparation and Execution

In order to obtain a better grasp of the processes, we choose to conduct semi-structured interviews with large and small manufacturers from the medical device industry. A

[1] "Impact of Medical Device Regulation on Developing Health Behavior Change Support Systems" written by Eunice Eno Yaa Frimponmaa Agyei, Sami Pohjolainen and Harri Oinas-Kukkonen (https://link.springer.com/chapter/10.1007/978-3-030-98438-0_1)

[2] https://www.medical-device-regulation.eu/

[3] Medical Device Knowledge Units (MDKU) https://knowledge-units.org/

[4] https://easymedicaldevice.com/blog/

semi-structured questionnaire is used to conduct all of the interviews. Our goal is to gain insights and understanding towards the certification process and stakeholder involvement in Germany by studying the processes of MDR-compliant manufacturers of medical software or devices. We select participant companies that develop medical devices or software that require certification under MDR (EU) 2017/745. The resource gap between large and small manufacturers is examined. Our expectations are to identify differences in the organizational structures, internal roles, challenges and opportunities. We are interested to gain information about young (founded in the last five years) as well as mature companies, expecting to discover innovative approaches. The interviews are performed according to a guideline, which includes a short introductory statement that explains the research's context and goals. The guideline's questions centered on the following five topics:

- The participant's professional background and their responsibilities and tasks in the company
- The company experience with MDR in terms of devices or software
- The roles and processes in the company with focus on MDR certification
- Approaches, best practices and (software) tools that support the certification process in the company
- Major challenges regarding MDR compliance and potential remedies

The second question section compels the interviewee to provide examples of medical devices manufactured by their company. The examples are used later on in the third section, when we refer to roles and processes. The interviews are conducted using Microsoft Teams Version 1.5.00.8070. All interviews are audio recorded.

3.2.2 Contacting Participants

In order to select a representative selection of newly founded companies, we visit the TUM Venture Labs' informational website[5]. Companies in the healthcare industry best fit our prerequisites. TUM Venture Labs Healthcare supports start ups that develop products in the fields of biomedicine, medical technology and digital applications. In most cases, the company founder is the direct contact person for compliance matters, so we reach out to them directly via email. Five time slots of 30 minutes for an online interview are suggested in each case. The participants that agree to a meeting also receive the questionnaire a few weeks beforehand in order to prepare accordingly. It is

[5]https://www.venturelabs.tum.de/en/venturelabs/home/

ensured that all answers are to be treated confidentially. All sessions are recorded and the recordings are shared with the participants.

4 Challenges of MDR compliance

This chapter aims to identify and analyse the challenges that small manufacturers are facing, in order to comply with MDR. We examine how the challenges arise and what are the consequences for small manufacturers. For this chapter, we review scientific publications and present the results.

4.1 Challenges and Obligations

4.1.1 Lack of Clarity

Due to changed classification rules, the MDR now applies more medical devices, even if they were not subject to regulation under MDD before. As discussed in Section 2.1.1, the placement of a software in the correct class is an obligation of the manufacturer. However, we find that this is not a trivial task. The core purpose of medical software is to monitor health and suggest diagnoses, otherwise it would not be considered medical software. According to a Johner Institute report [24], almost every medical software is now placed in a higher class than before because of monitoring and diagnostic capabilities. This means that software that used to be Class I is now Class II. Therefore, the very first obligation is that some products now have to be registered with a Notified Body and audited by a Notified Body.

The MDR affects many manufacturers who have no background experience with compliance issues. This is especially difficult for small organizations with limited team members and resources, such as startups. Their operations must be adapted to reallocate resources, discover what requirements apply to their products, how to implement efficient Quality Management System and Risk Management System, develop verifiable technical documentation, and undertake post-market monitoring. The organization must develop a continuous approach to fulfil all necessary requirements.

Even organizations that have had a well-established certification procedure under MDD face challenges in adapting to the new regulation. A case study performed by Noeleen McDevitt in 2017 [22] shows that "almost 46% [of participating companies] ranked Change Management as their #1 challenge" [22]. During the transition period from MDD to MDR, manufacturers are prohibited from making design or quality changes to their existing products to circumvent regulatory changes to classification

rules. Should a manufacturer make significant changes to the design or intended use of an existing product under an MDD certificate, the product must be re-certified under MDR.

Considering that this study was conducted shortly after the MDR was approved, it shows that companies are demanding more transparency and clarity regarding the new obligations. Companies were unsure of what actions are needed to maintain their market position. First, it was necessary to invest time and resources in learning the specifics of the MDR before starting to define a process that would meet all requirements. "The reality of the volume of work required to be completed is overwhelming [...]. The challenge here is that many medical device manufacturers have not hired staff specifically to deal with MDR. They are using existing workforce capacity. This is especially true for the small manufacturers and in many for the large manufacturers also." [22].

It is difficult for many companies to identify the required roles and tasks for a certification process. The first guidance documents from the European Commission were published in August 2020 [6] (recalling that the transition period started in 2017). Up to this point, the lack of official documents prevented many companies from taking the appropriate measures to achieve compliance.

4.1.2 Distribution of Accountability

During the interviews that we conducted, an interesting question emerged. The companies examined took the time to study the specifications of the regulation in detail. However, when the obligations are put in practice, inaccuracies arise regarding the distribution of responsibilities between the roles involved in the manufacturing process. The regulation, in itself, does not indicate how the requirements should be distributed among the actors. In addition, the MDR sets requirements for the owner and seller of the product, but nothing is mentioned regarding control over the supplier of the manufacturing materials. For example, a COVID-19 test kit contains a waste bag, so that the patient can safely dispose of the items used for the test. The seller of the test kit must include a waste bag in the packaging that meets the requirements of the MDR. But the supplier of waste bags is not obliged to comply with the regulation, because from his point of view, he is just a manufacturer of bags that are not in themselves a medical product. This case can also be transferred to medical software. The company that creates the software product is obliged to prove the quality of its product. However, libraries and frameworks can be used to create the software, that do not have to prove conformity with MDR. The intended purpose of a library is not related to medical purposes such as diagnostics, but it is quite possible that a software can make a wrong diagnosis based on a wrong result calculated by the library. In the

event of a malfunction caused by the framework or library, it is not clear which party should be held accountable.

A very common situation is that a start-up only does the design and drafting. The actual production is outsourced to subcontractors in Europe or outside the EEA. Such subcontractors are referred to as critical suppliers because they do the main manufacturing for the medical device while the start-up remains the legal manufacturer. In such cases, the notified body must also audit the critical supplier. The start-up should then make an agreement with the critical supplier beforehand, which clearly states that the manufacturing process will be audited by the Notified Body on site. The start-up is advised to conduct a mock inspection of production to ensure everything is in place.

4.1.3 Increase in Certification Costs

According to a factsheet by MedTech Europe [13, 21], there are 25,000 MedTech companies in whole Europe, with 95% of them being small and medium-sized enterprises (SMEs). The medical industry is a leader in innovation, judging by the number of patents registered each year. Given that 95% of the market in Europe is represented by small to medium-sized companies, this indicates that the relationship between innovation and regulation is worth studying, but in this section we want to shift the focus on the financial implications for small and medium-sized companies, as they represent a significant proportion of the market.

A case study conducted in the Czech Republic in 2021 outlines the challenges and risks faced by the European MedTech industry. Since a total of 50 Czech manufacturers of MDR-compliant medical devices were considered for this study, we can conclude that the results are meaningful and applicable to the situation in Germany. According to the findings, the new regulation will increase overall product safety and ensure a reliable solution to product recalls, but the expenses and administrative burden for manufacturers will be significantly increased [21]. We are particularly interested in this study because it analyzes the financial situation of mostly small producers who rely on an innovative factor for their operations. It is estimated that small and micro-enterprises suffer the most from the increase in costs associated with MDR certification. This is due to the fact that they produce mostly class IIb or higher medical software, where the cost of certification is high but the overall revenue is low.

Figure 4.1 compares the increase in certification costs (in red) for companies of different size, measured in number of employees. The red curve expresses the increase in certification costs, measured in percentages of revenues. We observe that companies with less than 20 employees experience the highest financial challenges. The new costs take up to 10,13% of revenues [21]. In some cases, this percentage is higher than the

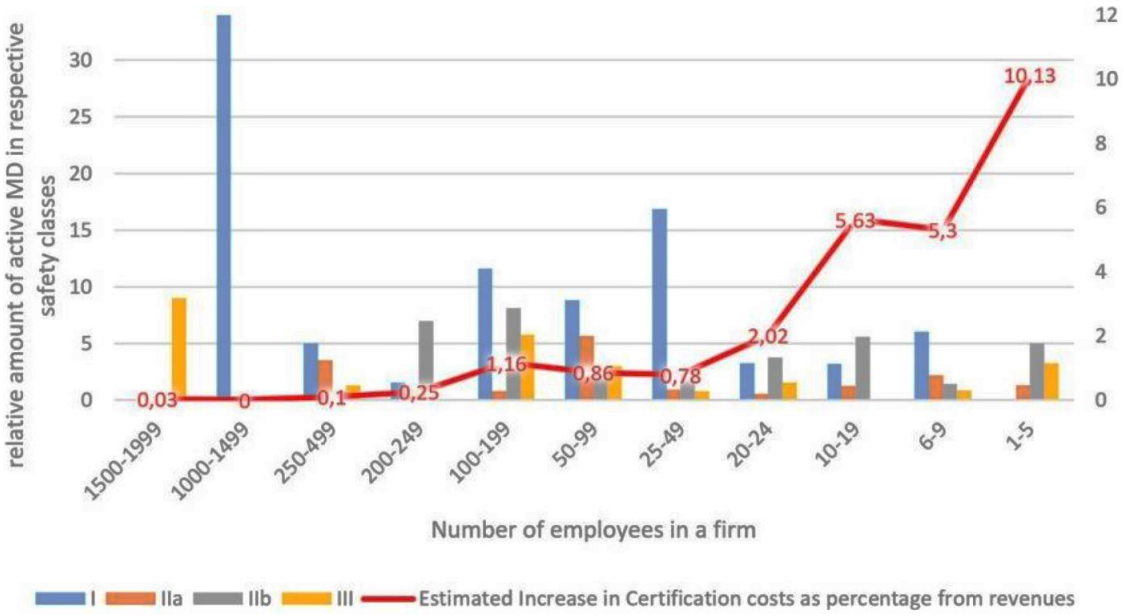

Figure 4.1: Increase in Certification Costs
The data and graph are from "[Do Regulatory Change Seriously Affect the Medical Devices Industry?]", by P. Maresova et al., 2021 [21]

profit margin, forcing the company to operate at a loss. More precisely, if the observed company has a turnover of 100 000 euros, the investment in compliance with MDR will be between 5 000 and 10 000 euros and this can be considered a huge budget for some companies. For large organizations with over 200 employees, the certification costs have a "negligible impact" [21].

This observation can be explained by a few key factors. Due to the small number of employees, there is a need for additional staff to take on compliance tasks. A common practice is to use an external consulting service and delegate most of the tasks to them. It can be observed that small companies in general produce less medical products. They choose to focus on a specific product that meets the requirements and needs of their customers. Resources and funding are focused on the development and improvement of this specific product in order to improve the service, affect a wide range of patients and increase the innovative factor of the company.

Larger companies, even with more than 50 employees, differ from small ones in that they have established a process for mass production of numerous products. It can be seen on Figure 4.1 that their range of products is much richer than the small manufacturer. Due to the already established processes for mass production, the costs

for certification are borne by more units produced. In addition, the availability of more staff facilitates the allocation of internal organizational roles to address regulatory issues.

The overhead in budget requires small to medium sized businesses to start making plans for future survival on the market, if they want to continue selling medical products in the EEA. Some companies may choose to stop selling in Europe and instead only focus on markets outside of the EEA, although there are similar obstacles there too, as CE marking is turning into a world wide standard for the MedTech industry.

Due to the financial difficulties, many small companies will find themselves in a situation where the easiest way out is to be bought out by larger organizations. As a result of financial pressure, mergers and acquisitions of medical companies can be expected. This creates an opportunity for the larger organization to more easily expand and gain a larger market capitalization.

4.2 Technical Documentation

Based on our findings so far, we need to emphasize the significance of technical documentation and the role it plays in the certification process. By definition, every medical device must have an intended purpose, which serves as the foundation for the classification as well as for the selection of the applicable general safety and performance requirements. The classification and these general safety and performance requirements are documented by the manufacturer and they play a key role in the certification process. The documents must be in order when the product is initially registered, because each audit by the authorities is paid extra. Also, the authorities are only obliged to audit the content. In case the documents are not in order, the manufacturer bears responsibility to correct and supplement the content, as well as to bear the costs of the audit and future inspections. From this point of view, the manufacturer has an incentive in providing compliant documentation on the initial audit by the notified bodies.

Based on a previous study in this area, conducted with the goal of creating the Medical Device Knowledge Units project [1, 31], some key challenges in providing compliant technical documentation are outlined.

4.2.1 Completeness of Content

One of the most challenging tasks when creating the technical documentation is the completeness of the information. During the software development life cycle, people often search for information for a variety of reasons. Sometimes the information is somewhere in the list of documents, sometimes it's missing entirely. After a closer

look, it is usually not a case of missing particular papers, but rather missing content from these documents. A good example would be the incompleteness of the product description. All use cases of the product must be described in detail. If compatibility with other medical devices is not described or is missing, the notified body will reject the application. Then the company must re-examine the documentation and add the missing data before requesting another audit. This, of course, leads to further increase in the certification costs and blocks the further progress of the certification process.

4.2.2 Consistency of Information

From the perspective of a Notified Body, a common reason for rejection of an application is the inconsistency of the submitted information. Under MDR there are rules defined for the content of the clinical evaluations. The intended purpose of the medical product must be stated in the clinical report. On manufacturer's side, the intended purpose appears in various other places in the list of documents as well, such as the device description. It is also the foundation for a post market surveillance plan, risk management system, clinical follow-ups, user manual, etc. If the intended purpose is changed even slightly at any moment, the notified body will question the authenticity of the data. The application will be returned to the applicant with the request to unify the repeating contents across all reports and data. This implies that manufacturers, as well as government authorities, face a significant barrier in transferring the same information around reliably across several documents.

4.2.3 Traceability across Documents

Further findings of the MDKU project [31] explore the complexity and retrievability of information. From a start up point of view, it is a common misconception that once the technical documentation has been submitted, or even after the CE mark has been granted, the certification process is complete. Changes and adjustments to the content of the documentation must remain possible. The need for this is most evident in the post-market surveillance phase and during post-market clinical follow-ups. Changes must be traceable across all documents, it must be clear how and which changes were triggered and whether these changes were made consistently at different points in time.

Optimally, this complexity should be able to be represented, i.e. through interrelationships of information in different documents. The need for a modification, for example, may arise through post-market surveillance or a post-market clinical follow-up. This change must, of course, first be reflected in the clinical evaluation report. The report must be updated with the new clinical data. This may then result in further activities, such as an update of the risk management system, because the benefit-risk assessment

always interacts with clinical effects on the patient. This can in turn trigger a change in the definition of the intended use, if a contraindication arises there. And all of these changes would be considered interrelationships between documents - depending on what you need to change, it could affect a huge amount of documents. The change process needs to be managed, so that changes are controlled, carried out consistently, and completed.

Changes to the individual documents are then, of course, applied to the technical documentation. In the worst case, the technical documentation has been submitted for approval prior to the changes, so the notified body needs to be informed about the changed elements. This means the notified body now needs to carry out other time-consuming activities to adjust the documents on their site. As a result, the whole certification process is delayed.

4.3 Interrelations between Challenges

Referring to the findings so far, we can deepen the analysis of the challenges by interpreting the interrelations between the individual challenges discovered in the certification process, which will contribute to the overall understanding of the matter and guide us towards complex approaches to overcoming the challenges. We want to see what influence the first three challenges have on the creation and maintenance of technical documentation. On the other hand, we want to examine how the potential flaws in the documentation affect the whole certification process. Table 4.1 compares the identified challenges with regulatory compliance with the potential flaws of the technical documentation.

We want to analyze how the existence of a challenge affects the added certification efforts. To do this, we look at the main challenges individually and discuss situations where additional resources are needed to resolve the issues. We also assess the potential damage to small manufacturers of medical software, such as startups.

4.3.1 How Does Lack of Clarity Affect the Technical Documentation

As discussed in Section 4.1.1, it is common for manufacturers of medical products to find themselves in a situation where they do not know what regulatory obligations apply to their products. This challenge is indicated as "Lack of Clarity" in table 4.1. This challenge has a negative impact on technical documentation in two ways. When the manufacturer is unfamiliar with the specifics of the regulation, he sees difficulties in, for example, correctly determining the classification of the product. Accordingly, the problem arises that there is no way to determine which documents should be included in the documentation, what should be the content of individual documents, what is

		Challenges of MDR Compliance		
		Lack of Clarity	**Distribution of Accountability**	**Increase in Certification Costs**
Flaws of Technical Documentation	**Incompleteness of Content**	Documents are completely absent	Hindered separation of tasks among teams, Need for additional coordination	Increase in labour hours, Re-submission fees, Clinical examination fees, Going over the certification budget
	Inconsistency of Information	Content is missing from existing documents		
	Impeded Traceability across Documents	Difficulty to replace or add documents retroactively	Difficulty to replace business partners	

Table 4.1: Interrelations between Flaws of Technical Documentation and Challenges of MDR Compliance
Source: own depiction

the procedure for obtaining them, etc. Subsequently, an audit then reveals that parts of the content of the documentation are missing. For example, it might be discovered that there is no document examining the compatibility of medical software with other devices from another manufacturer for the treatment of concomitant diseases, because the software manufacturer was not informed that such an examination should be conducted. The manufacturer is required to withdraw the application and request clinical compatibility studies before the certification process can proceed.

Once a clinical report is available, it should be appended to the documentation and it should be examined whether the new findings contradict previous findings from other documents. The necessity to revise individual clinical reports (or completely replace them) results in inconsistent statements about the medical feasibility of the product. A new document can trigger a chain reaction requiring the replacement of previously valid papers. Thorough knowledge of document content and specifications is required so that changes can be effectively tracked through all documents and reports, maintaining consistency in content.

4.3.2 Impact of Unclear Distribution of Accountability on Technical Documentation

In section 4.1.2 we discussed the possible challenges posed by the uncertainty of how responsibilities are distributed between the roles in the certification process. Here we want to look at the implications of this challenge with a view to technical documentation.

As already mentioned in section 4.1.2, the critical suppliers play an important role to the certification process. They are not a part of the organization that needs to ensure MDR compliance, yet the entire CE Mark application could be denied due to flaws on the supplier's side. The legal manufacturer could then decide that it is more economically advantageous to change supplier during the development or certification process. This in turn triggers the need to replace and renew documents that have already been completed. And if the first audit is in process or has already passed, then an application must be made to replace documents already filed with the authorities. That is, not only is there additional work on the part of the manufacturer, but the authorities are also burdened with additional work. As a result, the certification process is delayed in time and the manufacturer has to wait several more weeks, at worst months, until the new application is processed.

Concluding from the interviews we conducted, the situation with most startups is such that the entire team consists of experts in different scientific fields and each prefers to focus on tasks that fit their expertise. The tasks of the certification process remain in the background, and when their turn comes, it is not clear how the documents will be put together. If the team is pressured by deadlines and the documentation tasks are split between several team members, then there is a huge risk of compiling incomplete and inconsistent data. Potentially, a product flaw could be discovered during clinical research that would need to be subsequently recorded in the user manual. If two separate team members have taken on the tasks for the user manual and for clinical reports, they should coordinate their work to have correct and up-to-date information in each document and to avoid contradictions. In general, this coordination is needed among all members working on the certification process. If there is no clear system for tracking changes and additions among the documents, the amount of work increases and the need for additional working hours is created. The activities of the certification process do not bring any income to the company, on the contrary, they create a cost. The company must be flexible enough with resource planning to anticipate complications in the process and to be able to adapt without serious financial consequences.

4.3.3 How the Technical Documentation Leads to Increased Certification Costs

Problems related to documentation have the greatest impact on the budget allocated for certification. Large medical device manufacturers can more easily manage the costs of certification by spreading the total cost over a larger number of products to bear the expense. In this way they are able to keep the cost of production relatively low and the final price is less affected. This can hardly be said for the small manufacturer, who generally places a small number of products on the market.

Problems with technical documentation lead primarily to an increase in labour hours. When inaccuracies, contradictions or inconsistencies in the information are discovered, additional time has to be invested in fixing them. Often these flaws in the documentation are only discovered after the first audit by the notified bodies. This means that documents already submitted for approval have to be corrected. Each submission and verification of the documentation is subject to a fee by the authorities. Clinical examinations also have a high fee, so it is optimal to conduct them only once. The manufacturer has an interest in avoiding re-submissions.

Corrections to documentation steal from product development time. Certification activities do not generate revenue for the company. In fact, they prevent other operations from performing revenue-generating activities. Therefore, it is worth the initial investment to develop a system for quality creation and management of conformance technical documentation that also takes care of quick implementation of corrections. Having a method to easily track and manage changes early on is more cost-efficient and improves the overall certification process.

5 MDR Compliance through Business Processes

This chapter focuses on the practical implementation of business processes to establish a continuous approach to medical device certification under MDR. This chapter discusses the findings of literature review as well as the results of semi-structured interviews with industry experts who provide us with first-hand information from the field.

We first consider potential solutions to the challenges of compiling technical documentation based on a study and concept by Avasis. Then we examine how the individual steps of the certification process are arranged over time. Working on numerous tasks at once is necessary for an effective certification procedure. We explain how the activities are managed, what dependencies exist between them, and under what circumstances one process might begin based on the outcomes of another. We then continue with an outline of the certificate renewal process. Subsequently, we evaluate the software tools used. Based on the processes discussed, we can assess the actors involved in the certification process and the importance of their roles, as well as how they interact with each other.

5.1 Overcoming the Challenges of Compiling Technical Documentation

As discussed in Section 2.2, the MDKU address the challenges for the manufacturer as well as for the auditor related to the compilation of technical documentation. Their solution is to compile units of interrelated information, called knowledge units, which exchange information when necessary. The idea behind this is that a document contains a different amount of information and it is the information that is useful. For example, if we look at the "Device Description" document, we can find in it information about the intended use, the target patient group, product configurations, compatibility with other therapies, etc. All the information from this document can be viewed as individual units of knowledge. If we wrap these units of knowledge in a conceptual container, we will know in the future where to find the information. This is useful both for the manufacturer, who can reuse the information to prepare or update new

documents, and for the auditor, who aims to verify the meaningful content of the technical documentation. This example can be applied to any element of the technical documentation. That is, all the required information can be formed into separate knowledge units that can later help in the examination (verification and validation) of complete, consistent and traceable technical documentation. In the use of MDKU it becomes irrelevant exactly which document a piece of information is in, as long as it is available.

Furthermore, the MDKU offers a solution to the problem of completeness of content [31]. When a strategy for the certification process is defined, targets are set for the completion of given knowledge units. When documents are inserted into a knowledge unit, placeholders are automatically populated - each placeholder contains a unit of information. The placeholders then indicate whether the information is there or not. If parts of the information needed to complete a knowledge unit are missing, a list of the missing data is automatically (and dynamically) compiled. Accordingly, if 100% of the information is present, then the manufacturer is also informed that no more work is needed on the given topic. This greatly facilitates the auditor's verification process - he does not have to re-trace the completeness of the documents. Also, the manufacturer does not get into a situation where retrospective submissions are required after the initial submission.

The Medical Device Knowledge Units also offer a solution to the second problem of information inconsistency [31]. The MDKU data model presents an approach to distinguish between first-source and subsequent-use information. Each piece of information is assigned a unique identifier, such as an ID number. The MDKU data model ensures that (i) each knowledge unit is unique, (ii) there is only one original source, and (iii) in subsequent documents the information is only reused. When information is managed in this way, it is very easy to detect inconsistencies with the information.

According to Avasis, about 37% of the information is reused in later documents [1]. For example, data and results from the clinical research process are passed into the risk management system. The seamless transfer of information between processes must be ensured. The MDKU data model aims to identify interrelationships between individual knowledge units and thus eliminates the need to version documents. We can then associate the knowledge unit "Clinical risk" with the knowledge unit "Risk", the former being a subset of the latter. The MDKU data model supports automatic analysis of data traceability and easy management of changes to the data [31], thus offering a solution to the problem of consistency.

In conclusion, we can deduct that the MDKU concept serves as the link between the conventional way of compiling, managing and verifying documentation and a new and innovative approach. While it offers solutions to challenges with technical

documentation, it also presents a more efficient way to conduct the certification process that saves resources and hours of work for both the manufacturer and the auditor.

5.2 Timeline of MDR Certification

The classification and the general safety and performance requirements, as well as their documentation, serve as the basis for the conformity assessment resulting in CE marking. This means that the CE mark is awarded when the requirements have been verified and proof of conformity has been provided at the end of the conformity assessment procedure. The following section examines how these aspects are covered on the manufacturer side. Usually, companies have the development process as the most significant process at the core of the business model. Many interface processes such as risk management, usability or clinical evaluations are also integrated into the development process. This implies that companies must demonstrate that they satisfy the MDR requirements as part of the development process [26].

As a rule, the first step is to determine whether the product being developed is actually a medical device. Medical software is also treated as a medical device under the MDR. The intended purpose is best suited for determining whether a device requires MDR certification. By definition, medical devices are used for one or more of the following specific medical purposes [26]:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
- providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,
- devices for the control or support of conception

As discussed with the example of heart rate measurement function of smartwatches in section 2.1.1 - if the device is used for fitness purposes, it does not serve a medical purpose and does not require certification under MDR. However, if the intended purpose is to diagnose or monitor a disease, the device is classified as a medical device [26]. The intended purpose also determines the risk class of the product. The risk associated with the usage of the product determines the classification of the product

under MDR. It is important to establish the circumstances at the earliest stage in order to be able to start adequate planning for the implementation of the project and to integrate the certification process in it.

At this point in time, most companies reach out to external consultants. Consulting services address the first challenge for manufacturers, namely the lack of clarity about their regulatory obligations. The consultant company receives a description of the product, including intended purpose and risk classification, by the manufacturer and determines a timeline plan for the certification. The consultant informs the manufacturer of the necessary documents and estimated activities that need to be done. The manufacturer also needs to appoint a Person Responsible for Regulatory Compliance who has to deal with all further activities during the certification process and represent the manufacturer in front of the notified bodies [26]. The role of a PRRC includes tasks such as checking the conformity of the device, maintaining the technical documentation, drawing up a Declaration of Conformity, performing post-market surveillance and coordinating clinical tests and post-market clinical follow-ups [2].

In Figure 5.1 we can find the first four steps that need to be done before moving on to creating a Quality Management System. First the classification of the product should be determined, then a consulting firm should be contacted, which would help to sketch the process and lay out the objectives. A Person Responsible for Regulatory Compliance (PRRC) is appointed. At the same time, the manufacturer should start researching opportunities for clinical research [2]. After all of this is done, the manufacturer can start working on a QMS.

Once the intended use has been determined and it is clear for what medical purposes the device will be used, evidence must be provided to support these claims. The clinical evaluation serves as evidence that the product actually benefits patients. However, medical studies are time-consuming and involve a lot of work on the part of the manufacturer and the medical person conducting the study. Therefore, in the optimal case, the manufacturer should start developing a Clinical Evaluation Plan (CEP) in parallel with the start of the development [32].

The next stage in the certification process should be the creation of a Quality Management System. A QMS is also required for class I devices. The manufacturer has to have an available QMS, but it does not need certification by a Notified Body. For devices of a higher class, the QMS should be certified by a Notified Body. The QMS describes the guidelines or the rules of the development process [18]. It identifies all processes and the interactions between processes. Furthermore, it defines instructions how to perform process steps in a qualitative way. A QMS should be seen as alive and must be constantly managed and updated. All of this is documented, e.g. using standardized templates or checklists, in the QMS. The goal of a successful QMS is to improve the organization and the development process [18]. The Quality Management

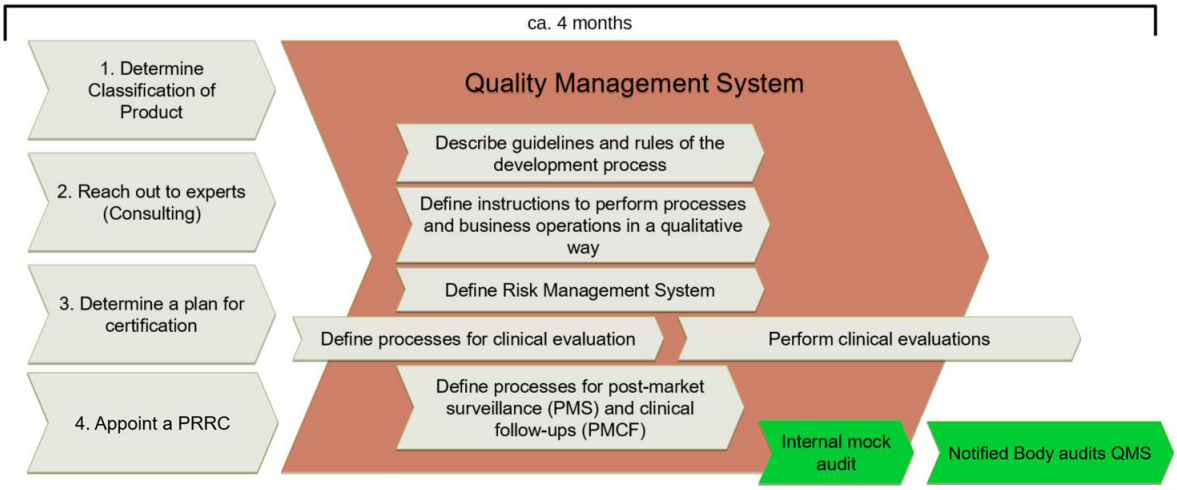

Figure 5.1: First steps of Certification Process
Source: own depiction

System should describe processes for risk management, clinical Evaluation, post-market surveillance, post-market clinical follow-ups, and more [28]. It is important to keep in mind that the QMS should be easily and continuously updated throughout the whole certification process. Findings of The Johner Institute suggest that it takes six to nine months between the start of the project and the final audit [18]. This rounds up to about 30 to 50 person days for small and medium sized companies [18], depending on the specifics of the medical product. The findings are estimating only how long it takes to certify a Quality Management System for the first time, but does not take into account the effort to improve and re-certify the QMS in the future.

Once the QMS is prepared, the manufacturer should proceed with an internal trial audit or "mock" audit [2], during which the company evaluates the QMS from the perspective of a Notified Body. The consulting firm also takes part in the "mock" audit by assessing whether all tasks have been completed successfully, consistently and are easily traceable. The goal is to eliminate the possibility of problems during the actual audit by the Notified Body. Given all goes well, the company can request the very first audit from a Notified Body. This is also called a stage one audit and it reviews the documentation of the QMS and the described procedures [10]. The Notified Body determines whether the manufacturer is ready for the next steps in the certification process. It is also checked whether the intended use actually corresponds to the information provided by the manufacturer. The results of the audit are summarized in a report and used by the manufacturer as a basis of the conformity assessment

procedure [2, 10]. It is important to note that the applications are always rejected after three unsuccessful audits [10].

Before drawing up a conformity assessment procedure, manufacturers must prepare the technical documentation for their medical device. Based on the technical documentation, the Notified Body assesses whether the essential requirements of the regulations are met and whether the manufacturer conforms the QMS. As discussed in section 4.2, without consistent and complete technical documentation, manufacturers cannot prove that their medical device meets the essential requirements for approval or that their quality management system is effective.

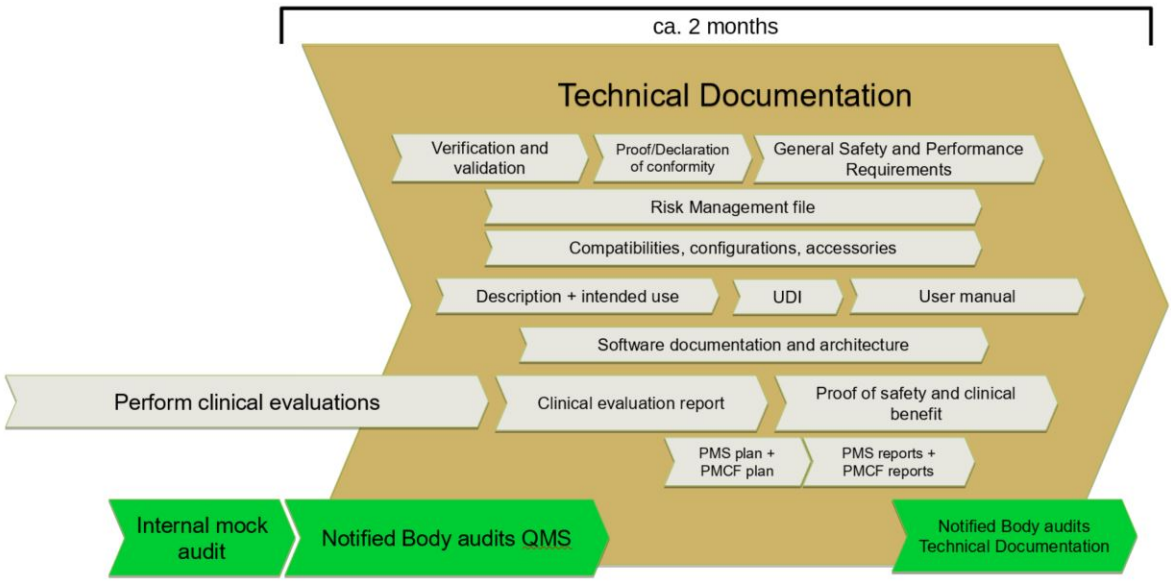

Figure 5.2: The Technical Documentation in the Certification Process Timeline
Source: own depiction

A clinical evaluation report should also be included in the technical documentation. It serves as proof of the safety and clinical benefit of the device. Good planning of the clinical evaluation increases the quality of the product and could potentially save time and costs by performing the clinical research at the beginning together with market analysis and risk research. The clinical evaluation must be performed by or with subject matter experts. The manufacturer bears the responsibility to contact an authorized person or team to conduct the clinical evaluation for them. In the common case, the same person or team takes over the post-market clinical follow-ups.

Usually after one or two months after the stage one audit, the stage two audit takes place [10, 18], which also indicates that the technical documentation should be ready in

about two months. The second audit is done always on premise at the manufacturer. The Notified Body evaluates the technical documentation and needs to ensure that the development is compliant with the Quality Management System, which was already approved at the stage one audit. If the Notified Body finds a nonconformity, it is included in the report. At this point, the Notified Body specifies dates for the first surveillance visit in the following months. If the stage two audit is successful, the manufacturer receives the CE mark.

5.3 Continuous Verification

The life cycle of medical devices and software is also subject to control under MDR, as the materials used are aging over time, or electronics can become defective after prolonged use. The product should always fulfil the most recent standards [22]. The technology industry is evolving rapidly and it is common to adapt new standards for both hardware and software. It is the responsibility of the manufacturer to define the re-certification cycle [26], but the authorities also have a say in the decision, as they can impose a shorter time frame than foreseen for riskier products.

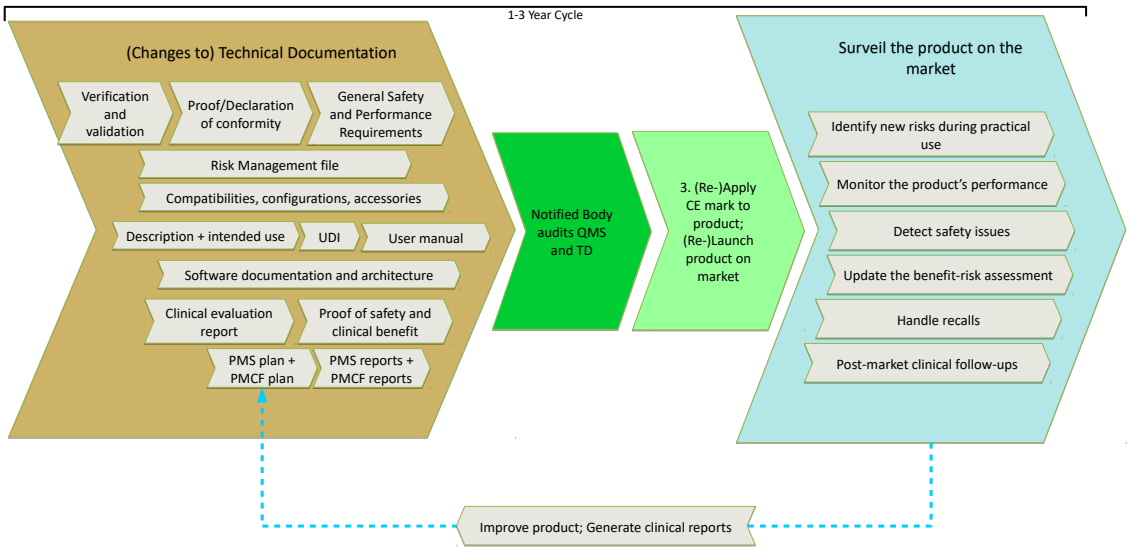

Figure 5.3: Post-Market Surveillance and Clinical Follow-Ups as Part of the Certification Process
Source: own depiction

The CE mark is valid for a maximum of three years [12], and for high-risk medical products it can be reduced to one year. This means that some steps of the certification

process have to be carried out periodically. When a MDR certificate is renewed, it must be established whether there have been any changes to the QMS and whether the changes have been reflected in the actual product development process. This is done through periodic audits by the Notified Body - usually once a year [2]. During an audit, the technical documentation is reviewed again, but the main focus falls on the Post-market surveillance plan and its execution. Particularly important are the reports of Post-market clinical follow-ups, which indicate whether there have been any incidents with the product and whether it is still safe to use. As long as the manufacturer is able to prove compliance with MDR during each audit, the certificate is renewed by the Notified Body with a new expiration date. Discipline is required and employees must follow the quality rules defined in the QMS through every stage of the development process [2].

Figure 8.1 in the Appendix contains a graphical overview of the certification process for the general case.

5.4 Involved Stakeholders in the Certification Process

In this section we identify key roles and how they share accountability. We analyze the interaction between the roles and reveal aspects of the certification process.

The analysis of the certification process so far highlights the manufacturer as a central figure. It is the one with the most duties and responsibilities. Roles must be assigned within the manufacturer's team to represent the company to the authorities, prepare and monitor clinical studies, communicate with a consulting firm, communicate with critical suppliers, and prepare technical documentation. These are complex tasks that require significant financial commitment. At the same time, the manufacturer bears the greatest risk because failure to comply with the regulation prevents products from being placed on the market. Non-compliance with the regulation can be caused by reasons beyond the manufacturer's control - for example, when the supplier of materials does not meet the requirements. As can be seen in Table 5.1, the supplier has an interest in trading with the manufacturer on a long-term basis, as well as receiving payments on time. In order for trade between the two stakeholders to be successful, the supplier needs to cover regulatory compliance. The supplier may view the effort to meet compliance as a financially disadvantageous decision - where the effort outweighs the gains. It is then more advantageous for the supplier to sever the partnership with the manufacturer. From this perspective, we can conclude that the manufacturer is responsible for finding a suitable business partner and, more importantly, bears the risk of losing a supplier at any time.

Consulting firms are a valuable partner to the manufacturer as they resolve the

Stakeholder	Main interest
Manufacturer/Start-up	Placing a new medical (software) product on market. Return on investment.
Critical Supplier	Regular orders from the manufacturer. Manufacturer can pay for supplies.
Consulting Firm	Help businesses achieve compliance under EU MDR.
Medical Personnel	Improve therapeutic treatment methods (e.g. through testing of innovative methods). Discover the clinical benefit of new technologies.
Notified Body/Auditor	Exercise control over the quality and safety of the product. Work with easily traceable and verifiable documents.
Competent Authority (CAMD)	Supervise Notified Bodies, dissemination of regulatory requirements
Patient	Receive high-quality, risk-free treatment and technical advancements.

Table 5.1: Identified Stakeholders in the Certification Process
Source: own depiction

challenge of lack of clarity in the early stages of product development. They perform advisory services to the manufacturer, thereby helping to facilitate the certification process to the greatest extent. This includes giving an initial certification plan, a list of papers to be obtained, organizing the arrangement, and preparing the documents for submission to the authorities for audit. In the context of the certification process, from a manufacturer's point of view, the risk to the consulting firm is minimal. Instead, they reduce the risk of potential application denial for the manufacturer.

The role of medical personnel is important in the early stage of development and also after product launch. They should be authorized to conduct clinical studies according to the regulation. According to a consulting firm [4], "the evaluators should have [...] a degree from higher education in the respective field and 5 years of documented professional experience; or 10 years of documented professional experience if a degree is not a prerequisite for a given task". These requirements complicate matters for

manufacturers, given that they are obliged to find a qualified medical partner. It is impossible to initiate a certification process for a medical product without involving medical personnel. In addition, medical personnel are heavily involved in post-market activities that are subject to evaluation by the authorities and without such activities it is impossible to certify the product.

The length of the certification process is most seriously affected by the role of the auditor. The Notified Body is tasked with verifying that the product complies with the regulation. Typically, organisations that act as Notified Bodies specialize in (one or a few) specific regulations. To perform its duties, the Notified Body verifies and validates all documents related to the medical product (technical documentation) during audits. Due to the relatively small number of companies authorized to act as Notified Bodies [22, 30], the review process sometimes takes longer and therefore slows down the manufacturer's business. If the manufacturer has to change documents after submission, the auditor's work is prolonged, as unforeseen additional work significantly delays assessment time.

Competent Authorities are organizations that have the legal right to control, monitor and supervise Notified Bodies [5].Each of these organisations is under the umbrella of the main organisation, the Competent Authorities for Medical Devices (CAMD) [5], which is responsible for placing competent authorities in each EU member state and monitoring compliance with regulatory requirements. The CAMD can accredit organisations that wish to take on the role of a Notified Body. The Competent Authority oversees the operations of Notified Bodies. Typically, there is a single organization in each EU member state that acts as a Competent Authority [9]. In Germany this is the Federal Institute for Drugs and Medical Devices Paul Ehrlich Institute (Bundesinstitut für Arzneimittel und Medizinprodukte)[1] [9].

Using a dependency network diagram [3], we express the interactions and dependencies between the different actors in the certification process in Figure 5.4. Each identified stakeholder in Table 5.1 is represented by his role in Figure 5.4. The goals (G1,...,Gn) are achieved through activities (A1,...,An). A dependency between two roles is represented by an edge that connects the two roles when a goal of the dependent role is achieved by an activity of the independent role and cannot be achieved by the actions of the dependent role alone [3]. The power of a dependency can be denoted as A (asymmetric) when "it is difficult for the [dependent] role to find an easy replacement for the resource-providing role but not vice versa" [3] or S (symmetric) when "there are alternative sources available from which a needed activity or resource can be obtained" [3].

We find that the Start-up is the most dependent on other roles. Its only goal G1 is

[1] https://www.bfarm.de/

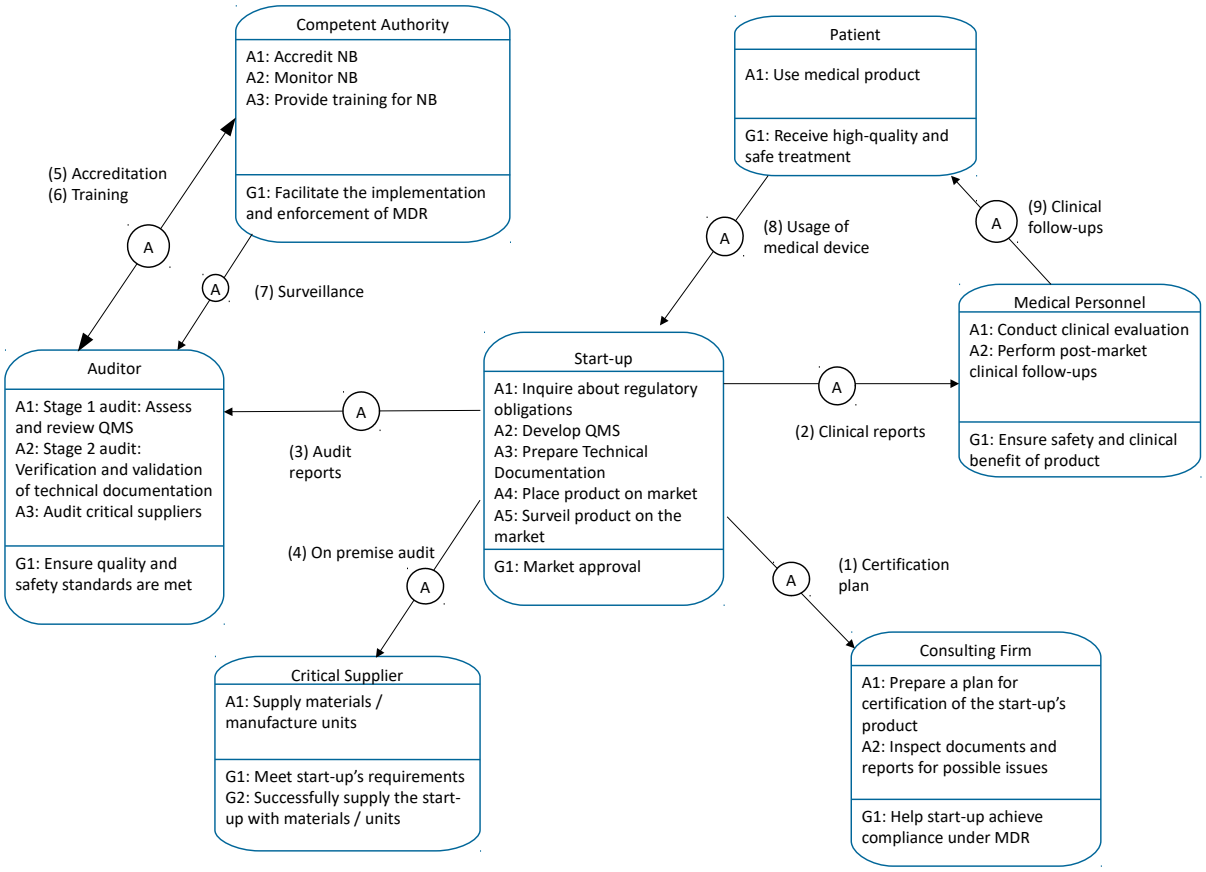

Figure 5.4: Interactions and Dependencies between Roles in the Certification Process
Source: own depiction

to obtain market approval. In order to perform action A1, inquire about regulatory obligations, he must seek help from Consulting Firms that guide him in the certification process. The Consulting Firm provides information and creates a plan for certification for the Start-up (dependency 1). Only then the Start-up can begin action A2, development of a QMS. We find that action A3 of Start-up, compiling technical documentation, is dependent on two other roles, namely to Medical Personnel and Auditor. Action A3 of Start-up depends (i) on the results of the actions of the Medical Personnel, the results of the clinical evaluation (dependency 2), (ii) and actions of the Auditor, the report after stage one audit (dependency 3). Placing the product on the market (action A4) depends on the report after a stage two audit. If the stage two audit is successful, a CE mark is granted to the Start-up. Completing action A4 achieves goal G1, but it

also initializes action A5, post-market surveillance. Action A5 is requiring reports on post-market clinical follow-ups, conducted by the Medical Personnel.

The Consulting Firm is interested in providing the Start-up with guidance on how to comply with the MDR (goal G1). This goal is achieved through actions A1 and A2. The Consulting Firm is not dependent on the other roles in the certification process.

The Medical Personnel has the only goal to ensure that the new product is safe to use and has a clinical benefit to patients (goal G1). The Start-up depends on the actions performed by the Medical Personnel, as it provides mandatory clinical reports to the Start-up (dependency 2), that need to be included in the technical documentation. The Medical Personnel is responsible for conducting the clinical research (action A1), thus achieving its goal G1. After the product has been launched on the market and patients start using it in practice, Post-market clinical follow-ups (action A2) are also performed by the same Medical Personnel [32]. Reports from PMCF are a key component of the Start-up's post-market plan, which is also governed by the regulation. Furthermore, the Medical Personnel requires real data on the use of the medical product collected from patients as part of the Post-market clinical follow-ups (dependency 9).

The Patient's only goal G1 is to receive high-quality and safe therapy. The goal is achieved by using the medical product manufactured by the start-up (action A1 of Patient). The bidirectional dependency 8 between patient and start-up is outlined: the Start-up must achieve its goal before the patient can start its action A1. On the other hand, the Start-up action A5 (Post-market surveillance) requires actual use by the patient.

When production or development begins, the Critical Supplier plays an important role. He supplies the Start-up with materials, and in some cases even the production itself happens on the Supplier's premises. He is subject to inspection by a Notified Body during a stage two audit. In other words, passing the second audit is impossible if the supplier has not demonstrated, or cannot demonstrate, compliance with the requirements of the regulation. In this sense, the Start-up is dependent on the Supplier (dependency 4) to be able to execute the production of the product smoothly, followed by a market launch (action A4 of Start-up). The goals of the Critical Supplier are (i) to meet the regulatory requirements for safety and quality (goal G1) and (ii) to ensure long term cooperation with the Start-up as business partners (goal G2).

The Notified Body is represented by the component "Auditor" in the dependency network diagram 5.4. The main function of this role is check the conformity of products before being placed on the market. The only goal G1 of the Auditor is therefore to ensure that quality and safety standards are met, before product launch. It does so by performing a (i) stage one audit to assess the QMS created by the Start-up (action A1), (ii) a stage two audit (on premise) to validate and verify the technical documentation and assess whether the product was developed according to the procedures defined in

the QMS (action A2) and (iii) audit performed at the premise of the Critical Supplier (action A3). A dependency between the Auditor and the Critical Supplier cannot be established as any failure in action A3 prevents the Start-up from completing its actions and does not prevent the Auditor from completing its actions.

The Competent Authorities for Medical Devices is represented by the role Competent Authority (CA) in Figure 5.4. This organization is responsible for the correct implementation and enforcement of the MDR requirements [9]. This responsibility is represented by its goal G1. In order to achieve its goal, the Competent Authority must first appoint an Notified Body (action A1). The appointment of Notified Bodies is represented by dependency 5, because action A1 of CA requires the involvement of an NB to be authorized to conduct audits. The Competent Authority must then supervise its appointed Notified Bodies [9], described by action A2 of CA and dependency 7. Generally, Competent Authorities should conduct training of organizations that act as Notified Bodies [9] (action A3 of CA and dependency 6). We discover a strongly connected relationship between CAs and NBs since the actions of the CAs are entirely dependent on the involvement of the NBs in the process. The CA cannot carry out its actions using resources other than from cooperation with the NB. At the same time, Notified Bodies cannot undertake any of their actions without obtaining training and permission from the Competent Authorities. Therefore, dependencies 5 and 6 are bidirectional, as both parties require actions of the other party to be completed before starting their own actions.

Although the Start-up can change the actual Supplier, the Consulting Firm or the Medical Personnel at any time, the resources gained from their interaction cannot be obtained in other ways. This means that even if the actual partner is changed, its role (actions and goals) remains the same. Therefore, the dependencies found are denoted as asymmetric.

5.5 Defining a Framework

This chapter highlighted the important steps in the certification process from the perspective of a small manufacturer. It then distinguished the key roles involved in the process as well as their duties, interests, activities and interrelationships. Following a systematic literature review, common barriers to MDR compliance were identified in Chapter 4, which are particularly prevalent among small to medium-sized companies. Through these challenges we find general conclusions about the difficulties in the certification process in Germany. The analysis so far helps us to translate the findings to create a supporting framework to serve small start-ups producing medical devices.

Chapter 5 describes the certification process in general terms and for the general

case. In this section, we deepen the analysis by looking at how difficulties are overcome during the certification process as well as during the development itself, by presenting and analyzing different strategies.

For better understanding of the proposed framework, table 5.2 summarizes the challenges and the actors affected by them.

	Stakeholders in the certification process				
Challenges of MDR Compliance	Start-up	Critical Supplier	Consulting Firm	Medical Personnel	Notified Body
Lack of Clarity	✓	✓	✓		
Distribution of Accountability	✓	✓	✓		
Increase in Certification Costs	✓				
Challenges of Compiling Technical Documentation					
Completeness of Content	✓		✓	✓	✓
Consistency of Documentation	✓		✓	✓	✓
Traceability across Documents	✓		✓	✓	✓

Table 5.2: Interactions and Dependencies between Roles in the Certification Process Source: own depiction

As the analysis so far has been conducted from the standpoint of a start-up, all of the challenges identified apply to medium to small-sized companies. Table 5.2 annotates once again precisely this - all of the discovered challenges are typical of a start-up. In Table 5.2, we explore for additional interrelationships between actors and challenges in the certification process. A relationship between an actor and a challenge is annotated, in case the actor is affected by the challenge, and in case the actor helps to overcome a challenge.

The critical supplier is affected by the first two challenges. For him to work together with the start-up, he must comply with MDR. The problem for the critical supplier arises from a lack of understanding regarding the quality and performance standards it must secure. Furthermore, there are actions that go beyond the competence of the supplier's services, and it must be determined which duties relate to which actor under the regulation.

The consulting firm serves to solve the first two challenges. The consultant is tasked with understanding the most current industry standards and controls to which the product being developed is subject. Ideally, the consultant should identify critical partners for the product development as well as identify obligations that apply to them. In a sense, overcoming the first two challenges can be provided through a consulting service. The solutions happen at the expense of the start-up certification budget. Additionally, the consulting firm can address the problems related to the technical documentation. An efficient approach to compiling documents and gathering information from different sources can be proposed, as well as a simple approach to data management. As discussed in Section 2.2 and Section 5.1, there are conceptual data models that offer a goal-oriented way of working, e.g., MDKU that organize information into knowledge units.

From a medical personnel perspective, documentation issues need to be resolved prior to performing clinical research. It is important for the medical staff (i) to be given a clear description and information about the product being studied, (ii) to be clearly described which functions are being studied, and (iii) to be able to easily follow the documents through the documentation provided.

Flaws in technical documentation lead to complications in the start-up certification procedure, as discussed in Section 4.2. They also have implications for the work to be done by Notified Bodies. Since there are a small number of authorized firms that can act as Notified Bodies, and the volume of paper work has increased since the introduction of the regulation, Notified Bodies suffer from re-submissions of documents. As the notified body is responsible for verifying and validating the content of documents, it is crucial that all information be obtained without any missing aspects and elements.

Generally, the challenge "Lack of Clarity" arises in the early stages of the certification process. At that point, the manufacturer and the critical supplier are focused on the development of the medical product. Before the concept of the medical product is clarified, it is difficult to talk about certification. To determine which obligations apply to the manufacturer and supplier, the product description, what the capabilities and functions will be, must be clearly and rigorously defined. However, this does not preclude the possibility that clarity issues may arise further along in the certification process. One of our interviewees shared that in his case he had encountered difficulty with clarity late in the process - when registering the product on the unified database used across Europe, EUDAMED. Despite the availability of information services from the EUDAMED institution, the problem of "lack of clarity" is largely solved with the help of a consultancy firm that accompanies the manufacturer through all steps of the certification process, not only in the early stages.

As mentioned in Section 4.1.2, one of our interviewees had only encountered the problem of "Distribution of Accountability" when the certification process had already

begun and some of the necessary documents had to be put together. It could be argued that the two problems, lack of clarity and allocation of responsibilities, are interrelated. If the first of the two is resolved in time, the second challenge can be avoided. A rigorous certification plan should be clarified at the outset of product development, with clear objectives for all parties involved. This puts a lot of responsibility on the consulting firm as well as risk on the manufacturer. The safest approach to these challenges is to take preventive measures with the help of a partner consultant before work on the certification process begins.

The budget for certification is highly specific to the nature of the product being produced. Regarding the estimated costs, it is important to discuss with the consulting firm, which can give an initial estimate based on submission and processing fees from the Notified Body, as well as fees for clinical studies. However, the real challenge occurs when subsequent resubmissions, additional document processing, repeat clinical evaluations, and activities of a similar nature that are not part of the original certification plan are required. Such activities occur unpredictably during the creation and the substantive processing of the Quality Management System and/or technical documentation. In addition to the fees required by the Notified Body to process the information, there is also the danger of overtime being put in the project by the start-up team or by a consultant. Working overtime hinders the actual development of the product because time is wasted in activities without financial return. To avoid the need for extra labour, the conceptual data model of Avasis can be applied in a preventive way. Through the conceptual structure offered by the Knowledge Units, the need for additional labor hours is minimized [1]. The overall data management is automated so that operations costing more time can be scrapped in an efficient and time-saving manner.

It should also be mentioned that for large medical device manufacturers, the cost of certification is easier to manage. Having an all-round qualified staff allows assigning tasks to experts who prioritize certification in their duties. In this case, the certification process does not interfere with the product development process. Additionally, large organizations typically produce a large range of products. Thus, the budget of the certification department is spread over multiple cost carriers. This gives the large manufacturer an advantage in the market because it can offer a lower end price for its products. In the case of start-ups, the assumptions are different because (i) the team that develops the product is also involved in the certification process, (ii) in general a small range of products is developed, and (iii) the cost of certification falls on a small number of cost carriers. The possibility that the certification budget exceeds profits is a real concern [21]. This forces the start-up to offer a higher final price to the market. For products where multiple alternatives are available from large manufacturers, there is a high risk to the start-up of insufficient sales to cover the operational expenses. Most

start-ups therefore focus on developing innovative products, relying on there being no cheaper alternative on the market, or on niche specific products for which a sales opportunity was discovered before start of development.

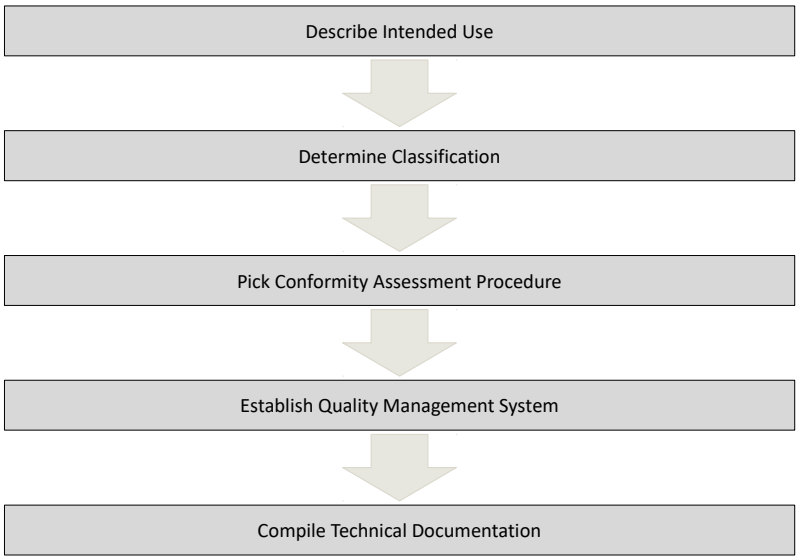

Figure 5.5: Certification Process Guideline
Based on source: The Johner Institute Starter Kit [20]

Based on the findings of The Johner Institute [19], we can compile a summary of the certification process to serve as a guideline for small and mid-sized manufacturers. Figure 5.5 shows the five important steps to successful medical device or software certification. The first step to take is to uniquely define the intended use. This is not always a simple task as companies always aim to develop a new innovative product that may have no equivalent in the market. There is then no one to compare the procedure with. Consulting firms come in to help the company with the determination of intended use as well as with the second step, the determination of product classification. The

third step is to select a conformity assessment procedure. Figure 5.6 shows the different procedures based on the classification of the product. Once it has been established which Conformity Assessment Procedure will be followed, the manufacturer can move on to the next steps - drawing up a quality management system as well as compiling technical documentation.

The manufacturer has to choose one of the three procedures based on the decisions of the first two steps. For the certification of Class I products (described with a blue path in Figure 5.6), the intervention of a Notified Body is not needed - the manufacturer then submits a Declaration of Conformity and obtains a CE Mark based on the technical documentation only. For Class I* and IIa (described with a black path in Figure 5.6), the procedure requires an audit by a Notified Body to verify the Product Conformity document and issue a certificate covering Annex XI of the MDR. For Class IIb and III the procedure is the same, however an Annex X certificate must be procured via a Type Examination carried out by a Notified Body. For all devices involving software (described with a red path in Figure 5.6), the procedure requires involvement of a Notified Body to verify all aspects of the development, production and other processes. The procedure follows the rules described in Figure 8.1, as discussed in Section 5.2 and Section 5.3 of this chapter - the manufacturer must compile technical documentation for the software, establish a quality management system, and establish a post-market surveillance plan, all according to the rules of MDR. After inspections by a Notified Body, the manufacturer obtains an Annex IX certificate. The manufacturer can then submit a Declaration of Conformity to require the issuance of a CE mark.

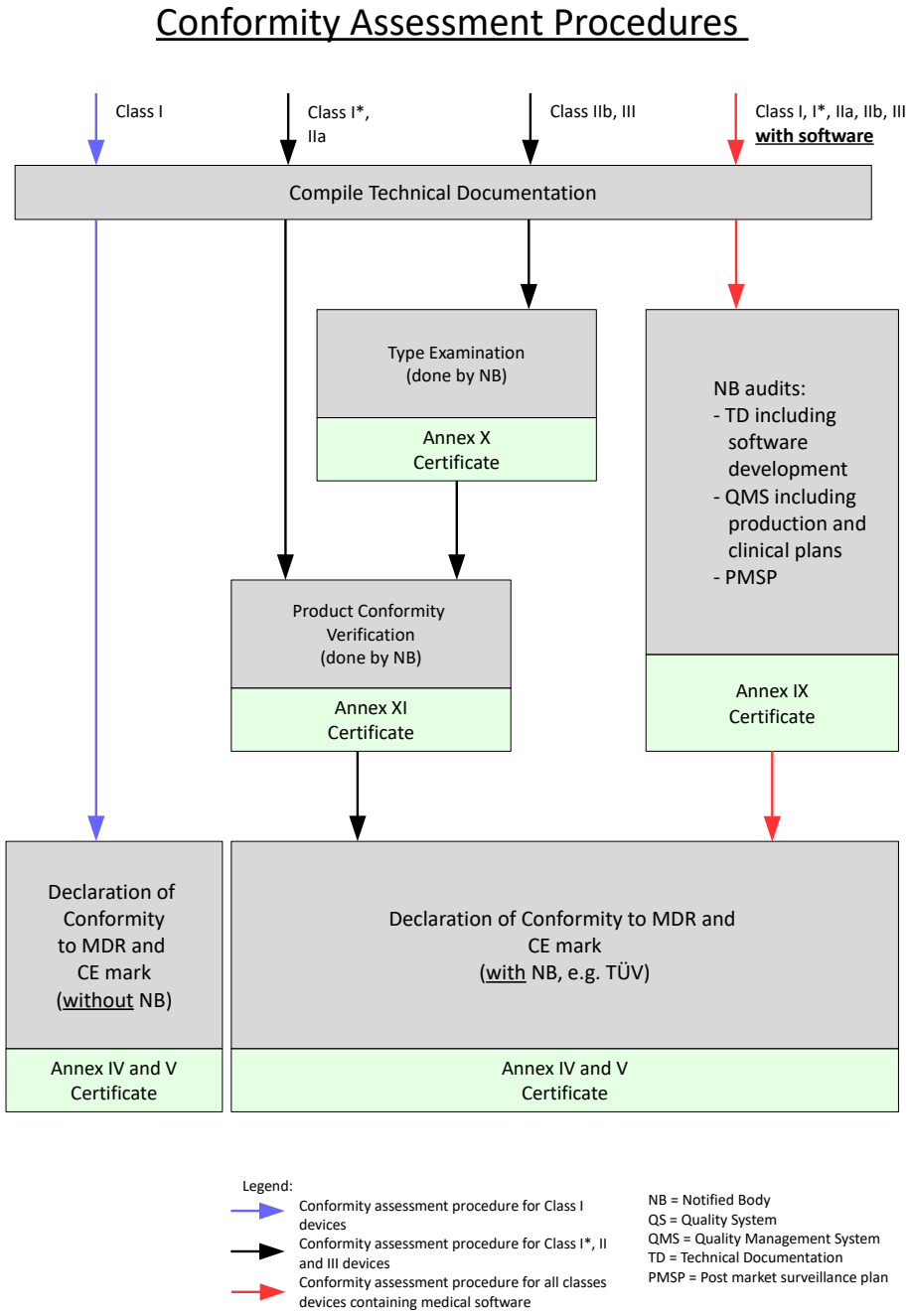

Figure 5.6: Conformity Assessment Procedures for Different Classes Medical Devices and Software
Based on source: The Johner Institute Starter Kit [20]

6 Evaluation and discussion

In this chapter we apply our proposed framework for streamlining the certification process under MDR for medical software and devices. Based on an example of a medical device, we want to analyze the certification process. We trace the individual steps in the process, where we analyze the involvement of each stakeholder. We explore what challenges arise and how they can be overcome.

For the purpose of this chapter, we will focus on a specific example of a medical device - an Interoperable Automated Glycemic Controller, e.g. "Omnipod 5 Automated Insulin Delivery System" [15]. This device periodically measures the patient's blood glycerin level and automatically prepares and injects a dose of insulin into the bloodstream. This device is of interest to us because it relies on a software part that analyzes the patient's internal physiological processes and determines a strictly-individual diagnosis based on its calculations. Furthermore, the calculated insulin dose is immediately delivered into the patient's bloodstream [14, 15]. It is because of these characteristics that the device is classified in Class II [14]. The risks associated with its use are, for example, that if the software calculates a wrong dose of insulin, it can cause serious harm to the patient. From the perspective of a start-up, we would like to follow the entire certification process for the Interoperable Automated Glycemic Controller device.

Usually a start-up consists of experts in different fields who together can develop the overall product and often there are no individuals in the team who know the details of the regulatory obligations. In addition, the MDR has specific requirements for the company's representative to regulatory bodies. In order to overcome the initial barrier of uncertainty, the start-up should seek help from a consulting firm. Initially, the start-up that manufactures the device and the software has to contact a consulting firm and the consultant will guide it through all the steps along the certification process for the manufactured device. The consultant and the start-up communicate with each other details about the device - what features it has, what is the indented purpose, what the target group of patients is, how the therapy works using the device, etc. Generally, the consultant processes the information and analyzes which regulatory requirements are applicable to this product. The consultant informs the start-up about the necessary actions and information that must be provided by the start-up to ensure compliance with MDR. In our case, we have verified that devices such as the Interoperable Automated Glycemic Controller are allocated to Class II [14]. We

need to provide certification for both the hardware part and the software part of the product. Referring to Figure 5.5, we will notice that the first two steps are completed. Determining the correct intended use and classification are closely related to each other because classification is entirely dependent on the risks associated with the use, which in turn are entirely dependent on the specified intended use and capabilities of the software. Since the software can calculate insulin doses that are injected into the bloodstream, the correct execution of the software is critical and bears risk to the patient's health.

According to Figure 5.5, the next step is for the consultant to present the Conformity Assessment Procedure for Certification of Class II devices using software for diagnostic purpose to the start-up. The procedure that applies to our example corresponds to the steps described by the red line in Figure 5.6, because we need to provide certification for the software part of the product. This means that we need to involve a Notified Body, that would issue an Annex IX certificate to the start-up after the following is verified:

- Technical Documentation of product including documentation of software
- Quality Management System including production inspection and clinical evaluation plans
- Post-market surveillance Plans and Post-market clinical follow-ups

The chronological sequence of required actions begins with the development of a QMS. It should describe all processes for work on the product that the start-up undertakes, as well as the essential manufacturer if the preparation is outsourced to another company. In our example, the start-up can be expected to have several partners developing different components of the final product in parallel. For example, one team writes the software code while a subcontractor performs the production of hardware components and delivers them to a third partner for packaging. The start-up is responsible for ensuring that each of the key partners complies with the regulatory requirements that apply to them. The consultant can help the start-up with the allocation of responsibilities among the subcontractors by informing the start-up of the details of the regulatory requirements and can prepare contract templates to be signed by all parties involved in production. The start-up in turn informs each of its key partners that they must be able to meet a representative of the Notified Body to assess the working conditions and verify that the defined quality rules are actually being followed.

A key part of the Quality Management System is the plan for conducting clinical studies to determine the clinical safety and benefit of the medical device. For this purpose, the start-up should contact an accredited medical personnel that could conduct

clinical evaluations over the next few months. If the start-up has difficulty finding a suitable medical partner, the consultant should be able to assist the start-up. As these studies need to be repeated periodically to renew the sales permit on the market, the selected medical staff should be engaged for future joint work with the start-up. The medical personnel should assess the clinical benefit of the use and ensure that the use does not pose a health threat to patients. Multiple tests are performed on different aspects: compatibility with parallel therapies such as drugs and other medical devices, device performance tests in pediatric population.

The task of medical personnel carries a huge responsibility, but other non-clinical tests should not be neglected either. As part of a Risk Management System, the various risks associated with use must be listed and accordingly how the start-up intends to perform extensive software tests in different environments, warning statements and precautions in labeling must be drawn up, the relationship between our device and other digitally connected devices must be tested. Additionally, we need to ensure that the patient will not misuse the device through human factors testing, user training plan, listing of compatible devices in labeling, and product-specific warning statements and precautions in labeling. Finally, a plan of action and liability in case of defective products found on the market should be drawn up as part of the post market surveillance plan. Rules should be defined for carrying out post market clinical follow ups.

The start-up must also appoint one person from its team to represent the manufacturer to the Notified Bodies, the so-called PRRC. In case the start-up is located outside the EU, this person can also be a member of the consultancy firm [17]. The PRRC takes responsibility for communication between the start-up and the NB.

After about 3-4 months [18], the start-up should be ready with the QMS. Together with the consulting firm, an internal audit can be performed to recreate the verification that a Notified Body would do to verify that performance standards are met. During this internal audit, there may be issues, missed points or other concerns that need to be addressed before the first actual audit is requested from the Notified Body as there is a fee for this. According to an information page on TÜV SÜD's website [27], the audit fees are 290 EUR for the audit of a QMS, 290 EUR for verification of changes made after the submission and 390 EUR for assessment of the Technical Documentation, as of July 2022. As TÜV SÜD have received a huge number of requests for their services as a Notified Body [27], it is difficult to set an exact deadline for conducting an audit, and to give an exact timeframe for the duration of the audit. In order to cope with the large number of requests, TÜV SÜD provides an online registration platform for manufacturers of medical devices. Our start-up can use the online platform to request to have an audit of the QMS conducted.

While the start-up waits for the audit to take place or to receive results, they can begin working on the Technical Documentation. In essence, the Notified Body creates reports

after first audit, that the manufacturer needs to include in the technical files [10]. With this, the start-up demonstrates that the rules under which the product is developed are in line with the regulatory requirements for quality standard. Now all that remains is to document the development process, and to write software documentation that describes the architectural decisions and technicalities of the computing system. For this purpose, there are ready-made templates, a cast structure of the Technical Documentation, in which only the placeholders need to be filled in [20]. These templates can be used as a checklist for the necessary information to be gathered from different institutions, partners and other sources. Alternatively, the Medical Device Knowledge Units already mentioned in previous sections can be applied.

The Medical Device Knowledge Units, proposed by Avasis, offer a conceptual data model that needs to be further adapted to the product being developed. Some commitment to the approach is required, but in the long run it helps to process information quickly and manage changes to the Technical Documentation consistently. The MDKU do an excellent job of creating complete, consistent and traceable documentation. The goal of the Knowledge Units is to extract useful information from each document, then tag it with a unique identification number. For example, all necessary data related to the partners of a start-up can be wrapped in a single Knowledge Unit consisting of multiple Information Units [1]. In the event that the collaboration with a partner needs to be discontinued and a new partner brought in, we know (i) exactly where to find the information about the old partner, (ii) where it was reused, (iii) where it needs to be updated, (iv) why the change was undertaken, and (v) which team member undertook the change [31]. This allows the data to be consistently and flawlessly maintained to its most up-to-date state at any point in time. Another example of the usefulness of the MDKU is the preparation of clinical assessment reports. The results provided by the medical personnel to the start-up after the clinical trials should be reused to produce various documents - e.g. Risk Management System, General Conformity Assessment, etc. The MDKU allow us to wrap the information from clinical research into one Knowledge Unit, and the individual pieces of information exist as self-contained Information Units. When information is reused in other Knowledge Units, a link is made using the unique identifier of each Information Unit [1, 31]. Thus, it is known at all times which Knowledge Unit depends on which Information Unit. This allows us to analyze the complexity and the interrealtions between all data.

For projects with a dynamic development environment, where changes happen frequently, this approach is highly suitable. According to the design of the MDKU concept, the room for error is minimized while work efficiency is maximized. This means - less overtime work will go out for the start-up, while the Notified Body will be able to process requests much faster and more efficiently. From the Notified Body's perspective, issues such as incomplete information, inconsistencies among documents,

and untraceability of documentation will be automatically detected by the MDKU implementation and will be flagged even before an audit occurs [31]. This ensures that an audit will only check the non-trivial part of the documentation. This will reduce the time required to verify and validate the Technical Documentation, free up more time for the Notified Body to process more requests and speed up the overall certification process for all parties [31].

Once the Technical Documentation is complete, and the consultant has reviewed and approved it, the start-up can submit it for evaluation by the Notified Bodies. In the event that data is actually missing or something needs to be corrected, this is still possible, but it still costs a fee and after the third failed attempt to pass an audit, the manufacturer's entire submission is terminated [10]. Depending on the size of the Technical Documentation, audit results can be expected in one or two months. If the second audit is passed, the Notified Body issues reports to the start-up together with the long-awaited CE mark. The start-up has to place the CE mark on each unit of the device produced. The start-up is then ready to start sales.

But the work is not finished yet. The Post-market surveillance Plan has yet to be put into effect and the medical personnel still needs to periodically conduct Post-market clinical follow-ups. Over a period of one year, the start-up is audited by the Notified Body and it is verified that the quality and safety standards have been met and that the procedures defined in the Post-market surveillance and Post-market clinical follow-ups plans have been followed. Three years later, during one of the annual audits, the Notified Body reissues the CE mark to the start-up. It is truly worthwhile that the rules for quality workmanship are fully integrated into the development process, rather than only being followed for a short time before an audit. The start-up must demonstrate long-term that it adheres to the established rules.

7 Conclusion

For this thesis was conducted a market analysis of the MedTech industry. The most common challenges to certification under MDR have been investigated, as well as the possible solutions to those challenges. We found that lack of clarity regarding the obligations and requirements that should apply to the developed product is the predominant challenge for start-ups. Other main challenges include how are responsibilities distributed across the involved stakeholders and how the certification costs are increased with regard to the new rules of the regulation. The certification process for new medical products in Germany has been outlined and analyzed. The involved stakeholders were identified and their roles have been examined with respect to their main interests, responsibilities and goals, as well as their overall contribution to the certification process. We examined the interrelations between the involved stakeholders and the discovered challenges for start-ups. A framework has been proposed to streamline the whole certification process which serves as a guideline for manufacturers and SMEs, unfamiliar with the specifics of the MDR. Our results show that the current market situation is challenging for the small manufacturer in terms of certification costs and the amount of paperwork that needs to be done before profit generating activities can be undertaken.

7.1 Limitations

The scope of this work is limited to young start-up companies with less than 100 employees, that manufacture a single medical device. This work does not propose strategies to tackle (certification) budget constraints. During our research, we were only able to reach small manufacturers and analyze their positions. Furthermore, this work addresses the market situation approximately one year after the regulation has come into effect. Some of the reviewed literature looks only at expectations and predictions about the effect of MDR on SMEs. It is to be expected that the MedTech market will continue to develop further and our results might take on a different meaning in the long term.

7.2 Future Work

Data on the long-term financial development of small manufacturers can contribute to a comprehensive understanding of the effect of regulation on the market. It would be interesting, from a scientific point of view, to compare the challenges between large and small companies, as access to resources differs in the two cases. In the longer term, it could be explored whether concerns about a decline in innovation have been realized and to what extent, as well as whether cases of small companies leaving the market due to financial difficulties have increased.

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8 Appendix

8.1 Questionnaire for the Interviews

1. Entry
   a) Do you have any objection if this discussion is recorded?
   b) How long have you been with your current company?
   c) What is your professional background and your tasks?
2. Previous experience with MDR compliance
   a) What is your company's experience with MDR compliant devices or software?
   b) Could you provide some examples of compliant products developed by your company?
3. Roles and processes
   a) What are the main roles in your team and their respective tasks?
   b) Is there an external partner involved in the certification process? What responsibilities are outsourced to them?
   c) How long does a certification process usually take for your products? What factors affect the duration?
4. Approaches and software tools
   a) Which are the guidelines and best practices that support the MDR certification in your company?
   b) In your experience, what software tools have proven useful in the certification process of your products?
5. Challenges and remedies
   a) In your opinion, what are the biggest challenges when certifying products according to the MDR?
   b) How are these challenges overcome?

6. Conclusion
    a) Have we missed a question that you were expecting? Do you have any additional remarks?

8.2 Complete Timeline of Certification Process

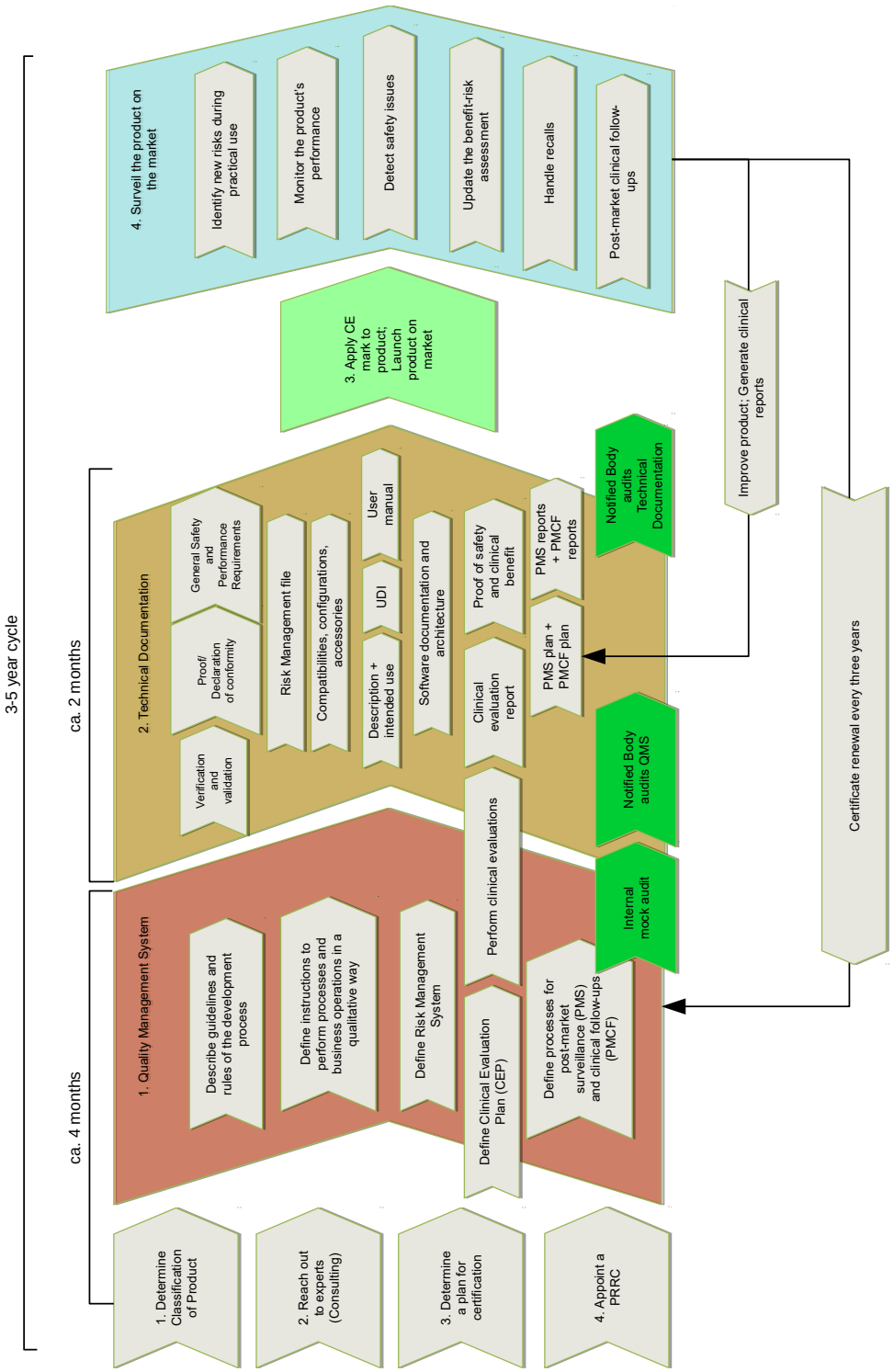

Figure 8.1: Complete Timeline of Certification Process, Source: own depiction