Optimization of Quality Management System in a Company Producing Medical Devices

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Master's thesis
2023

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Akademický rok: 2022/2023

ZADÁNÍ DIPLOMOVÉ PRÁCE

(projektu, uměleckého díla, uměleckého výkonu)

Jméno a příjmení:	**Bc. Štěpán Tichý**
Osobní číslo:	**M210208**
Studijní program:	**N0413A050020 Management ve zdravotnictví**
Forma studia:	**Kombinovaná**
Téma práce:	**Optimalizace systému řízení kvality ve společnosti vyrábějící zdravotnické prostředky**

Zásady pro vypracování

Úvod
Definujte cíle práce a použité metody zpracování práce.
I. Teoretická část

- Zpracujte literární rešerši týkající se systému řízení kvality ve vybrané organizaci.

II. Praktická část

- Proveďte analýzu současného stavu systému řízení kvality.
- Vyhodnoťe analýzu a definujte nedostatky systému řízení kvality.
- Navrhnětě optimalizaci systému řízení kvality a řešení.

Závěr

Rozsah diplomové práce: **cca 70 stran**
Forma zpracování diplomové práce: **tištěná/elektronická**
Jazyk zpracování: **Angličtina**

Seznam doporučené literatury:

JUUSO, Ilkka. *Developing an ISO 13485-Certified Quality Management System: An Implementation Guide for the Medical--Device Industry*. 1. UK: Productivity Press, 2022, 347 s. ISBN 9781032065731.
ABUHAV, Itay. *ISO 13485: 2016: A Complete Guide to Quality Management in the Medical Device Industry*. Second Edition. USA: CRC Press, 2018, 877 s. ISBN 978-1138039179.
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REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC. In: . EU, 2017, ročník 2017, 02017R0745, s. 228. 32017R0745. Dostupné také z: https://eur--lex.europa.eu/legal-content/CS/ALL/?uri=CELEX:32017R0745 .

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Ústav průmyslového inženýrství a informačních systémů

Datum zadání diplomové práce: **10. února 2023**
Termín odevzdání diplomové práce: **21. dubna 2023**

L.S.

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prof. Ing. Boris Popesko, Ph.D.
garant studijního programu

Ve Zlíně dne 10. února 2023

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ABSTRAKT

Hlavním cílem této diplomové práce je optimalizace systému řízení kvality v organizaci vyrábějící zdravotnické prostředky. Teoretickou část tvoří rešerše literatury týkající se systému managementu kvality a legislativy pro výrobu zdravotnických prostředků. Poskytuje podklady a porozumění pro analytickou část. V analýze je představena organizace Dina-Hitex spol. s r. o. a je představen a analyzován stávající systém managementu kvality dle normy ISO 13485:2016. Je provedena GAP analýza, která ukazuje chybějící procesy s normou ISO 13485:2016 A11:2021 a Nařízením o zdravotnických prostředcích 2017/745. V poslední části se projekt zaměřuje na optimalizaci systému řízení kvality a nabízí řešení, která jsou uvedena do praxe.

Klíčová slova: ISO 13485, systém řízení kvality, zdravotnické prostředky, GAP analýza, optimalizace

ABSTRACT

This diploma thesis's main goal is to optimise a quality management system in an organisation producing medical devices. The theoretical part consists of literature research regarding quality management systems and legislation for the production of medical devices. It provides a background and understanding for the analytical part. In the analysis, the organisation Dina-Hitex spol. s r.o is introduced, and the current quality management system is presented and analysed as per ISO 13485:2016. Gap analysis is performed to show missing processes with ISO 13485:2016 A11:2021 and Medical Device Regulation 2017/745. The last part of the project focuses on optimising the quality management system by offering a solution which is put into practical use.

Keywords: ISO 13485, quality management system, medical devices, GAP analysis, optimisation

I want to thank my supervisor, doc. Ing. Petr Briš, Csc, for his guidance, time and help while writing the thesis. I want to thank my employer Dina-Hitex spol. s r.o. for letting me use their company and data in this thesis. I also want to thank my fiancé for constant support and encouragement during the writing process.

I hereby declare that the print version of my Bachelor's/Master's thesis and the electronic version of my thesis deposited in the IS/STAG system are identical.

Motto

"Waste no more time arguing what a good man should be. Be one."

Marcus Aurelius

CONTENTS

INTRODUCTION

Production of medical devices has specific requirements. Focus on the safety and quality of the products is imperative, as well as the special clean environment in which they are produced. They require a specialised quality management system, preferably certified with ISO 13485:2016. Because medical devices are used in life-or-death situations, the public and legislation view them as very important. They are part of the standard people see in hospitals, private clinics, nursing homes and other healthcare establishments. Due to these things, the organisation must ensure a quality product that will satisfy the customer`s requirements and perform as desired.

This thesis is written to optimise the quality management system in an organisation producing medical devices. Dina-Hitex spol. s r.o. produces disposable medical devices and, in 2023, will be recertificated by a new Notify Body. The recertification subject is the quality management system per ISO 13485:2016 and the CE mark on their devices per Medical Device Regulation 2017/745, a new regulation for producing medical devices in Europe. The new regulation brought an update to the existing version of ISO 13485:2016 called A11:2021. The core of the thesis lies in performing a gap analysis and finding which parts of the quality management system need to be updated to show compliance and pass the audit. The optimisation is viewed as identifying the missing requirements and offering solutions for the problem, preparing the quality management system for recertification.

The theoretical part of the thesis focuses on establishing the legislative background. Basic introduction and requirements of ISO 13485:2016, medical devices in general and regulation for them. Relationships between Medical Device Directive and Medical Device Regulation 2017/745 and the connection between ISO13485:2016 and Medical Device Regulation are described. The end briefly describes the analysis methodology. The summary of the first part provides an overview of the theory.

The analysis starts with introducing the organisation Dina-Hitex spol. s r.o., whose quality management system is then optimised. The organisation is analysed through SWOT, PESTLE and Porter`s Five Forces analysis. The core of the analytical part is describing the current quality management system of Dina-Hitex spol. s r.o., with introducing how chapters of ISO 13485:2016 are compliant. The next part lies in performing a gap analysis of ISO 13485:2016 A11:2021, Medical Device Regulation 2017 and the quality management system of Dina-Hitex. Findings are identified, and non-conformities are

specified and summarised. The summary of the second part provides an overview of the analysis.

The project part deals with the optimisation process. Two solutions are shown and evaluated based on the available data. The two solutions are presented to the company`s top management. The chosen solution is put into practice and executed. The summary of the project provides an overview of the project.

OBJECTIVES AND METHODS OF PROCESSING

The main objective of the thesis is an optimisation of the quality management system by assessing the implementation of the new update of ISO 13485:2016 A11:2021. The partial objectives of the thesis are:

- Create a theoretical overview of the requirements for the production of medical devices.
- Analyse the current state of the company.
    - Analyse the company and the QMS.
    - Perform a GAP analysis of the new version of ISO 13485:2016 A11:2021
- Analysis review and define the non-conformities of the quality management system.
- Suggest solutions for the findings and optimise the QMS.

The analytical part primarily focuses on selected organisations producing medical devices. A company description serves as an overview of its activities and is introduced by SWOT and PESTLE analysis. The current state of the quality management system is reviewed to comply with ISO 13485:2016 requirements. Based on the review of the quality management system is performed a gap analysis of ISO 13485:2016 and ISO 13485:2016 is. After the gap analysis, a review defines the biggest non-conformities, which are then evaluated, and a solution for optimising the quality management system is proposed. The thesis output is the practical use of the implementation to update the quality management system.

I. THEORY

1 QUALITY MANAGEMENT SYSTEM

For this thesis, a widely used standard, ISO 9001:2015 – Quality management systems - Requirements, provides a sufficient definition of a Quality Management System (QMS) as a "set of policies, procedures and processes used by an organisation to ensure that their product or services meet or exceed customer expectation". Alternatively, as Ilkka Juuso (2022) puts it: "we do quality management because we believe managing quality is the best way to ensure a good outcome with as little risk as possible."

1.1 Use of Quality Management Systems

Quality Management Systems (QMS) have become increasingly important for organisations across various industries in recent years. QMS help organisations to meet customer requirements, comply with regulations, improve efficiency, and enhance overall quality. According to Pyzdek and Keller (2013), quality management systems can be used in various industries, including manufacturing, healthcare, and service. Organisations use quality management systems to improve their products or services, streamline processes, reduce costs, and increase customer satisfaction. By implementing a quality management system, organisations can also improve their ability to comply with regulatory requirements.

1.2 ISO Standards

ISO (International Organization for Standardization) is a non-governmental organisation that develops and publishes international standards to ensure the quality, safety, and efficiency of products and services across various industries (ISO 9001, 2015). ISO standards are recognised globally to promote good business practices, facilitate international trade, and protect consumers. These standards are developed by international experts from various industries and are reviewed and updated periodically to ensure relevance and effectiveness. The official website states that ISO standards cover multiple topics, including quality management, environmental management, occupational health and safety, food safety, and information security. ISO standards are voluntary, but many organisations choose to implement them.

Publication ISO 9001:2015 for Small Businesses by Tricker (2017) states that ISO standards help organisations reduce costs, improve efficiency, and manage risk effectively. By implementing ISO standards, organisations can enhance their operational performance

and use their resources better. Additionally, ISO standards provide a structured approach to identifying and mitigating risks, leading to better risk management practices.

1.3 ISO 9001:2015 Quality Management Systems - Requirements

ISO 9001:2015 is an internationally recognised standard for quality management systems (QMS) that has existed since its initial publication by the International Organization for Standardization (ISO) in 1987. Over the years, it has undergone several revisions, with the latest version being the 2015 standard. The standard provides a framework for organisations to consistently meet customer requirements and enhance customer satisfaction. The ISO 9001:2015 standard is based on several principles, including customer focus, leadership, engagement of people, process approach, improvement, evidence-based decision-making, and relationship management. (ISO, 2015)

Cochran (2018) writes that implementing an ISO 9001:2015 QMS has several benefits, the most significant being improved customer satisfaction. Organisations that focus on meeting customer requirements and enhancing customer satisfaction can gain a reputation for delivering high-quality products and services and increasing their competitiveness in the market. Another critical point is that QMS based on ISO 9001:2015 can improve the organisation`s processes and reduce waste, resulting in higher customer satisfaction.

Although certification to ISO 9001:2015 is not mandatory, it can benefit organisations that want to demonstrate their commitment to quality and gain a competitive edge in the marketplace. Certification involves an independent assessment by a certification body to ensure that the organisation's QMS meets the standard's requirements (ISO, 2015). The organisation describes ISO 9001:2015 as one of the most widely recognised and respected standards for QMS. It gives organisations a solid framework to establish and maintain a quality and continuous improvement culture.

2 STANDARD ISO 13485:2016

ISO 13485:2016 is an international standard that specifies the requirements for a QMS for medical devices (ISO, 2016). The ISO developed the standard in collaboration with the International Electrotechnical Commission (IEC) and other regulatory bodies. ISO 13485:2016 places a greater emphasis on the role of top management in the QMS. Top management must demonstrate their commitment to the QMS by establishing policies and objectives, providing resources, and monitoring performance. The standard also includes requirements for risk management, post-market surveillance, and control of outsourced processes (ISO, 2016).

One of the fundamental changes in ISO 13485:2016 is including risk management throughout the QMS. The standard requires organisations to establish and maintain a risk management system appropriate for their operations' size and complexity. This includes identifying and assessing risks associated with designing, developing, producing, and servicing medical devices. As stated in ISO 13485:2016, it also contains requirements for controlling outsourced processes and requires organisations to evaluate and select suppliers based on their ability to meet regulatory requirements.

Another significant change in ISO 13485:2016 is the inclusion of requirements for post-market surveillance. The standard requires organisations to establish procedures for monitoring and analysing information from post-market activities, such as complaints and product recalls. This information must be used to identify improvement opportunities and ensure the ongoing safety and effectiveness of medical devices (ISO, 2016).

2.1 Introduction to the standard ISO 13485:2016

As stated previously, ISO 13485:2016 is an international standard that specifies the requirements for a QMS to produce medical devices (ISO, 2016). It is intended to help medical device manufacturers and other organisations involved in the medical device supply chain to demonstrate their ability to meet customer and regulatory requirements consistently.

ISO 13485 was first published in 1996 and was based on the ISO 9001 quality management standard. The standard was developed specifically for the medical device industry and was designed to help organisations establish and maintain a QMS that meets regulatory requirements. The first version of the standard focused on the design,

development, production, installation, and servicing of medical devices. In 2003, a revised version of the standard was published, which included additional requirements related to regulatory compliance (ISO, 2003). The standard was revised to align more closely with the European Union's Medical Device Directives (MDD).

Another standard revision was published in 2016, the current version of the standard (ISO, 2016). This revision includes several significant changes to the standard, including risk management throughout the QMS and post-market surveillance requirements. The standard also places a greater emphasis on the role of top management in the QMS.

ISO 13485:2016 is now the internationally recognised standard for QMSs in the medical device industry. The standard is recognised by regulatory bodies such as the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) as evidence of compliance with regulatory requirements.

The standard has evolved over time, with revisions published in 2003 and 2016. The current version of the standard places a greater emphasis on risk management and post-market surveillance and is recognised by regulatory bodies as evidence of compliance with regulatory requirements. In 2021 an amendment was published called “A11:2021”, and it clarifies regulatory compliance with Medical Device Regulation 2017/745, which this thesis will cover later.

2.2 Scope and purpose of the standard ISO 13485:2016

ISO 13485:2016 is an internationally recognised standard for quality management systems (QMS) in the medical device industry (ISO, 2016). The standard outlines requirements for developing, implementing, and maintaining an effective QMS, emphasising the safety and efficacy of medical devices.

One of the primary reasons for using ISO 13485:2016 is to demonstrate compliance with regulatory requirements. Many countries, including the European Union, require medical device manufacturers to comply with specific regulations and standards to ensure the safety and effectiveness of their products (FDA, 2018). ISO 13485:2016 provides a framework that helps manufacturers meet these regulatory requirements and demonstrates their commitment to quality and safety.

Another reason for using ISO 13485:2016 is to improve organisational efficiency and effectiveness. The standard provides guidelines for establishing a systematic and efficient

QMS that enables organisations to meet customer and regulatory requirements consistently. Implementing ISO 13485:2016 can improve product quality, reduce costs, and increase customer satisfaction.

Additionally, ISO 13485:2016 provides a common language and framework for communication within the medical device industry. The standard is recognised and respected globally, facilitating communication between manufacturers, regulators, and customers across borders. Compliance with the standard also helps to mitigate risks and improve collaboration throughout the supply chain. Juuso (2022) writes that everything in the standard is made through a process – everything has defined inputs and outputs, and somehow there is refined and added value.

The standard focuses on the entire product lifecycle of a medical device, from design and development to post-market surveillance and maintenance. Risk management is a critical aspect of the standard, and organisations must identify and manage risks associated with their products throughout the entire product lifecycle. The purpose of ISO 13485:2016 is to provide a framework for establishing an effective QMS in the medical device industry. By implementing the standard, medical device manufacturers can establish a systematic and efficient QMS that consistently meets customer and regulatory requirements. Compliance with the standard can also provide a competitive advantage in the industry.

2.2.1 Specification of ISO 13485:2016 and differences to ISO 9001

ISO 13485:2016 and ISO 9001:2015 are two widely adopted standards for QMS that aim to improve the performance of organisations. Although they share many commonalities, there are significant differences between the two standards specific to their respective domains. (ISO 2015; ISO 2016)

ISO 9001:2015 is a generic standard applicable to all industries and provides a framework for organisations to establish and maintain an effective QMS. (ISO, 2015) The standard is based on the principles of customer focus, leadership, engagement of people, process approach, improvement, evidence-based decision-making, and relationship management. ISO 13485:2016, on the other hand, is specific to the medical device industry and provides requirements for QMS in this domain. It includes the same principles as ISO 9001:2015 and additional conditions specific to the medical device industry. (International Organization for Standardization, 2016)

One of the key differences between the two standards is the focus on risk management. While both standards require organisations to identify and manage risks, the emphasis differs. ISO 13485:2016 places a greater focus on risk management related to product safety and effectiveness. The standard requires organisations to implement a risk management process considering the entire product lifecycle, including post-market surveillance. ISO 9001:2015, on the other hand, focuses on risk management related to the QMS itself, such as identifying and addressing risks that may affect the organisation's ability to meet customer and regulatory requirements. (International Organization for Standardization, 2015)

Another significant difference between the two standards is the requirements for design and development. ISO 13485:2016 requires organisations to establish and maintain a design and development process that includes planning, input, output, review, verification, validation, and transfer. It also requires organisations to document the design and development activities and establish design change procedures (ISO, 2016). On the other hand, ISO 9001:2015 also includes requirements for design and development but provides more flexibility in terms of the level of documentation required. (ISO, 2015)

ISO 13485:2016 includes additional requirements related to regulatory compliance specific to the medical device industry. The standard requires organisations to establish and maintain procedures for obtaining and maintaining regulatory clearance or approval for their products. It also requires organisations to develop and maintain systems for vigilance and post-market surveillance activities.

In conclusion, while both ISO 13485:2016 and ISO 9001:2015 share common principles and requirements, there are significant differences between the two standards that are specific to their respective domains. Organisations must carefully consider these differences when deciding which standard to adopt or when implementing a QMS that complies with both standards.

2.2.2 The necessity of ISO 13485:2016 for the production of Medical devices

ISO 13485 was created to produce medical devices because it is a quality management system (QMS) standard for the medical device industry. The standard provides a framework for organisations to ensure that their medical devices are safe, effective, and compliant with regulatory requirements. ISO 13485 also helps organisations to minimise

risks associated with their products and to ensure the consistency of their products and services.

According to the European Commission, compliance with ISO 13485 is a prerequisite for obtaining the CE marking, a mandatory requirement for medical devices sold within the European Union (EU) (European Commission, 2019). Additionally, compliance with ISO 13485 is also required by regulatory bodies in other regions, such as the United States, Canada, and Japan (RegDesk, 2021).

ISO 13485 helps medical device manufacturers to establish and maintain a QMS that is specific to the requirements of the medical device industry. The standard requires organisations to implement a risk management process considering the entire product lifecycle, including post-market surveillance. This helps organisations to identify potential risks associated with their products and take appropriate measures to mitigate them.

In conclusion, ISO 13485 is necessary for the production of medical devices because it provides a comprehensive framework for organisations to ensure that their medical devices are safe, effective, and compliant with regulatory requirements. Compliance with ISO 13485 is also required by regulatory bodies in many regions and is essential for obtaining market access to medical devices.

2.3 Notify Bodies & Audits

Notify bodies, also referred to as Notified Bodies (NB), are organisations that are designated by national authorities to evaluate the conformity of products and services to specific regulations related to health, safety, and environmental protection (European Commission, 2020). These organisations play a critical role in the conformity assessment process, particularly for products that require a high level of safety, such as medical devices.

In the EU, Notified Bodies are designated by member state authorities and are responsible for conducting conformity assessment procedures according to the requirements of the relevant EU directives and regulations (European Commission, 2019). These procedures involve the organisation`s purpose, from assessing products' design, manufacturing conditions, and performance to meeting the applicable safety and performance requirements. Once a product is deemed to conform with the relevant requirements, the

Notified Body issues a conformity assessment certificate, which allows the product to be placed on the market.

NBs operate independently of the manufacturers whose products they assess to ensure impartiality and to maintain public trust in the conformity assessment process (European Commission, 2019). They must perform their duties with objectivity, competence, and confidentiality (International Accreditation Forum, 2016). Moreover, they must comply with relevant regulations and standards, including ISO/IEC 17065, which specifies the requirements for bodies certifying products, processes, and services (International Accreditation Forum, 2016).

As stated by the European Commission (2020) NBs face several challenges in performing their duties, including the increasing complexity and diversity of products, changing regulatory requirements, and the need for continuous improvement. Moreover, in past years, the COVID-19 pandemic has created additional challenges, such as the need to assess new medical devices, handle the increased demand for conformity assessments, and adapt to remote assessment methods (European Commission, 2021).

External audits are fulfilling the subject's overview. Juuso remarks that external audits work as an "opportunity to discuss the topic and perhaps even develop new ideas." (2022, p287) rather than seeing external audits as something to be feared of. Every issued certificate needs to be audited and controlled. In Annex VII of MDR (2017), requirements to be met by notified bodies are put in, and these conditions are set by the EU publicly for everyone to read and to know what the NB must fulfil to perform their responsibilities well. In the case of the standard ISO 13485:2016, the requirements and review of the instructed process meet the needs and whether the subject is meeting those instructed processes (Juuso, 2022).

2.4 General requirements of the standard ISO 13485:2016

In today's highly regulated medical industry, the production of medical devices must adhere to strict quality management systems. ISO 13485:2016 is an international standard that specifies the general requirements for quality management systems specific to medical device manufacturing.

ISO 13485:2016, on page 6 in clause 4.1.1, describes the basic general requirements that the organisation shall document a quality management system and maintain its

effectiveness following the requirements of the standard ISO 13485 and applicable regulatory requirements. This means that the organisation must ensure the application of said standard and any other regulatory requirements set by the state in which the organisation is located. The general requirements then continue: "The organisation shall establish and maintain, document, and implement a documented quality management system within the organisation with conformity to the requirements of the ISO 13485 Standard and applicable regulatory requirements." (ISO 13485, 2016) The standard ensures that the QMS will function and adhere to the conditions necessary to ensure the standard's quality and essential regulations.

ISO 13485:2016 then puts the requirements for the organisation to apply the necessary quality processes through the company, use a risk-based approach and define the interaction of these processes. The standard ISO 13485 then goes into more detail about individual process requirements. (ISO 13485,2016)

The general requirements do not provide any guidance or plan of how to perform said tasks; it only says to perform them, and this approach is found through the standard. Juuso writes that the standard sets inputs and outputs but mostly leaves out the actual work.

To put forward some of the other requirements set by the standard, a few critical parts of the ISO 13485:2016 can be viewed as an essential part of the general requirements, even though they are not under chapter 4.1.1:

- Management Responsibility

Top management must demonstrate their commitment to the QMS by establishing and communicating the quality policy and ensuring it is understood and applied throughout the organisation (ISO 13485,2016). They must also appoint a management representative with the authority and responsibility to ensure the QMS is established, implemented and maintained (ISO 13485,2016)).

- Resource Management

ISO 13485:2016 requires organisations to determine and provide the necessary resources to establish, implement, and maintain the QMS (ISO 13485,2016)). This includes the provision of appropriate infrastructure, work environment, and personnel and the availability of suitable equipment, software, and hardware.

- Product Realization

The standard requires organisations to establish and maintain processes for designing and developing medical devices, including risk management processes (ISO 13485,2016)). They must also establish procedures for purchasing, production, and post-production activities and identify and document the medical device (ISO 13485,2016)).

- Measurement, Analysis, and Improvement

ISO 13485:2016 requires organisations to establish and maintain processes for measuring, analysing, and improving the QMS and medical device effectiveness (ISO 13485,2016)). This includes the use of appropriate monitoring and measurement methods, the analysis of data to identify opportunities for improvement, and the implementation of corrective and preventive actions.

In conclusion, ISO 13485:2016 specifies the general requirements for quality management systems specific to medical device manufacturing. The standard requires organisations to establish, implement, and maintain a QMS that meets customer and regulatory requirements and ensures the safety and effectiveness of the medical device.

3 MEDICAL DEVICES

3.1 Introduction

Medical devices are instruments, apparatuses, machines, implants, or similar articles intended to diagnose, treat, or prevent disease or other medical conditions. They may also be used to alleviate pain, injury, or disability. Medical devices can range from simple tools such as tongue depressors and bandages to complex and sophisticated devices such as MRI machines, pacemakers, and artificial organs.

The definition of a medical device varies by country and regulatory authority. In the United States, medical devices are defined by the Food and Drug Administration (FDA) as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or another similar or related article, including any component, part, or accessory, which is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease." (FDA, 2022) Similarly, the European Union's definition of a medical device includes "any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific medical purposes." (European Commission, 2022)

Medical devices play a crucial role in modern healthcare, and their use has increased dramatically over the past few decades. The need is supported by Boccato (2022), stating the ageing of the population and the need to treat chronic illnesses. In addition to their importance in diagnosing and treating disease, medical devices are also used in research, clinical trials, and drug development. Medical devices must meet specific safety and effectiveness standards to be approved for use. These standards vary by country and region but generally include requirements for clinical testing, risk assessment, and manufacturing processes.

3.2 Specification of the production

The production of medical devices is a crucial process that requires adherence to specific requirements to ensure the safety and efficacy of the products. These requirements are necessary to meet regulatory standards, safeguard public health, and minimise the risks associated with medical device use.

One of the most critical requirements for the production of medical devices in compliance with regulatory standards. These standards set the guidelines and expectations that medical device manufacturers must follow to ensure their products are safe and effective. In the United States, the Food and Drug Administration (FDA) is responsible for regulating medical devices and enforcing compliance with regulatory standards (FDA, 2019). Manufacturers must adhere to the FDA's requirements for designing, developing, and testing medical devices to ensure their products are safe and effective for healthcare professionals and patients.

Another essential requirement for the production of medical devices is the use of appropriate manufacturing processes and techniques. Medical device manufacturers must use validated manufacturing processes and techniques to ensure their products are consistently manufactured to meet quality and performance specifications (FDA, 2013). This requires rigorous quality control procedures and testing to ensure that each device produced meets the required specifications.

In addition, medical device manufacturers must conduct thorough risk assessments and evaluations to identify and mitigate potential risks associated with their products. This includes evaluating the safety and efficacy of the device, identifying potential hazards and risks, and implementing appropriate measures to minimise these risks (ISO 13485, 2016). Manufacturers must also monitor the performance of their devices post-market to identify and address any safety concerns that may arise.

Lastly, medical device manufacturers must adhere to ethical standards and maintain transparency in their operations. This includes ensuring that their products are produced ethically and responsibly, transparent communication with stakeholders, and commitment to the highest standards of ethical conduct (ISO, 2016).

The production of medical devices requires adherence to specific requirements to ensure the safety and efficacy of the products. These requirements include compliance with regulatory standards, appropriate manufacturing processes and techniques, thorough risk assessments and evaluations, and ethical conduct. Medical device manufacturers must adhere to these requirements to safeguard public health and ensure their products meet the highest quality and performance standards. The importance of quality and safety of medical devices is mandatory even for the different legislative systems worldwide, but the regulatory requirements are different. Focus on specific regulatory requirements for the European market, followed in chapter 4.

4 LEGISLATION FOR THE PRODUCTION OF MEDICAL DEVICES

The production of medical devices is subject to various regulations and legislation aimed at ensuring the safety and effectiveness of the devices. The regulations and legislation governing medical devices have evolved, reflecting technological changes and the increasing complexity of medical devices. In this chapter, the focus is placed on two legislative systems. The first is legislation for the European market, and the second for comparison is for the United States.

4.1 Legislation for the European market

The current situation in the European market is complicated. Medical devices are regulated under the Medical Devices Regulation (MDR) (European Commission, 2017). The MDR was adopted in 2017 and replaced the Medical Devices Directive (MDD), which had been in place since 1993. However, MDR is still in its transition period, and due to recent delays, the full force of the regulation will come at the end of 2028. The most significant difference between the old MDD and MDR is that MDR aims to improve the safety and effectiveness of medical devices by strengthening regulatory requirements, enhancing post-market surveillance, and improving transparency.

Under the MDR, medical devices are classified into four classes based on the level of risk they pose to patients (European Commission, 2017). Class I devices are considered low-risk and do not require the involvement of a notified body. Class IIa and IIb devices are considered a moderate risk and require the involvement of a notified body to assess their conformity to the MDR's safety and performance requirements. Class III devices are considered high risk and require the involvement of a notified body and additional scrutiny, including a clinical evaluation before they can be placed on the market.

The MDR also includes provisions for clinical investigations of medical devices, including requirements for informed consent, ethics committee approval, and reporting of adverse events (European Commission, 2017). The MDR also includes requirements for post-market surveillance (PMS) and monitoring of medical devices, including reporting incidents and safety concerns.

Individual nation-specific laws then support the regulation of MDR. They are more specific for each country, and they specify some discrepancies and can provide further

clarification. Nevertheless, one of the essential parts of the individual laws is that these laws put specific fines and fees if the subject breaks the MDR. These fines are different for every country (for the Czech Republic it is specified in 375/2022 Sb. Zákon o zdravotnických prostředcích a diagnostických zdravotnických prostředcích in vitro)

4.2 Legislation for the United States

In the United States, medical devices are regulated by the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act (FFDCA) (U.S. Food and Drug Administration, 2019). The FFDCA was enacted in 1938, providing the legal authority for the FDA to regulate medical devices.

In 1976, the Medical Device Amendments to the FFDCA were passed, establishing a comprehensive regulatory framework for medical devices (U.S. Food and Drug Administration, 2019). The Medical Device Amendments require that medical devices undergo premarket review by the FDA to ensure their safety and effectiveness. The FDA classifies medical devices into three classes based on the level of control necessary to ensure their safety and effectiveness.

Class I devices are considered low-risk and subject to general controls, such as labelling requirements and adherence to manufacturing standards. Class II devices are considered moderate-risk and require individual controls, such as performance standards, post-market surveillance, and patient registries. Class III devices are considered high-risk and require premarket approval, which involves a rigorous review of clinical data and manufacturing processes (U.S. Food and Drug Administration, 2019).

The legislation for the production of medical devices has evolved, reflecting changes in technology and the increasing complexity of medical devices. The regulations governing medical devices aim to ensure the safety and effectiveness of these devices and protect patients from harm. In the United States, medical devices are regulated under the FFDCA, while in Europe, medical devices are regulated under the MDR. These regulations provide a framework for developing, testing, and marketing medical devices, ensuring patients receive safe and effective treatments.

4.3 History of legislation of medical devices in Europe

The regulation of medical devices in Europe has a long history that dates back to the early 1990s. Over time, the regulatory framework has evolved, reflecting technological changes

and the increasing complexity of medical devices. In 1993, the European Union (EU) adopted the Medical Devices Directive (MDD), which established a framework for the regulation of medical devices in the EU (European Commission, 1993). The MDD required that medical devices undergo conformity assessment by a notified body to ensure their safety and effectiveness. The MDD also established the classification system for medical devices, which classified devices into four classes based on the level of risk they posed to patients.

In 2007, the EU adopted the Active Implantable Medical Devices Directive (AIMDD), which established additional requirements for active implantable medical devices, such as pacemakers and defibrillators (European Commission, 2007). The AIMDD required that these devices undergo additional testing and monitoring to ensure their safety and effectiveness.

In 2012, the EU began a review of its regulatory framework for medical devices, prompted by concerns about the safety and effectiveness of specific medical devices, such as metal-on-metal hip implants and breast implants (European Commission, 2012). The review culminated in adopting the new Medical Devices Regulation (MDR) in 2017.

The MDR replaces the MDD and the AIMDD and aims to improve the safety and effectiveness of medical devices by strengthening regulatory requirements, enhancing post-market surveillance, and improving transparency (European Commission, 2017). The MDR introduces a new classification system for medical devices, which includes stricter rules for high-risk devices, such as implantable devices and devices intended for life-supporting or life-sustaining purposes.

As MDD and same under the MDR, medical device manufacturers must demonstrate compliance with the regulation through conformity assessment by a notified body (European Commission, 2017). The MDR also requires manufacturers to provide more detailed information about their devices, including clinical data and information about the supply chain. Generally, the MDR is stricter than the MDD, which is visible comparing the length of both legislative documents. MDD has 23 articles and 18 annexes, which provide more detailed guidance on specific aspects of the production of medical devices. The total number in the MDD is around 60 pages. MDR has 123 articles and 17 annexes and, depending on the version, has around 220 pages.

In addition, the MDR includes provisions for clinical investigations of medical devices, including requirements for informed consent, ethics committee approval, and reporting of adverse events. As mentioned before, requirements for post-market surveillance and monitoring of medical devices, including reporting vigilance systems, are thoroughly described and required (European Commission, 2017).

Regulation of medical devices in Europe has evolved, reflecting technological changes and the increasing complexity of medical devices. The adoption of the MDR in 2017 represents a significant step forward in ensuring the safety and effectiveness of medical devices in Europe. The MDR provides a comprehensive framework for regulating medical devices, including new requirements for conformity assessment, clinical investigations, and post-market surveillance.

4.4 Medical Device Directive

The Medical Devices Directive (MDD) is a European Union (EU) regulatory framework introduced in 1993 to ensure the safety and effectiveness of medical devices sold in the European market. The MDD has undergone several revisions since its inception, reflecting technological changes and the increasing complexity of medical devices.

The MDD requires that medical devices undergo conformity assessment by a notified body to ensure their safety and effectiveness. The conformity assessment process varies depending on the device's classification based on the level of risk the device poses to patients. The MDD classifies medical devices into four classes: Class I, IIa, IIb, and III, with Class III devices posing the highest risk to patients (European Commission, 1993).

European Commission (1993) also specifies that manufacturers of medical devices must also comply with essential requirements, which include general safety and performance requirements, such as risk management, clinical evaluation, and post-market surveillance. These essential requirements ensure that medical devices are safe, effective, and meet the needs of patients. The MDD also requires manufacturers to provide documentation, including technical documentation, labelling, and instructions for use, to ensure that medical devices are used correctly and safely.

In 2012, the EU began a review of the MDD, prompted by concerns about the safety and effectiveness of specific medical devices (European Commission, 2012). The review culminated in the adoption the new Medical Devices Regulation (MDR) in 2017.

As stated in previous chapters, the MDR replaces the MDD and aims to improve the safety and effectiveness of medical devices by strengthening regulatory requirements, enhancing post-market surveillance, and improving transparency and traceability (European Commission, 2017). The MDR introduces a new classification system for medical devices, which includes stricter rules for high-risk devices, such as implantable devices and devices intended for life-supporting or life-sustaining purposes.

However, the transition from the MDD to the MDR has yet to be smooth, with concerns about the capacity of notified bodies to handle the increased workload and the potential impact on small and medium-sized enterprises (SMEs) (Richter, 2020). Some SMEs have reported difficulties obtaining the required certification under the MDR, leading to concerns about market access and innovation (European Parliament, 2021). Moreover, due to concerns about the lack of medical devices on the European market, the Parliament decided to prolong the transition period, depending on the risk class of the medical device.

MDD has played a crucial role in ensuring the safety and effectiveness of medical devices sold in the European market. However, the adoption of the MDR in 2017 represents a significant step forward in ensuring higher safety and effectiveness of medical devices in Europe.

4.5 Medical Device Regulation

The Medical Device Regulation (MDR) is a new regulatory framework adopted by the European Union (EU) in 2017 to ensure the safety and effectiveness of medical devices sold in the European market. The MDR replaced the previous Medical Device Directive (MDD) and introduced several significant changes to the regulatory requirements for medical devices.

The MDR applies to all medical devices sold in the European market, regardless of origin, and includes a wide range of products, from surgical gowns and simple bandages to complex implantable devices (European Commission, 2017). The MDR aims to improve the safety and effectiveness of medical devices by introducing more stringent regulatory requirements and enhancing post-market surveillance.

The MDR requires medical device manufacturers to comply with several new regulatory requirements, including stricter rules for clinical investigations, enhanced post-market surveillance, and the introduction of a new classification system for medical devices.

Under the new classification system, medical devices are classified based on their risk to patients. Class III devices, such as implantable devices, are subject to strict regulatory requirements.

The MDR also requires manufacturers to provide more detailed technical documentation, labelling, and instructions to ensure that medical devices are used correctly and safely. Additionally, the MDR introduces new requirements for reporting adverse events and the transparency of clinical data.

Compared to the MDD, the MDR represents a significant step forward in ensuring the safety and effectiveness of medical devices in Europe. While the MDD focused primarily on the pre-market approval process for medical devices, the MDR emphasises post-market surveillance and medical devices' ongoing safety and effectiveness. This can be seen in the importance of article 120 of MDR. (European Commission, 2017).

One of the key differences between the MDR and the MDD is the new classification system for medical devices. The MDR introduces stricter rules for high-risk devices, such as implantable devices and devices intended for life-supporting or life-sustaining purposes. Additionally, the MDR emphasises clinical evaluation and requires manufacturers to provide more detailed clinical data to support their applications for regulatory approval.

Another significant difference between the MDR and the MDD is introducing a new regulatory framework for notified bodies, the organisations responsible for assessing the conformity of medical devices with regulatory requirements. The MDR introduces new requirements for notified bodies, including enhanced competence and capacity requirements, to ensure they can effectively carry out their responsibilities under the new regulatory framework.

Medical Device Regulation represents a significant step in ensuring the safety and effectiveness of medical devices sold in the European market. The MDR introduces several new regulatory requirements, including stricter rules for high-risk devices, enhanced post-market surveillance, and more detailed clinical data requirements.

4.6 Other legislative systems

Every state has different requirements for regulating production, not medical devices. Boccato et al. (2022) describe in Medical Devices Improving Healthcare Through a multidisciplinary Approach that the differences do not lie only in the classification of the

devices but in the overall process, the quickness of approval etc. If one is designated in Europe and wants to be in the business of medical devices, the subject needs to focus on and direct by the legislation of previously explained MDD or MDR. However, if the subject expects to expand into another market, the subject must be prepared to implement the requirements from other legislative systems. Quality Management planning is essential, so the documents are prepared to comply with multiple legislation systems. In this chapter, only two legislation systems are described.

4.6.1 FDA – America, Canada, Australia

The U.S. Food and Drug Administration (FDA) is a government regulatory agency responsible for safeguarding the safety, efficacy, and security of human and veterinary drugs, vaccines, medical devices, and other products related to public health (U.S. Food and Drug Administration 2021). The FDA plays a crucial role in protecting public health by setting and enforcing product safety, efficacy, and quality standards. It has broad authority to regulate products sold in the United States, including drugs, biologics, medical devices, food, cosmetics, and tobacco products (U.S. Food and Drug Administration, 2021).

One of the primary responsibilities of the FDA is to review and approve new drugs and medical devices before they can be marketed to the public. The agency conducts a rigorous review of data from clinical trials and other sources to ensure the product is safe and effective for its intended use. Additionally, the FDA monitors and responds to adverse events and safety concerns related to existing products, issues recall and warnings, and takes enforcement actions against manufacturers who violate regulations (U.S. Food and Drug Administration, 2021).

The FDA operates under a complex regulatory framework that includes laws, regulations, and guidance documents. The primary legislation governing the FDA is the Federal Food, Drug, and Cosmetic Act, which grants the agency the authority to regulate products related to public health (U.S. Food and Drug Administration, 2021). The FDA also has the power to issue regulations, which have the force of law, and guidance documents, which provide recommendations and best practices for manufacturers.

The FDA has undergone significant changes and updates to its regulatory framework in recent years. The Food and Drug Administration Safety and Innovation Act (FDASIA) of 2012 introduced reforms to the FDA's regulatory process, including creating a

breakthrough therapy designation for certain drugs and a new pathway for the expedited review of medical devices (U.S. Food and Drug Administration, 2012). The 21st Century Cures Act of 2016 aimed to accelerate the development and approval of new medical products and included provisions to streamline the FDA's regulatory review process, improve the agency's use of real-world evidence in decision-making, and increase funding for medical research (U.S. Food and Drug Administration, 2016).

The agency employs various regulatory tools to fulfil its mission, including reviewing and approving new products, regulating existing products on the market, and taking enforcement actions against manufacturers who violate regulations. The FDA operates under a complex regulatory framework that includes laws, regulations, and guidance documents. In recent years, it has undergone significant changes and updates to improve its regulatory process and accelerate the development and approval of new medical products.

4.6.2 UKCA

V The UKCA (UK Conformity Assessed) mark is a new marking that signifies compliance with the applicable safety, health, and environmental protection requirements for medical devices sold in Great Britain. This marking is required after the end of the Brexit transition period and is governed by the Medical Devices Regulations 2002 (as amended) and the Medical Devices Regulations 2019 (EU Exit). These regulations apply to medical devices sold in Great Britain, including those manufactured in the UK and those imported from other countries (Department of Health and Social Care, 2020). Manufacturers must meet specific requirements and comply with applicable conformity assessment procedures to affix the UKCA mark to their products.

The UKCA regime is similar to the EU's CE marking requirements, but some key differences exist. For example, under the UKCA legislation, manufacturers must use a UK-based approved body for conformity assessment procedures. In contrast, under the EU's CE marking regime, manufacturers can use any approved body within the EU. Additionally, products already affixed with the CE mark can continue to be sold in the UK until the end of the transition period. However, after that point, the UKCA mark will be required (Department for Business, Energy & Industrial Strategy, 2020). The UK government has stated that it will continue to align with international standards and best practices to ensure that UK medical devices remain safe and effective, even with the shift

away from the EU's regulatory framework (Medicines and Healthcare Products Regulatory Agency, 2021).

UKCA mark is a new marking required for medical devices sold in Great Britain after the end of the Brexit transition period. It signifies compliance with UK legislation's applicable safety, health, and environmental protection requirements. Manufacturers must meet specific requirements and comply with applicable conformity assessment procedures to affix the UKCA mark to their products. While there are some critical differences between the UKCA regime and the EU's CE marking regime, the UK government has stated that it will continue to align with international standards and best practices to ensure the safety and effectiveness of UK medical devices.

5 MEDICAL DEVICE REGULATION 2017/745

5.1 Introduction to MDR2017/745

The Medical Device Regulation (MDR) is a new regulatory framework that supersedes the Medical Device Directive (MDD). The MDR was introduced to address concerns around the safety and efficacy of medical devices and to provide a more robust regulatory system for medical devices sold in the European Union (EU).

The MDR was introduced in 2017 and became fully applicable in May 2021, replacing the MDD, which had been in place since 1993. The MDR aims to ensure that medical devices are safe and effective by increasing scrutiny and oversight of the devices and the companies that manufacture them. (European Commission, 2017).

One of the key reasons for introducing the MDR was to address concerns about the safety and quality of medical devices. The MDR introduces new requirements for manufacturers of medical devices, including stricter rules around clinical testing and post-market surveillance. This is intended to ensure that devices are tested thoroughly before making them available to patients and that any safety issues are identified and addressed promptly. (TÜV SÜD, 2021).

Another reason for introducing the MDR is to provide a more robust regulatory system for medical devices sold in the EU. The MDR is intended to provide a more transparent and harmonised regulatory framework for medical devices across the EU, making it easier for manufacturers to sell their products in multiple EU member states.

The MDR introduces new requirements for manufacturers, including appointing a person responsible for regulatory compliance (PRRC), stricter clinical data requirements, and increased supply chain transparency. The MDR also introduces new classifications for medical devices, which will impact the scrutiny and oversight required for each device.

5.2 Medical devices in MDR 2017/745

The MDR (2017) provides a detailed definition of what constitutes a medical device. According to Article 2 of the MDR, a medical device is defined as “any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes”:

- Diagnosis, prevention, monitoring, 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 for medical or diagnostic purposes using in vitro examination of specimens derived from the human body including organ, blood, and tissue donations, and which does not achieve its principal intended action by pharmacological, immunological, or metabolic means, in or on the human body, but which may be assisted in its function by such means. (European Commission MDR, 2017).

This definition includes a wide range of products, from simple diagnostic tools like blood glucose meters, surgical masks, surgical gowns, and sterile scalpels to complex implantable devices like artificial heart valves and CT machines. The MDR also includes requirements for software, and mobile applications (Article 8 and Annex I) used for medical purposes and accessories and components used in conjunction with medical devices.

Not all products used in a medical context are considered medical devices under the MDR. It is directly compared to the definitions of medical devices in Article 2. For example, products that are solely intended for cosmetic purposes, or those that are intended to be used for research purposes only, are not considered medical devices under the MDR.

The definition of a medical device under the MDR is broad. It includes various products to diagnose, treat, or prevent disease or other medical conditions. The MDR provides a detailed definition of a medical device, including software and mobile applications, accessories, and components used with medical devices. (TÜV SÜD, 2021).

The Medical Device Regulation (MDR) 2017/745 classifies medical devices based on their risk level to patients and users to determine the appropriate level of scrutiny and regulatory requirements for each device. The MDR introduces a new concept of "qualification" for specific high-risk devices that require additional scrutiny and evidence.

The MDR classifies medical devices into four different classes, ranging from Class I (low risk) to Class III (high risk), considering factors such as the intended use, duration of use, invasiveness, and potential harm to patients and users (TÜV SÜD b, 2021).

As mentioned in Chapter 4.1., medical devices under the MDR are classified into four risk classes based on the level of risk they pose to patients (European Commission, 2017). Class I devices are considered low-risk and subject to self-certification by the manufacturer, but only if these devices are non-sterile. Class I devices have in total four group types, and three of them then require certification by a notified body: Is (sterile devices), Im (medical devices with measuring function) and Ir (reusable medical devices). These devices include bandages, tongue depressors, and surgical gowns and drapes. Class IIa and IIb devices are considered moderate-risk and require conformity assessment by a notified body. Examples of these devices include an infusion pump, a group of surgical instruments used during operations, or syringes and needles. Class III devices are considered high-risk and require premarket approval by a notified body – these devices are implantable devices, life-supporting equipment, or medical devices using nanomaterials.

In addition to classification, the MDR introduces the concept of "qualification" for specific high-risk devices, such as implantable devices, active implantable devices, and devices that incorporate medicinal substances. The qualification process requires manufacturers to provide additional evidence to demonstrate the safety and effectiveness of these devices, including clinical data and post-market surveillance data (European Commission, 2017; TÜV SÜD, 2021). The qualification process ensures that these devices meet the highest safety and performance standards and benefit patients the most.

The MDR's classification and qualification systems ensure that medical devices meet the highest safety and performance standards and benefit patients the most. The classification system considers various factors, and the qualification process applies to specific high-risk devices to ensure that they meet the highest standards of safety and effectiveness.

5.3 Requirements of MDR 2017/745 for Medical Devices

The European Union's (EU) Medical Device Regulation (MDR) requires medical device manufacturers to comply with strengthened production requirements, including Technical File and Clinical Evaluation, to ensure the safety and performance of devices sold within the EU. The Technical File is a critical component of the MDR, providing a comprehensive overview of the device's design, manufacturing process, labelling,

instructions for use, and clinical evidence supporting its safety and performance, as well as a risk assessment to identify and mitigate potential hazards (TÜV SÜD, 2019). As MDR 2017/745 states, the Technical File must be up-to-date and complete, kept for ten years after the device's placement on the market, and updated when there are changes to the device's design, intended use or safety and performance information becomes available.

Similarly, the MDR requires a Clinical Evaluation, a systematic and comprehensive assessment of clinical data relevant to the device's safety and performance, to confirm its safety and intended performance under normal use conditions. Manufacturers must base their Clinical Evaluation on clinical data collected from literature or clinical investigations and update it regularly to reflect the latest scientific knowledge and safety and performance information, documenting it in the Technical File.

The Technical File and Clinical Evaluation are significant requirements under the MDR, aiming to improve patient safety and ensure medical devices sold within the EU are safe and perform as intended (European Commission, 2020).

5.4 Requirements of MDR 2017/745 for conformity assessment

According to the Medical Device Regulation (MDR), Annex IX lays down the requirements for conformity assessment of medical devices based on the Quality Management System (QMS) and technical documentation. The conformity assessment is performed by a notified body to ensure that the medical device complies with the regulatory requirements of the MDR.

5.4.1 Conformity Assessment based on QMS:

The QMS requirements for conformity assessment under Annex IX of the MDR are laid down in Article 10. The medical device manufacturer must establish, implement, and maintain a QMS that meets the requirements of the MDR. The QMS must cover all aspects of the production of the medical device, including design and development, manufacturing, packaging, labelling, and distribution. The QMS must also include the procedures for monitoring and controlling the production process, including the identification and traceability of the medical device.

The QMS requirements for conformity assessment are designed to ensure that the medical device is produced in a consistent and controlled manner and that it meets the requirements of the MDR. The conformity assessment based on the QMS is performed by a notified

body, which assesses the QMS to ensure that it complies with the requirements of the MDR. The notified body also performs regular audits to maintain and update the QMS as required. The MDR does not specify what type or kind of QMS the subject must implement and how it must look and behave; it only states the requirements that need to be covered. However, it is strongly implied that the subject or manufacturer will have implemented its QMS with ISO 13485. The relationship between MDR and ISO 13485 will be discussed later.

5.4.2 Conformity Assessment based on Technical Documentation:

The technical documentation requirements for conformity assessment under Annex IX of the MDR are laid down in Article 11. The technical documentation must contain information on the medical device's design, manufacture, and performance. The technical documentation must also include information on the results of any clinical evaluation and post-market surveillance activities.

The technical documentation requirements for conformity assessment are designed to ensure that the medical device meets the requirements of the MDR and is safe and effective for use. The conformity assessment based on technical documentation is performed by a notified body, which assesses the technical documentation to ensure that it contains all the required information and demonstrates compliance with the MDR. The notified body may also request additional information or clarification from the manufacturer if required.

5.4.3 Importance of Conformity Assessment:

The conformity assessment is an essential part of the production of medical devices under the MDR. It ensures that the medical device complies with the regulatory requirements of the MDR and is safe and effective for use. The conformity assessment also assures patients, healthcare professionals, and regulatory authorities that the medical device meets the required standards.

The conformity assessment based on the QMS, and technical documentation is critical as it covers all aspects of the production of the medical device. It ensures that the medical device is produced in a consistent and controlled manner and that it meets the requirements of the MDR. The conformity assessment assures patients, healthcare professionals, and regulatory authorities that the medical device meets the required standards and that a

notified body performs it. The conformity assessment based on technical documentation also ensures that the technical documentation contains all the required information and demonstrates compliance with the MDR.

6 RELATIONSHIP BETWEEN MDR 2017/745 AND ISO 13485:2016

The Medical Device Regulation (MDR) 2017/745 is a set of regulations established by the European Union to ensure the safety and performance of medical devices. On the other hand, the International Organization for Standardization (ISO) 13485:2016 is a standard that outlines the requirements for a quality management system (QMS) to produce medical devices.

Firstly, it is essential to note that ISO 13485:2016 is recognised by MDR 2017/745 as evidence of compliance with the QMS requirements. This means that companies that comply with ISO 13485:2016 are already meeting some of the requirements of MDR 2017/745, making it easier for them to transition to the new regulation. However, compliance with ISO 13485:2016 alone does not guarantee compliance with MDR 2017/745. The regulation has additional requirements that go beyond the scope of the standard.

MDR 2017/745 imposes stricter requirements than its predecessor, the Medical Device Directive (MDD) 93/42/EEC. The regulation requires medical device manufacturers to implement and maintain a QMS that meets the requirements of ISO 13485:2016 and MDR 2017/745. This means compliance with the ISO standard is a prerequisite for MDR 2017/745. As presented in the previous chapter, MDR 2017/745 requires manufacturers to conduct a conformity assessment based on the QMS and technical documentation. This assessment is an essential aspect of MDR 2017/745 and aims to ensure that the medical device is safe and effective.

Secondly, the relationship between MDR 2017/745 and ISO 13485:2016 impacts the medical device industry. The new regulation requires medical device manufacturers to have a more robust QMS than required under MDD 93/42/EEC. Companies must invest more resources in their QMS to comply with the new regulation. The ISO 13485:2016 standard provides a framework for implementing a QMS that meets the requirements of MDR 2017/745. However, companies must also ensure that their QMS addresses the additional requirements of the regulation.

The relationship between MDR 2017/745 and ISO 13485:2016 also has implications for conformity assessment bodies (CABs). These bodies are responsible for assessing the conformity of medical devices with the regulation. To conduct this assessment, they must thoroughly understand the QMS and technical documentation of the medical device.

Compliance with ISO 13485:2016 ensures that the QMS meets the requirements, which can streamline the assessment process for CABs.

In conclusion, the relationship between MDR 2017/745 and ISO 13485:2016 is critical to ensuring the safety and performance of medical devices. Compliance with the ISO standard is a prerequisite for compliance with the new regulation, but companies must also ensure that their QMS meets the additional requirements of MDR 2017/745. The relationship between the two also has significant implications for the medical device industry and conformity assessment bodies. As such, medical device manufacturers must understand this relationship to comply with the new regulation successfully.

ISO 13485:2016 provides a framework for developing, implementing, and maintaining QMS for medical device manufacturers. Manufacturers often use it to demonstrate compliance with regulatory requirements, including the MDD and the MDR. The MDR, however, has made several changes to the regulatory requirements that manufacturers must comply with, which also impact the application of ISO 13485:2016.

As stated by the European Commission in the journal of L 117/1, one of the significant changes the MDR introduced is the requirement for a more extensive and rigorous clinical evaluation of medical devices. Manufacturers are now required to provide more robust clinical data to demonstrate the safety and effectiveness of their products. This requirement also affects the application of ISO 13485:2016, as it places additional emphasis on risk management and post-market surveillance.

In the same document, another change mentioned is the requirement for more detailed documentation and traceability throughout the device's life cycle. The MDR requires manufacturers to maintain a Technical Documentation File (TDF) that contains all relevant information about the device, including design and development, manufacturing, clinical evaluation, and post-market surveillance. This requirement also affects the application of ISO 13485:2016, requiring manufacturers to have a comprehensive QMS to manage and maintain the necessary documentation.

Furthermore, the MDR also emphasises the role of notified bodies in the conformity assessment process. Notified bodies are responsible for reviewing and assessing manufacturers' technical documentation and conducting audits of their QMS to ensure compliance with regulatory requirements. The MDR introduces more stringent requirements for notified bodies, including increased competence and capacity

requirements and ongoing monitoring and supervision by regulatory authorities. These changes also impact the application of ISO 13485:2016, as manufacturers must ensure that their QMS meets the new requirements for conformity assessment under the MDR.

In conclusion, the MDR has significant implications for applying ISO 13485:2016. The MDR introduces new requirements for clinical evaluation, documentation, and conformity assessment, which impact the application of ISO 13485:2016 in developing, implementing, and maintaining QMS for medical device manufacturers. Therefore, manufacturers must ensure that their QMS meets the new requirements under the MDR to ensure compliance with regulatory requirements and maintain market access in the EU.

6.1 ISO 13485:2016 A11:2021

ISO 13485:2016 is a widely used medical device quality management system (QMS) standard. It provides requirements for the design, development, production, and delivery of medical devices, focusing on ensuring the safety and effectiveness of these products. In 2021, the standard was updated with a new amendment, A11:2021, which updates the existing requirements. Correction A11 describes the relationship between ISO 13485:2016 and regulations. It rewrites Annex of ISO 13485:2016 ZA and ZB, which were adapted for the old regulation MDD and IVDR. With the new legislation MDR 2017/745 and for IVDR`s 2071/746, the annexes of ISO 13485 were obsolete and are concerning the old legislation. Therefore A11:2021 describes the relationship between the standard for a quality management system for producing medical devices and parts of the legislation required for conformity assessment of QMS. The standard is reviewed every five years, so this amendment now confirms the version of ISO 13485:2016 to be valid for another five years.

One of the fundamental changes introduced by A11:2021 is the requirement for the QMS to cover the entire life cycle of the medical device, from conception to post-market surveillance. This means manufacturers must have a holistic approach to their QMS, ensuring that all product life cycle stages are adequately covered. This change aligns with the European Union Medical Device Regulation (MDR), which requires manufacturers to have a comprehensive QMS covering the entire product life cycle.

Another significant change introduced by A11:2021 is the requirement for risk management to be integrated into the QMS. Risk management was required for medical devices even in previous legislation. However, ISO 13485 does not state specifically the

conditions. A different standard sets them - ISO 14971:2019 *Medical devices – application of risk management to medical devices.* Manufacturers need to demonstrate that they have identified and evaluated risks associated with their products and have implemented appropriate controls to mitigate these risks. This change reflects the growing importance of risk management in the medical device industry and aligns with the requirements of the MDR.

A11:2021 also introduces new requirements for validating computer software used in medical devices. Manufacturers must ensure that software validation is included in their QMS and covers all software development life cycle stages. This change is in response to the increasing use of software in medical devices and the need to ensure that these products are safe and effective.

Another change introduced by A11:2021 is the requirement for manufacturers to establish procedures for managing outsourced processes. This includes ensuring that outsourced processes are adequately controlled, monitored, and evaluated. This change reflects the increasing use of outsourcing in the medical device industry and the need to ensure that outsourced processes do not compromise the safety and effectiveness of medical devices.

ISO 13485:2016 A11:2021 brings significant changes the existing requirements for quality management systems for medical devices. These changes reflect the evolving regulatory landscape in the medical device industry and the growing importance of ensuring the safety and effectiveness of these products.

7 ANALYSIS METHODOLOGY

The methodology used in this chapter is further applied in the analysis part to evaluate the specific requirements of the organisation and this thesis. Every method is used for a specific reason, as their function reflects the need to understand the organisation or the specific aim of this thesis.

7.1 SWOT Analysis

SWOT analysis is one of the most used methods for evaluating the internal and external environment. Its acronym is taken from the four parts of the analysis used for the method – strengths, weaknesses, opportunities and threats. Thomas et al. write: "Although it has its issues, the simplicity of its design allows an easy grasp of the four essential components needed to evaluate the feasibility of projects…" This framework is then used in this thesis to evaluate the said organisation.

7.2 PESTLE Analysis

So-called PESTLE analysis is a tool used for describing the external factors of the organisation on a macro scale level. There are six different factors which are being taken into consideration. They are political, economic, social, technological, legal and environmental. Together these factors help the organisation to understand their external environment (Mind Tools Content Team a, 2022).

7.3 Porter`s Five Forces

This tool analyses competitive forces in an industry. As the name suggests, five forces are considered: competitive rivalry, supplier power, buyer power, the threat of substitution, and the threat of new entry. When these factors are analysed, the organisation can understand the environment in which it operates and potentially improve its position in the market (Investopedia, 2023).

7.4 GAP Analysis

The last method is Gap Analysis. It is a tool that identifies the gap between the current situation and the future desired state and describes the tasks needed to close the gap. Desired stages could typically include defining the current state, defining the desired state, identifying the gaps and developing an action plan (Mind Tools Content Team b, 2022).

8 SUMMARY OF THEORY

The theory part of the thesis introduces the necessary background to understand the analysis and reasons for optimising the organisation's Quality Management. At first, the Quality Management and ISO standards are introduced and explained. As the analysis deals with medical devices and their production of them, a specific standard is necessary. It is imperative to have an overview of the ISO 13485:2016 standard.

The standard ISO 13485:2016 is described, its scope and specific requirements. It is also compared to the broader Quality Management standard – ISO 9001:2015, which is a standard for any Quality management system.

In Chapter 3, medical devices are introduced, and legislation for production is described. It covers the legislation in the European Union and the United States. However, the biggest focus is put on the legislation system in the European Union, as this is where the organisation, on which the analytical part focuses, sells its products. For this reason, a Medical Device Directive is introduced, as it is still valid legislation, even though it is superseded by the new regulation Medical Device Regulation 2017/745. The new regulation is introduced, and its product requirements and conditions are described. Finally, a relationship between regulation MDR and ISO 13485:2016 is the core of the optimisation process.

A summary of the analytical methodology is given at the end of the theory part of the thesis. This includes a SWOT, PESTLE, Porter`s Five Forces, and gap analysis.

II. ANALYSIS

9 INTRODUCTION OF DINA-HITEX SPOL. S R.O.

The next parts of the thesis will focus on the optimisation of quality management system in a specific organisation. That organisation is Dina-Hitex spol. s r. o., which currently employs the author as its Quality Manager. Due to these circumstances, the analytical part will be used as a source of improvement, and the organisation is sharing all data with permission.

9.1 Basic characterisation of the company

Dina-Hitex spol. s r.o. is a private limited liability company based in the Czech Republic that specialises in producing and distributing medical devices. It is based in South Moravia in Bučovice (about 35 km from Brno). The company's CEO is Shashidar Singh, and Pavel Hrabovský holds the director position. The company employs about 750 employees on three continents (about 40% are in the Czech Republic). The company`s primary focus is on the Czech market; however, due to offshore branches, an important part of the production goes to Slovak and Polish markets. A critical supplier is being held by an outsourced company, Hitex Healthcare, in India, which supplies Dina-Hitex with non-sterile semi-finished products. The company's sister in Tunisia supplies the North African market.

Picture 1 Dina-Hitex (source www.dina-hitex.com, 2023)

9.2 Company History

The company was founded in 1992 and has since established a reputation for quality products and excellent customer service. Through the years, several significant events happened:

- 1992 – the founding of HITEX
- 1995 – the transformation of the company into DINA HITEX
- 2000 - Building ISO 7,8 class cleanrooms
- 2005 - ETO sterilisation chamber
- 2005 – Purchasing an automatic packaging line
- 2010 – Adding a lamination line for the production of multi-layered materials
- 2010 - Establishment of Hitex Healthcare India
- 2011 - Fully automatic drape production line
- 2015 - Establishment of Medica HitexTunis
- 2016 - Expansion of ISO Class 8 cleanroom
- 2018 - Construction of administration building and testing laboratory.
- 2021- Establishment of new production and clean room in village Hodějice
- 2022 – Building of new warehouses (O nás, DINA-HITEX, 2023)

Currently, the company is preparing for the transition to new legislation and therefore holding and keeping its position in the European market as a reliable supplier of medical devices. And as a new large project

9.3 Portfolio of Medical Devices

Medical devices produced by the company include sterile and non-sterile surgical drapes, surgical gowns, covers, protective devices, absorbent towels and fixation elements. These devices ensure a sterile and clean environment during a specific procedure. However, the biggest part of the portfolio consists of 39 000 different variations of products packaged in procedural sets specifically designed for healthcare experts to use during operation or any other procedure. There are sixteen groups of the intended use of the procedural sets, such as gynaecology, ophthalmology, or cardiology procedural sets. These sets combine the

large portfolio of devices, and the organisation ensures that the devices are safely put together and delivered to the customer in a desired way.

9.4 Future of the company

The situation in the European market is quickly changing and still evolving. Due to the Covid-19 pandemic and the change in regulative legislation, the company must transfer to the new regulation MDR 2017/745 as soon as possible to ensure a stable environment for supplying the market and its competitive ability with its larger competitors. Two large regulative projects are expansion to the United Kingdom and American market. These markets have their regulations and requirements (as previously mentioned), so to deliver on these markets, it is necessary to focus on obtaining the necessary legislative requirements.

There are multiple large projects which the company wants to tackle: a new and larger sterilisation unit, a new warehouse, an update the warehouse software for an online solution and a focus on faster and less expensive production. This will be further described in the following analyses.

9.5 PESTLE

9.5.1 Political

In the Czech Republic, the State Institute of Medical Devices (SÚKL) determines the legislation on medical devices. This institute precisely determines everything regarding medicines, medical devices, pharmacies, pharmacopoeias, drug outages, drug sellers and other important information on the national level.

Dina-Hitex spol. s r.o. must follow the regulations issued by SÚKL. However, it also needs to comply with the regulations set by the European Union, in this case, the Medical Device Regulation. The European Union has programs that try to improve people's health, prevent major diseases, and harmonise the healthcare methods of the respective countries.

9.5.2 Economic

Inflation

In recent years, the Czech Republic has faced high inflation rates, affecting the population's purchasing power, investment, and economic growth. In 2020, inflation was

affected by the covid-19 pandemic, which significantly impacted the economy and consumer behaviour. At the beginning of the pandemic, there was a sudden drop in demand for services such as tourism, entertainment, and catering. On the other hand, there was an increase in demand for goods such as food, sanitary products, and electronics. However, this increase in demand was accompanied by a sudden reduction in supply, leading to a rapid price increase. Inflation continued to be high in 2021 due to the following factors. The ongoing COVID-19 pandemic, corporate closures, high demand for real estate and energy surge (CBN, 2023).

According to Petr Král (CNB, 2023), inflation will rise again from January 2023, affecting the end of the energy-saving tariff. However, during 2023, price increases should slow down due to the capping of electricity and gas prices, and inflation could fall to single digits. The reduction should be driven by further easing cost pressures, slowing external economic growth, reduced domestic demand and tighter monetary policy, which will impact the labour market.

Gross domestic product

The value of all final goods and services produced in an economy over a specified period. This tells us that if GDP increases, so will the money in circulation, and hence there is also a greater concern of businesses about GP.

The interest rate

The interest rate influences households in how much they save. If the interest rate rises, households can get a higher return on their savings in the bank so that they will reduce consumption. If the interest rate falls, people start spending more. So, the lower the interest rates are, the more companies will want to invest, in our case, in health care, and people will borrow more, so there will be more money in circulation.

9.5.3 Social

Healthcare services and the safety of the population are very important because the higher the healthcare system's competence, safety, and quality, the higher the demand for healthcare resources and services. In some cases, people travel to better health conditions because they do not have or do not trust the health services in their country, which may not be well developed in their country of origin.

In the Czech Republic, social healthcare insurance is a requirement for every person. With insurance, a person can be treated and taken care of. Because the devices, Dina-Hitex sells are not meant for the public but for medical experts, the insurance companies cover the expenses. Therefore, the price of the devices does not play as big of a role for the customer as in other countries.

9.5.4 Technology

Technological influence in the health sector is highly advanced and very important to us(users). Thanks to artificial intelligence it is possible to discuss the patient's symptoms just with artificial intelligence instead of the doctor. In healthcare, this is the influence of e-health and m-health, and in the future, there will be more uses, and presumably, it will make healthcare more affordable to anyone.

There are also lots of new machines that make medical materials faster and easier, but unfortunately, this reduces employment in the company, as the machine replaces several dozen workers.

9.5.5 Legal

The healthcare industry must comply with all provisions, legislations, laws, standards, rules and regulations set by the state. For medical devices in the Czech Republic, it is Act no. 375/2022 sb, which specifies some parts of the legislation in the Medical Device Regulation 2017/745. For example, it specifies the fines and responsibilities of the Czech Institute for Healthcare (SUKL)

Dina - Hitex is regularly audited like other companies in the same sector to ensure that it meets all the requirements of the medical device business. In the theoretical part, the standards that the company must meet are discussed in detail.

9.5.6 Environmental

This impact is primarily concerned with the environment. A corporate environmental department is present in the company, which plays a substantially important role. This includes laws on waste disposal, environmental protection, ethical sourcing, regulation of consumption and energy or the transition to sustainable sources. An important role in the company is also to allocate containers for hazards. As the company manufactures medical devices, it is necessary to have specially dedicated containers. If the company does not

emphasise the environment and does not meet important environmental standards, it would be denied the right to trade in the healthcare market. A standard for environmental compliance is ISO 140001:2015 Environmental management, which in its compliance ensures good practices of how to manage environmental responsibilities.

9.6 Porter`s Five Forces

9.6.1 Competitive Rivalry

The situation in the European market was very stable during the Medical Device Directive, which set the requirements for the production of medical devices. However, the current regulation Medical Device Directive tightens the opportunities and brings harsher conditions to manufacturers, distributors, and importers. One of the impacts of this regulation is that many rivals and competitors will not continue with production after the Medical Device Directive is no longer supported in Europe. That will bring further opportunities for expansion, but at the same time, it will allow larger competitors to secure themselves as deeply rooted with their customers. Therefore, getting new customers or trying to find a new supplier will be hard for any manufacturer of medical devices.

Dina-Hitex spol. s r.o. has contracts with hospitals, ambulances and large companies using semi-finished products, and these contracts are a vital part of surviving in the medical devices market. Because they have been in place for a long time, it is predisposed that these ties will not break and only strengthen in the coming years, ensuring the company’s survival.

9.6.2 Supplier Power

Dina-Hitex spol. s r. o. can supply any facility: hospital, clinic, private retirement home etc. Due to this ability and predisposition to supply any healthcare facility, which could use products such as face masks, protective clothes or even simple surgical sets, its scope is immense. However, the most important customers are large hospitals and customers, which then distribute Dina-Hitex`s products further. In the European market, other centres in Slovakia and Poland ensure supplier power.

If the market is separated (geographically or legislatively), such as in Switzerland or in the United Kingdom, the supply is more complicated. However, it is possible due to specific contracts with customers who vouch for the company and function as importers and

representative bodies and due to these customers, Dina-Hitex spol. s r.o. can supply these markets.

9.6.3 Buyer Power

The company can produce six main categories of devices – drapes, gowns, covers, pouches, fixation elements and absorbent towels. These devices are packed into procedural sets. However, they alone do not fulfil the purpose of the whole package, and therefore, it is necessary to buy other devices such as scalpels, needles, scissors etc. That means that part of the production is sustainable by the company itself. Still, to function overall and fulfil most of the demands, it depends on the suppliers of these other devices, which the customers need for the procedures.

9.6.4 Threat of Substitution

One of the advantages of producing medical devices is that every medical device does not generally have a natural substitution. For example, surgical gowns have a set intended use of the device. They are meant for professionals and used in a specific environment. The legislation protects and compiles these devices to the groups under codes, so every Surgical Gown has the same intended use and serves the same purpose. A substitution comes with the advancement of technology. Face masks were, in the past, one-layered. Nowadays, a standard is two but rather three layers. When nanomaterials were more widespread, the substitution did not happen – the face mask still has the same purpose and intended use. However, its qualities got better. So, in the case of substitution threats, there are no threats, only in a technological sense. These are tied to new technologies and advancements dependent on the price of the technology and production.

9.6.5 The Threat of New Entry

As hinted in the new competitive rivalry, the market of medical devices has many barriers. Due to rising demands on the quality and safety of medical devices, there are certain predispositions which the manufacturer must fulfil. Because of the new regulation, MDR entry into the European market is quite difficult. There are requirements for a functional quality management system, preferably certified with ISO 13485:2016, and if the organisation is producing any medical device, it needs to comply with the individual requirements. The easiest are medical devices in risk class I, which are non-sterile, and these devices do not require certification by a Notify Body. However, even these devices

must fulfil biological and microbiological safety, which is not proven cheaply. Then the organisation must ensure that the customers want to buy from them. And this is very hard in an environment which likes a stable supply of medical devices (hospitals rely on their stocks of devices), and trust in their suppliers takes time. For these reasons, the threat of new companies is not impossible, but it is very hard for new companies to breach in.

9.7 SWOT Analysis

With SWOT Analysis shown in Table 1 of Dina-Hitex spol. s r.o. it is being shown the strengths and weaknesses in the company's internal environment and opportunities and threats of the external environment.

Table 1 SWOT Analysis of Dina-Hitex spol. s r.o.

Internal origin	**Strengths**	**Weaknesses**
	▪ Internal ETO sterilisation unit ▪ Outsourced company Hitex Healthcare supplies only to Dina-Hitex ▪ The unique packaging of procedural packs is suited for the specific needs of healthcare professionals. ▪ Internal lamination machine to produce textile materials.	▪ High costs of producing in the Czech Republic ▪ Limited product range – cannot include in the procedural pack every desired medical device. ▪ Dependence on outsourced process Hitex Healthcare for semi-finished products. ▪ The internal sterilisation cycle is too long, and external sterilisation is required.
External origin	**Opportunities**	**Threats**
	▪ Demand for quality and safe medical devices arises, so staying in this market in the coming years will bring opportunities. ▪ Increasing demand for personalised Healthcare, which suits Dina-Hitex`s	▪ Increasing competition due to new legislation, only the biggest companies will stay on the European market, threatening to overtake Dina-Hitex`s business. ▪ Demanding and costly regulatory changes The pandemic shutting down surgeries and

	portfolio. ▪ Exploring new markets such as Switzerland, the UK and the US if passing the certification. ▪ Expansion to German & French market.	therefore less demand for the products. ▪ Rising costs of shipping and energies disvalue outsourced process. ▪ Demand for the use of nanomaterials, and reusable medical devices

9.7.1 Internal origin

Internal SWOT analysis shows that Dina-Hitex spol. s r.o has a good position as an independent company, with one major problem. The advantage of internal sterilisation unit and not solely dependent on external sterilisation ensures that if an external provider fails, there is no threat of stopping selling. Despite being an older and slower unit, it is still a key factor and major strength and advantage of the company over the competition. Another huge advantage is producing procedural packages specifically designed to the needs of medical professionals. However, the major issue lies in the increasing production costs in the Czech Republic and being more dependent on the outsourced process of Hitex Healthcare in India, which has more risks and benefits.

9.7.2 External origin

Opportunities lie in the specific requirements of the market. Dina-Hitex spol. s r.o. has a unique portfolio of products which can be focused on meeting the individual needs of the customer. If the regulation allows selling in those new markets – new potential businesses can be targeted. However, this brings the higher costs of ensuring the certification processes. Rising energy and shipping costs mean that its critical supplier Hitex Healthcare becomes less valuable and therefore devalues its worth. And recent years have shown that if another pandemic happens, the infrastructure and relatively stable market, as is healthcare, can be affected by stopping general surgeries and procedures, which means stopping selling and producing products.

10 OBJECTIVES AND GOALS OF ANALYSIS OF QMS

Analysing and optimising the quality management system of every organisation is integrated into every quality management system certified by ISO. The main objective is to optimise Dina-Hitex`s QMS with the required requirements from the update (or correction) of ISO 13485:2016 A11:2021. By evaluating the state of the current QMS, performing a GAP analysis of the A11, and presenting a functional optimisation of the system, which can be used in practice. The thesis results will be used in practice during the recertification audit of ISO 13485:2016 in summer 2023, which must comply with A11:2021 and the regulation MDR 2017/745.

The analysis of the current QMS aims to present comprehensive compliance with ISO 13485:2016. Starting with Chapter 4 and ending with Chapter 8. Every chapter puts forward the requirements and demands of what the organisation is supposed to do, and the analysis describes how the organisation fulfils this point of the standard. Due to the nature of the standard and the ISO standard being protected from copying, it is impossible to copy the whole standard in detail. However, it is possible to use the chapters as references and describe the requirements. In this way, it will serve as an introduction to the QMS and then be compared with the A11:2021 with relevant changes visible.

11 ANALYSIS OF THE CURRENT STATE OF QMS

11.1 The current state of compliance with QMS

Table 2 Chapter 4 Quality Management Systems

4.	Quality Management Systems	
4.1	General requirements	Chapters 4.1.1, 4.1.2, 4.1.3,4.1.4,4.1.5 and 4.1.6 put the requirements on the organisation and how it should present its QMS. There are requirements for setting up the processes (described in Quality Management and individual documents). Apply a risk-based approach to control these processes – Dina-Hitex has a Risk management system in place and as per ISO 14971:2019. Documented in *IP12 Risk Management*. It describes how these processes must be controlled and what needs to be present for the functioning process. These processes are ensured through the company, as they have their documentation present (the comprehensive list in *List of Documentation 2023*) and requirements for documentation systems are presented in document *S2 Document Control*. Another requirement is put forward as in Change management procedures for documents and processes. These requirements are put set by the internal document *IP18 Change Control* and by *G2 Document Control.* Requirements are put on the outsourcing process and its control and implementation to the whole QMS. Dina-Hitex`s outsourced processes are covered in risk management FMEA as per ISO 14971:2019. There are multiple documents covering various outsourced processes: *IP2 External sterilisation* and *IP23 Outsourced process Hitex Healthcare.* Other parts, such as the requirements for laboratories and validation companies, are described in

		individual documents *IP4 Product Monitoring* and *IP35 Validation processes.*
4.2	Documentation requirements	
4.2.1	General	Dina-Hitex has documented quality policy and objectives. *Quality and environmental objectives for 2023* (updated yearly) and Quality and environmental policy (updated every review yearly, updated every 3 years). Quality Manual is created and updated yearly and follows ISO 13485:2016 requirements. Every document is set controlled by requirements set in document *G2 Document Control.* There are multiple levels of documents due to their importance. First level documents: Quality Manual, Organisation manual, Quality Policy and Objectives. Second level documents: Guidelines (G) – expanding and amplifying in detail the ideas presented in the Quality Manual. Third level documents: Internal Procedures (IP), Control and technological procedures (for production, are part of work orders), records, operation regulations, external documentation
4.2.2	Quality Manual	Requirements set for quality management include the scope of the quality management system, covering individual standard operating procedures (SOP), process maps and diagrams describing relationships between them. Quality manual also contains the reason for exclusion of some parts of the standard (more in 7.5.3, 7.54, 7.5.6 and 7.5.9.2)
4.2.3	Medical device file	Dina-Hitex maintains for each medical device family a file to demonstrate conformity to the requirements of IS O13485:2016, but mainly to the requirements of a regulation system (MDR 2017/745). There are technical files / Medical devices files for Drapes, Gowns, Covers, Pouches, Fixation

		elements, Absorbent Towels in the class I sterile and in class I non-sterile.
4.2.4	Control of documents	All documents falling into the QMS muse be controlled. A person responsible for documentation is appointed (Dina-Hitex`s Quality Manager)- Dina-Hitex has established processes for appropriate documents with their relevant version status assured against unintended use. Separate storage is in place for the original versions of the documents, which prevents deterioration or loss. Everything is described in G2 Document control.
4.2.5	Control of records	Dina-Hitex has set in procedures, which define control of records needed for the identification, storage, security, and integrity. Quality records are maintained in accordance with regulatory requirements and these requirements are described in G11 Control of records. The document also specifies how employees must handle external records.

Table 3 Chapter 5 Management responsibility

5.	Management responsibility	
5.1	Management commitment	Evidence of management commitment to development and implementation of the quality management system are shown by focus on customer: continuous monitoring of all requirements, definition of Quality and Environmental Objectives and Policy, annual revision of the QMS and EMS, accessibility of all resources, obtaining data through PDCA.
5.2	Customer focus	The satisfaction of the customer is put in the first place and therefore Dina-Hitex focuses on customers and their requirements, by assessing their complaints and requests to achieve full satisfaction of the customer.
5.3	Quality policy	Quality and Environment Policy is created by Managing Director and annually reviewed during Management Review for continuing suitability. The policy is written on the company's website and is available to everyone. The policy focuses on: Customer service, Products and Services Quality, Increasing the technical qualification of the employees and Environmental protection. Last update was in 2021, last review was in 2023.
5.4	Planning	
5.4.1	Quality objectives	Quality objectives are part of management review. They are annually set up and reviewed. Thorough the year, at the end of every quarter a meeting is done to ensure that the objectives are monitored and controlled. If needed, they are corrected or renewed.
5.4.2	Quality management system planning	Planning is done on different levels. There are Quality and Environment objectives, policy. Then there are training plans for the employees. Internal audit plan for internal audits and preventive inspections plan.

5.5	Responsibility, authority, and communication	
5.5.1	Responsibility and authority	There five organisational manuals in the company. General, production, purchasing, sales and sterilisation. These documents describe the individual places on the company and the workers responsibilities. There is also named a PRRC, as per MDR 2017/745, which is a person responsible for regulatory compliance. Another responsibility is given to the metrologist of the company by appointment.
5.5.2	Management representative	Quality Manager of Dina-Hitex was appointed to as the Management representative and by a decree has the necessary requirements and rights to act in the name of the management.
5.5.3	Internal communication	Processes for communication are established within the organisation in the form of CEO communications and orders, regular meetings including tasks for one week, in the form of Corrective and Preventive Measures and usage of notice boards.
5.6	Management review	
5.6.1	General	Every year the management is participating in a board meeting, where management review is presented. This way the top management is presented with the state of the QMS for the previous year. The document describing how and what is compiled in this report for every department is described in document *G21 Management review*. The management review is a comprehensive report, which compiles various data from the company. It presents them in form of reports, put as inputs and results as outputs. Together they show the compliance of the QMS and present shortcomings and suitability. The review has considered feedback, complaint handling, reporting to regulatory authorities, audits, monitoring and measurement of processes, monitoring and measurement of product,
5.6.2	Review input	
5.6.3	Review output	

		corrective action, preventive action, follow-up action from previous management review, changes, which could affect the QMS, recommendations for improvement and applicable regulatory requirements, which changed. These reports are then summarised and recorded as they influence the quality objectives and policy, resources needed for the functioning of the company and improvement needed to maintain the suitability and effectiveness of the quality management system and its processes.

Table 4 Chapter 6 Resource management

6	Resource management	
6.1	Provision of resources	The CEO of the company is responsible for creating and maintaining financial plans. Management review has an outline of the future projects and investments needed for the functioning of the company. These resources/projects are annually monitored and reviewed during the management review.
6.2	Human resources	Competence of the employees is ensured by a job description, which are prepared in the organisation manuals. The jobs have necessary competence for personnel and their responsibilities. Training is being controlled by document *G3 Human resources*. Document *IP 41 HR Module* defines the requirements for training and evaluation of the training in the company`s ERP system Qi.
6.3	Infrastructure	Requirements for production of medical devices is very specific and therefore the company has clean rooms and controlled production environments. Part of the infrastructure is building, workspaces and other utilities – meant for the microbiological standard. Process equipment and supporting service and devices. Software equipment is in the internal system EVIS. Management ensures maintaining the infrastructure necessary to achieve compliance with product requirements.
6.4	Work environment and contamination control	
6.4.1	Work Environment	Control of the work environment is described in multiple documents. Document *IP 13 Behaviour of employees in the company* describes how the workers must dress, behave and what to do if they are to be let into the clean rooms and other working facilities. Document *IP9* describes the same conditions, but for visitors. Standards for clothing and

		cleanliness are established.
6.4.2	Contamination control	Sterile medical devices must show that their contamination with microorganisms or particulate matter are controlled and checked. Procedure monitoring of environment in document *IP11 Working environment* describes the methods and ways of how the work environment is clean and how it is measured by microbiological controls. *IP4 Product monitoring* then sets requirements for bioburden testing of the products, which is necessary for the sterilisation process. Cleaning of the clean rooms and work environment are described in *IP5 Plan of Cleaning and Disinfection, IP 28 Cleaning of lamination workshop* and in *IP26 Environmental maintenance in Dina-Hitex.* As the clean rooms are following ISO 14644, they are validated every year as well as microbiologically tested 2 a year.

Table 5 Chapter 7 Product realization

7	Product realization	
7.1	Planning of product realization	The risk-based approach is applied and implemented in the QMS of Dina-Hitex. *IP12 Risk management* describes the process and works based on ISO 14971:2019 standard. Product realisation is a process that follows the whole product's life cycle and is integrated into the risk management system.
7.2	Customer related processes	
7.2.1	Determination of requirements related to product	Design and development describe conditions, which this point of the standard wants the manufacturer to determine. The customer specifies the price and term of delivery, which is in the hands of the sales department and their procedures. Requirements specified from the intended use – legislation and standards are included on the packaging and stated in the development stages.
7.2.2	Review of requirements related to product	The sales department controls requirements related to the product from customers through two documents *G14 Product requirements review* and *G19 Evidence and Realization of Orders.* These processes are tied into the production department, where customers' requirements are first transferred from sales to the production department. All records are kept and archived as per process *G11 Control of records* states and all changes are supervised by *G2 Document control.*
7.2.3	Communication	Dina-Hitex ensures that communication with customer is done by sales department, using sales representatives, catalogues, and website. This communication channel is used for receiving complaints and feedbacks, which are then discussed with Dina-Hitex`s quality department. (G13 Feedback) Regulatory affairs are responsible for advisory

		notices meaning with communication with nation governing bodies, this process is described in *IP14 Vigilance system.*
7.3	Design and development	
7.3.1	General	Procedures for design & development are described in detail in *IP7 Design &Development & Product design.* This process puts forth the requirements set by the standard for safe and quality medical devices. The standard puts requirements for D&D, which are comprehensive, and they cover the whole process of creation of the medical devices. Dina-Hitex has for each medical device group a D&D file, which covers the necessary aspects and data for production. Then, requirements for modification and product design are mentioned. There are 3 different methods: new product, new product from already approved materials and components and new product containing new components (used for procedural packs). D&D compiles all relevant data, which are needed to produce medical devices. It is part of the technical documentation and it compiles material safety, combability, biological information, safety, quality and production techniques used for manufacturing as well as requirements for the environment and expiration date etc.
7.3.2	D&D planning	
7.3.3	D&D inputs	
7.3.4	D&D outputs	
7.3.5	D&D review	
7.3.6	D&D verification	
7.3.7	D&D validation	
7.3.8	D&D transfer	
7.3.9	Control of D&D changes	
7.3.10	D&D files	
7.4	Purchasing	
7.4.1	Purchasing process	Purchasing from suppliers is done only by assessed suppliers, who can satisfy company's requirements. Approved vendors are listed and annually evaluated in management review. Purchasing of new components or raw materials is tied to the regulatory department, where it is important that the two departments cooperate. Verification of purchased products is performed by incoming inspection, which inspects the goods for quality, discrepancies and any damage, it could have. These processes are controlled by the
7.4.2	Purchasing information	
7.4.3	Verification of purchased product	

		purchasing department document *G12 Purchasing*. Incoming inspection is further written in *G17 Warehouse regulation*, which covers the storage of the purchased goods. Another purchasing information part is internal procedure *IP30 Instruction for use*, this document compiles everything, which is needed to put on an accompanying sheet as an instruction and is not produced by Dina-Hitex but bought from suppliers.
7.5	Production and service provision	
7.5.1	Control of production and service provision	System is set up that every device muse ensure that it is produced that it adheres to the specification. Monitoring of production is accomplished by Batch records, which contain the current information relating to the batch including the information about the person responsible for final release from production, sterilisation, and delivery. This is a requirement of a traceability system. Every equipment is monitored and evidence in a list of equipment, which is a responsibility of the company's metrologist.
7.5.2	Cleanliness of product	Dina-Hitex produces solely single use products and has documented requirements for cleanliness for non-sterile raw material and components which are subsequently sterilized. The monitoring is being done by bioburden testing described in *IP4 Product Monitoring.*
7.5.3	Installation activities	Medical devices produced by Dina-Hitex are single use disposable and they do not require installation activities; therefore, this part of the standard is eliminated and not applicable.
7.5.4	Servicing activities	Medical devices produced by Dina-Hitex are single use disposable and they do not require servicing activities; therefore, this part of the standard is eliminated and not applicable.

7.5.5	Particular requirements for sterile medical devices	Dina-Hitex`s products are sterilised by ethylene oxide sterilization process. There are two ways of sterilization: first in house sterilization unit and second by outsourced process by company Steris AST Czech Republic. The sterilization records are traceable and for each production batch are saved and stored. Internal process document is *G16 Sterilization* and for outsourced process it is *IP2 External sterilization process.*
7.5.6	Validation of processes for production and service provision	Validated are all processes for production, where resulting output cannot be verified by subsequent monitoring that means sterilization process (internal and external), sealing process on the sterilisation pouches i.e. validation of the sealing machines, computer software used in production, technology such as large devices automatically producing devices and clean rooms for ensuring the environment and its cleanliness. Controlling document is *IP 35 Validation processes.*
7.5.7	Particular requirements for validation of processes for sterilization and sterile barrier systems	Sterilization is validated with accordance to EN ISO 11135, and the sterile barrier system is set up to be following EN ISO 11607-2. There are validation reports and validation protocols stored and kept with accordance with internal document *G11 Control of records.*
7.5.8	Identification	The organisation puts a great effort to ensure that Identification is consistent thorough the whole production process. It is process, which is described in *G9 Identification and Traceability,* and it allows identifying used material, components and people participating on any batch.
7.5.9	Traceability	
7.5.9.1	General	The organisation puts a great effort to ensure that traceability

7.5.9.2	Particular requirements for implantable medical devices	is consistent thorough the whole production process. It is process, which is described in *G9 Identification and Traceability,* and it allows to trace used material, components and people participating on any batch. It ensures that the batch number is put with the products, as well as the sterilization records.
7.5.10	Customer property	Dina-Hitex identifies, verifies, and protects customers property – meaning – goods, which are not Dina-Hitex`s but are part of the production process. Quality Agreements are put in place with such customers, which ensure compliance with their requirements. Document *IP40 Customer`s property* and *G17 Warehouse regulation* describe handling, care, and requirements for use of customer`s product.
7.5.11	Preservation of product	Methods and handling of used devices ensure that purchased raw materials, semi-finished products and final products will not be interchanged, damaged, or exposed to unwanted conditions. These methods are written in *G17 Warehouse regulations* and are supported by *IP8 Identification labels*, which covers the correct labels and symbols used. The staff, that handles the products is adequately trained and they are in possession of a valid licence to drive handling devices where necessary. All requirements for storage. Are part of the risk management, and stability studies confirm and show the necessary requirements for the storage based on data.
7.6	Control of monitoring and measuring equipment	Documentation needed for control of measuring equipment is put in *G7 Metrology* and all equipment is calibrated and validated regularly. It is controlled by internal system EVIS, which compiles devices and equipment in the company. Calibration must clearly be defined for all equipment as it is recorded based on *G11 Control of records.* Special focus is put on Sterilization and devices needed for ensuring safety. These devices are falling under a different process and

		document: *G16 Sterilization* and *IP 37 Verification of sterilization* describe the handling of the components needed for the sterilization and their regular validation, calibration, and control.

Table 6 Chapter 8 Measurement, analysis, and improvement

8	Measurement, analysis, and improvement	
8.1	General	Management review serves as a compilation of all the measurements, analysis, and improvement. Dina-Hitex applies to monitoring and measuring processes on products, processes, and systems.
8.2	Monitoring and measurement	
8.2.1	Feedback	Procedures for the feedback process, which includes a provision to gather data from production and post-production activities, are in place. The sales department gathers customer feedback and gives it to the regulatory department, where they are compiled and processed as part of the post-market clinical follow-up (PMCF). This process is described in *G13 Feedback, IP 14 Vigilance system* and *IP32 Post Marketing Surveillance.*
8.2.2	Complaint handling	All customer complaints are logged and classified by the sales department. Complaints are numbered and forwarded to the quality department for investigation. Whenever appropriate, a root cause analysis will be done to identify the root cause of the nonconformity. This process is in detail recorded in *G13 Feedback.*
8.2.3	Reporting to regulatory authorities	If applicable regulatory requirements require notification of complaints that meet specified reporting criteria of adverse events or issuance of an advisory notice, the Regulatory Affairs Department of Dina Hitex follows established procedure on providing notification to the appropriate regulatory authorities. Vigilance procedure in *IP14 Vigilance system* dictates rules with accordance to MDR requirements and specifies everyone's responsibilities.
8.2.4	Internal audit	Every department has 2 internal audits done every year. Audits are planned at the beginning of the year by Quality

		manager and the director of the company. It is controlled by internal document *G10 Internal audits.* Every auditor was named and appointed in *Letter of appointment of internal auditors.* The impartibility is ensured by auditors not auditing their own department.
8.2.5	Monitoring and measurement of processes	Results of the processes are annually reviewed in management review. When they are not achieved a corrective and preventive action (CAPA) is opened to oversee the problem. The work is described in *G6 Corrective and preventive action.*
8.2.6	Monitoring and measurement of product	During the realization of the product, there are multiple stages, where the product is monitored and measured: input control (record is on incoming control), production (record is in work order sheet, final inspection (work order sheet registration cart – warehouse and work order sheet registration cart – sterilization), monitoring by external laboratories (test protocols) and post-marketing data – incident reports and complaints. These data are compiled in accordance with *G21 Management review.*
8.3	Control of nonconforming product	
8.3.1	General	QMS provides processes for identification, documentation, evaluation, separation, and disposition of non-conforming product. All non-conforming material is clearly marked, and adequate action is taken to eliminate detected nonconformity. The nonconforming product is accepted by concession (which is market in the ERP system Qi and is done by the head of the production) only if the justification with identity of the person authorizing the concession is provided. These processes are described in documents: *G8 Control of nonconforming product, S6 Correction, and findings* and for purchased products, which are nonconforming – in *G12 Purchasing.*
8.3.2	Actions in response to nonconforming product detected before delivery	
8.3.3	Actions in response to nonconforming product detected after delivery	

		When non-conforming product is delivered to the customer, then it is sales department responsibility to ensure communication with the customer and then forwarding the goods to Dina-Hitex to evaluate the damages and complaint.
8.3.4	Rework	Rework is part of the design and development of the products. Most of the devices are handmade and if a mistake happens, then it is evaluated if it can be corrected – reworked. With complaints and non-conforming products delivered to the customer it is different case, due to the products being already sterilized and therefore the cost and requirements on rework are different and dealt with on case-by-case bases.
8.4	Analysis of data	Analysis of data in important part of management review. As this it is guided by *G21 Management review.* Data analysis gathers findings, which are put with the respectable heads of the departments. Division of data analysis consists of: Customer feedback (sales and regulatory department), conformity to product requirements (production), trends of processes – established cards of processes with their own KPI`s, supplier evaluation (purchasing department) and internal and external audits (quality department).
8.5	Improvement	
8.5.1	General	Company identifies and implements any changes necessary to ensure and maintain the continued suitability and effectiveness of the quality management system and as well as medical device safety and performance using the quality policy, quality objectives, audit results, analysis of data, PMS, corrective/preventive actions, and management review. If any management finds QMS or any part of the QMS lacking, not suitable or not adequate or effective, the organization can issue a corrective action, which will correct the issue. This can be decided whenever in the year or after

		yearly management review.
8.5.2	Corrective action	Corrective actions are actions take to eliminate the cause of non-conformities to prevent reoccurrence. Corrective actions are appropriate to the severity of non-conformity. They are in the responsibility of quality department and issued in accordance with internal document *G6 Correction, and findings.*
8.5.3	Preventive action	Procedures for preventive and corrective actions are put in place. CAPA`s are opened by quality manager and are used for solving any issues, which requires a comprehensive and unique solving done with 8D report and methods used for finding the root cause. Internal document *G6 Correction, and findings* details work with CAPAs.

12 REVIEW OF ANALYSIS OF QMS

In the previous chapter, the quality management system of Dina-Hitex spol. s r.o. was introduced and analysed. It was done by taking the chapters of the ISO 13485:2016 standard and comparing the requirement to the documents and processes in the company. Because the QMS is annually certified and reviewed by Notify Body, there are no major flaws. Since the beginning of the certification in accordance with ISO 13485 in 2004, the company has improved and benefited from being periodically audited and reviewed.

The current iteration of QMS is stable and functions well. Its processes are well-established and defined. This is because the employees do improvement processes, as well as the top management, who understand the need for quality and safety of their products and strong and effective QMS is key to ensuring its function. Every aspect of the standard is covered and implemented into the QMS. The main document which describes the suitability and effectiveness of the QMS is the annual Management Review.

It all depends on the actual work and implementation of the processes. Because a human factor plays a role in the system, it is important to be prepared for mistakes and non-conformities, even though they are considered in the Risk Management system and minimised. An auditor might see some processes as lacking and insufficient. Still, as mentioned before, this is an opportunity for improvement, and non-conformities are another way of improving the QMS. In this state, the QMS is prepared to implement the correction of ISO 13485:2016 A11:2021, described in the next chapter.

As ISO 13485:2016 stands, the current iteration is implemented by Dina-Hitex sufficiently and effectively. This is supported by the fact that the company managed to fulfil the requirement of various auditors from Notified Bodies.

13 GAP ANALYSIS OF ISO 13485:2016/A11:2021

ISO 13485:2016 A11:2021 describes the relationship between the quality management standard for producing medical devices ISO 13485:2016 and the regulation Medical Device Regulation 2017/745, the legislative document required for the production of medical devices. The A11:2021 includes comparisons with three parts of the MDR 2017/745. The next two chapters show gap analysis with two relevant parts used by Dina-Hitex spol. s r.o to show compliance with the MDR 2017/745.

13.1 Gap analysis with Article 10 of MDR and ISO 13485:2016

Article 10 of MDR General obligations of manufacturers. This article puts forth the requirements that the organisation must fulfil to show conformity with the regulation, ensuring the quality and safety of the produced devices.

Table 7 Gap analysis of Article 10 of MDR and ISO 13485:2016

Requirements of Article 10 of regulation (EU) 2017/745	Clause(s) / Sub-clause(s) of EN ISO 13485:2016	MDR requirements of Article 10 in EN ISO 13485:2016	Dina-Hitex compliance and comments
1	4.1, 7.2.1 c), 7.2.2 c), 7.3, 7.5	Partially covered.	Dina-Hitex has implemented D&D requirements as per ISO 13485:2016 and Technical Documentation for the medical devices is created as per MDR.
2	7.1	Partially covered.	The organisation has Risk management requirements as per ISO 14972:2019, which covers the requirements of Article 10, second paragraph.
3		Not covered.	Clinical evaluation is updated with the requirements of Article 61 or Annex XIV.
4, 1st paragraph	4.2.3	Partially covered.	Requirements set for technical documentation are followed and the

			compliance is shown. Annex II (TD) and Annex III (PMS) is implemented to comply with ISO 13485:2016 and MDR 2017/745 because the system had to be prepared for non-sterile devices in 2021.
4, 2nd paragraph		Not covered.	The organisation has in place a procedure, which regularly check the validity of used standards and regulations to see any changes or updates.
5		Partially covered.	Dina-Hitex is not a manufacturer of custom-made devices, therefore this point does not affect its QMS.
6		Not covered.	Creation of Declaration of Conformity (DoC) is not set by the requirements for QMS, but the organisation has DoC made in accordance with relevant regulation.
7		Not covered.	Dina-Hitex has a system covering UDI codes (and internal procedure IP 40) which complies article 27, 29 and 31.
8, 1st paragraph	4.2.4, 4.2.5, 7.2.3	Partially covered.	The organisation has already set a storage of 10 years, therefore complying with this requirement.
8, 2nd paragraph	7.2.3	Partially covered.	The organisation does provide on request to competent authorities required documents.
8, 3rd paragraph		Not covered.	Dina-Hitex is not a manufacturer with a registered place of business outside the Union, therefore this paragraph does not apply.
9, 1st paragraph,	4, 5, 6, 7, 8	Covered.	Organisation has in place necessary procedures, which ensure compliance

1st sentence			with applicable regulatory requirements. All products are designed, monitored and produced to conform these requirements.
9, 1st paragraph, 2nd sentence	4.1.4, 4.2.4, 5.6.2, 5.6.3, 7.3.3, 7.3.9	Partially covered.	Products, which require usage of other standards are covered and used (such as gowns and rapes need EN ISO 13795). Any change is recorded and reported based on evaluation of risk to quality and safety.
9, 1st paragraph, 3rd sentence	4.1	Partially covered.	ISO 13485 does not have an explicit requirement for continual improvement, however due to the nature of QMS and auditing system, the company is pushed forward and forced to improve due to external and internal factors.
9, 2nd paragraph	4, 5, 6, 7, 8	Covered.	QMS covers and flows through the whole organisation, and it governs every structure and responsibility. Therefore, regulation is enforced in the whole company.
9, 3rd paragraph (a)	4.1.1, 7.3.9	Partially covered.	Explicit strategy for regulatory compliance is not mentioned in the organisation.
9, 3rd paragraph (b)	4.2.3, 7.2.1c), 7.3.3b), 7.3.4a), 7.3.5	Partially covered.	General safety and performance requirements are not stated in the QMS, but they are stated in the technical documentation. Harmonized standards and common specifications are part of the QMS.
9, 3rd paragraph (c)	5	Covered.	Dina-Hitex has defined responsibilities of the top management.
9, 3rd paragraph	4.1.5, 6,	Covered.	Dina-Hitex has defined responsibilities

(d)	7.4.1		for provision human resources.
9, 3rd paragraph (e)	4.1.2, 7.1	Partially covered.	Risk management follows Annex I, point 3. It is in compliance with ISO 14971:2019.
9, 3rd paragraph (f)		Not covered.	Clinical evaluation follows article 61 and Annex XIV.
9, 3rd paragraph (g)	7.1, 7.3.2, 7.3.8, 7.5.1, 7.5.4	Covered.	Product realisation, planning of design and development and planning of production is set up in QMS.
9, 3rd paragraph (h)		Not covered.	UDI system is set up as per MDR 2017/745 because the system had to be prepared for non-sterile devices in 2021.
9, 3rd paragraph (i)	8.2.1, 8.5.1	Partially covered.	Dina-Hitex has implemented requirements from article 83 as per MDR 2017/745 because the system had to be prepared for non-sterile devices in 2021.
9, 3rd paragraph (j)	7.2.3	Partially covered.	The organisation has not covered communication with regulatory authorities. It is not specified in the QMS.
9, 3rd paragraph (k)	8.2.2, 8.2.3, 8.3.3	Partially covered.	Dina-Hitex has implemented a vigilance system for reporting as per MDR 2017/745 because the system had to be prepared for non-sterile devices in 2021.
9, 3rd paragraph (l)	8.5.2, 8.5.3	Covered.	The organisation has a corrective actions and preventive actions system in place.
9, 3rd paragraph (m)	8.2.5, 8.2.6, 8.4, 8.5	Covered.	Requirements for monitoring and measurement of processes are part of data analysis procedure and are part of

			management review.
10	8.2.1, 8.5.1	Partially covered.	Dina-Hitex has implemented requirements from article 83 as per MDR 2017/745 because the system had to be prepared for non-sterile devices in 2021.
11	4.2.3 a), 7.3.3, 7.5.1 e)	Partially covered.	Dina-Hitex`s portfolio of products does not require IFU, due to the nature of use and design of the devices the use is clear from the use. Labels are covered by internal procedures to comply with Annex I point 23.
12	7.2.3, 8.2.2d), 8.2.3, 8.3.3	Partially covered.	In vigilance system procedure, there are set up processes for notification the whole supply chain including requirements of MDR 2017/745.
13	8.2.3	Partially covered	Requirements from article 87 and 88 as per MDR 2017/745 because the system had to be prepared for non-sterile devices in 2021.
14, 1st paragraph	7.2.3	Partially covered	The organisation has not covered communication with regulatory authorities. It is not specified in the QMS.
14, 2nd, 3rd. and 4th paragraph		Not covered.	The organisation has not covered communication with regulatory authorities. It is not specified in the QMS.
15	4.1, 4.2.3, 7.2.3, 7.4	Partially covered.	Dina-Hitex designs and develops its own products and does not use third parties. This part is excluded.
16		Not covered.	Dina-Hitex has an insurance covering requirement of MDR and specifically 85/374/EHS.

13.2 Gap analysis of Annex IX of MDR and ISO 13485:2016

Annex IX of the MDR 2017/745 Conformity assessment based on a quality management system and assessment of technical documentation sets the requirements for the notified body to certify the organisation`s system and documents.

Table 8 Gap analysis of Annex IX of MDR and ISO 13485:2016

Requirements of Annex IX of the regulation (EU) 2017/745	Clause(s) / Sub-clause(s) of EN ISO 13485:2016	MDR requirements of Annex IX in EN ISO 13485:2016	Dina-Hitex compliance and comments
1	4.1	Partially covered.	The QMS of the Dina-Hitex has been audited regularly since 2004. The system requirements of Article 10 of MDR 2017/745 are covered by applying to update the compliance of ISO 13485:2016 A11:2021.
2.1, 1st sentence		Not covered.	Application to the notified body is not covered by the system, however, the process is integrated and updated.
2.1, paragraph 1		Not covered.	The application to notify body contains requirements for details of the manufacturer, which are part of the quality manual.
2.1, paragraph 2	4.2	Covered.	The organisation has all relevant device information in the Quality Manual and technical documentation.
2.1, paragraph 3		Not covered.	Written declaration that no application was lodged with other NB is not part of QMS, it is part of

			the application to the new NB.
2.1, paragraph 4		Not covered.	QMS does not state how to draft a DoC, however, it was drafted as per Article 19 and Annex IV of MDR specify.
2.1, paragraph 5	4.2	Covered.	Dina-Hitex has covered, which documentation is part of the QMS in the Quality Manual.
2.1, paragraph 6	4.2, 5.1	Partially covered.	A documented policy is stated in the Quality Policy and other documents. Dina-Hitex is missing a description of procedures, which are in place to fulfil obligations of MDR 2017/745.
2.1, paragraph 7	4.1.4, 4.2, 5.1, 5.4.2, 5.6, 6.1, 8	Covered.	The organisation has a documented description of the procedures in place to ensure that the QMS is adequate and effective.
2.1, paragraph 8	8.2.1, 8.5.1	Partially covered.	Requirements from article 87 to 92 as per MDR 2017/745 because the system had to be prepared for non-sterile devices in 2021.
2.1, paragraph 9	8.2.1, 8.5.1	Partially covered.	Requirements from article 87 to 92 as per MDR 2017/745 because the system had to be prepared for non-sterile devices in 2021.
2.1, paragraph 10		Not covered.	Clinical evaluation is part of the technical documentation. Plan of clinical evaluation is part of the submission to NB.
2.1, paragraph 11		Not covered.	Dina-Hitex has implemented a

			procedure for updating clinical evaluation and state of the art.
2.2, 1st paragraph	4.1, 4.2, 5, 6, 8	Covered	QMS is established to implement all compliance with the necessary regulation of MDR 2017/745.
2.2,2nd paragraph (a)	4.2.1 a), 5.1 c), 5.3 c), 5.4.1, 7.1 a)	Covered.	Quality objectives are described and are part of the management review.
2.2, 2nd paragraph (b) indent 1	5.5.1	Covered.	Organisation structures with the assignment of staff responsibilities is in place in organisational manuals and in Quality Manual.
2.2, 2nd paragraph (b) indent 2	5.6, 7.3.5, 8.1, 8.2.1, 8.2.4, 8.2.5, 8.2.6, 8.3, 8.4	Covered.	Monitoring processes are defined to show compliance and processes reflect the desire to achieve desired design and device quality, including control of non-conforming devices.
2.2, 2nd paragraph (b) indent 3	4.1.5, 7.4.1	Covered.	Methods for testing and verification of devices, which are outsourced are set up and processes cover them.
2.2, 2nd paragraph (b) indent 4		Not covered.	Dina-Hitex has registered manufacturing place is the Union and therefore this paragraph does not apply.
2.2, 2nd paragraph (c)	4.2.5, 7.3,	Covered.	The organisation has set in place procedures for monitoring, verifying, validating and controlling of the design of the devices and corresponding

			documentation.
2.2, 2nd paragraph (c) indent 1	4.1.1, 7.3.9	Partially covered.	Strategy or procedure for regulatory compliance is not covered in the QMS.
2.2, 2nd paragraph (c) indent 2	7.2.1 c), 7.3.3	Partially covered.	The applicable general safety and performance requirements and solutions are described and set up in the technical documentation. Harmonized standards are mentioned and recognised.
2.2, 2nd paragraph (c) indent 3	4.1.2, 7.1	Partially covered.	The organisation has Risk management requirements as per ISO 14972:2019, which covers the requirements of Article 10, therefore section 3 of Annex I.
2.2, 2nd paragraph (c) indent 4		Not covered.	Clinical evaluation is updated with the requirements of Article 61 or Annex XIV.
2.2, 2nd paragraph (c) indent 5	7.3	Partially covered.	Pre-clinical evaluation is part of the requirements of Chapter II of Annex I and is part of the technical documentation.
2.2, 2nd paragraph (c) indent 6	4.2.3 a), 7.3.3 b). 7.5.1 e)	Partially covered.	The organisation has a procedure in place for devices and the information, which needs to be supplied with the device as per Chapter III of Annex I.
2.2, 2nd paragraph (c) indent 7	7.5.8, 7.5.9	Covered.	Identification procedures are drawn up and kept up to date, procedure for relevant documents and design and development.

2.2, 2nd paragraph (c) indent 8	4.1.4, 4.2.4, 5.6.2, 5.6.3, 7.3.3, 7.3.9	Partially covered.	The organisation has a change management covering any system changes and changes of design.
2.2, 2nd paragraph (d)	7.5.1, 7.5.5, 7.5.6, 7.5.7	Covered.	Dina-Hitex verifies and assures quality for devices during production including sterilisation.
2.2, 2nd paragraph (e)	7.4.3, 7.5.1, 7.5.9, 7.6, 8.2.5, 8.2.6	Covered.	Procedures for testing and trials, which are carrier thorough the life cycle of the medical devices are in place.
2.2 3rd paragraph	7.2.3	Partially covered.	Specific requirements, which are to be shared with NB are not placed anywhere in the QMS.
2.4	4.1.4, 7.2.3	Partially covered.	Changes made to the devices or QMS are part of change management procedure, which is part of the QMS.
3.2	7.2.3	Partially covered.	Dina-Hitex shares with NB everything required by them, however, specific documents as states MDR 2017/745 are not specified anywhere.

14 FINDINGS OF THE GAP ANALYSIS AND REVIEW

Previous chapters presented the analysis of ISO 13485:2016 and Article 10 of MDR 2017/745 and Annex IX, which were in the updated document ISO 13485:2016 A11:2021 set up as a part, which organisation needs to update to comply with the requirements set by the regulation. The first part of the gap analysis focuses on Article 10, and the issues the current QMS does not cover are listed in Table 7 and presented in Table 9. The second part of the gap analysis focuses on Annex IX, and the issues and non-conformities are listed in Table 10.

Table 9 Non-conforming parts of the QMS of Article 10

Requirements of Article 10 of regulation (EU) 2017/745	Clause(s) / Sub-clause(s) of EN ISO 13485:2016	MDR requirements of Article 10 in EN ISO 13485:2016	Dina-Hitex compliance and comments
9, 3rd paragraph (a)	4.1.1, 7.3.9	Partially covered.	An explicit strategy for regulatory compliance is not mentioned in the organisation.
9, 3rd paragraph (j)	7.2.3	Partially covered.	The organisation has not covered communication with regulatory authorities. It is not specified in the QMS.
14, 1st paragraph	7.2.3	Partially covered	The organisation has not covered communication with regulatory authorities. It is not specified in the QMS.
14, 2nd, 3rd. and 4th paragraph		Not covered.	The organisation has not covered communication with regulatory authorities. It is not specified in the QMS.

Table 10 Non-conforming parts of Annex IX

Requirements of Annex IX of the regulation (EU) 2017/745	Clause(s) / Sub-clause(s) of EN ISO 13485:2016	MDR requirements of Annex IX in EN ISO 13485:2016	Dina-Hitex compliance and comments
2.1, paragraph 6	4.2, 5.1	Partially covered.	A documented policy is stated in the Quality Policy and other documents. Dina-Hitex is missing a description of procedures which are in place to fulfil obligations of MDR 2017/745.
2.2, 2nd paragraph (c) indent 1	4.1.1, 7.3.9	Partially covered.	Strategy or procedure for regulatory compliance is not covered in the QMS.
2.2 3rd paragraph	7.2.3	Partially covered.	Specific requirements, which are to be shared with NB are not placed anywhere in the QMS.
3.2	7.2.3	Partially covered.	Dina-Hitex shares with NB everything required by them, however, specific documents as states MDR 2017/745 are not specified anywhere.

The gap analysis has shown that most of the QMS of Dina-Hitex spol. s r.o. is already in compliance with the MDR 2017/745. The company was preparing for the transition since the Medical Device Regulation was announced, and because it produces medical devices in class I non-sterile, which needed to be compliant with 2021. Therefore, the most critical parts of the Technical Documentation and QMS documentation, such as an update of Vigilance Systems, Post-Market Follow-Up procedures and implementation of Risk Management as per MDR, were done before. This also happened for the Clinical and pre-clinical as per Article 61 or Annex XIV of MDR 2017/745. These updates were quite large

processes and, in some cases, required new insights and systems, so they were prioritised and implemented first.

The analysis has shown that parts of the current QMS need to be updated. They are the main requirements considering the notified body and planning the communication with them. In previous regulation MDD, there were no requirements for documented strategies for application to the NB or a specific strategy for regulatory compliance. These issues do not point to a critical dysfunction of the QMS, which would directly influence the safety and quality of medical devices. However, they are important for updating the requirements of MDR and the update of the QMS. Most of the issues can be traced to the same root cause – missing described procedure, which would put the requirements for regulatory compliance. The next chapter in the project section focuses on the correction and optimisation of the QMS.

15 SUMMARY OF ANALYSIS

The analysis focused on presenting the core of the thesis. The organisation in question, Dina-Hitex spol. s r.o. was introduced from a general perspective, its history is presented, and a portfolio of medical devices was introduced. More detailed analysis and introduction of the company were done by SWOT Analysis, showing the internal strengths and weaknesses and external opportunities and threats. Second is the Pestle analysis, which presented the company with external factors influencing the organisation. The third analysis, Porter`s Five Forces, analysed the competitors and the market.

Analysis of the current state of the QMS of Dina-Hitex spol. s r.o. is done by comparing individual requirements of the current standard for quality management systems producing medical devices ISO 13485:2016. Each chapter described how the compliance is shown, and it showed how the processes work and presented in what documents more details can be found. As the current system is being regularly audited, all requirements are covered. The situation of the analysis is reviewed and deemed as compliant.

The next part of the analysis uses gap analysis with the new update for ISO 13485:2016 A11:2021. Gap analysis is a tool for comparing two things and seeing the differences. The analyses focus on two main parts, which are required for Dina-Hitex`s future compliance and recertification audit with the MDR requirements. The first is a gap analysis of Article 10 of MDR and ISO 13485:2016, and the second is a gap analysis of Annex IX and ISO 13485:2016.

The final part of the analysis depicts the parts that are not covered and therefore need to be optimised, as is the aim of this thesis. That leads to the project part, which is then the optimisation itself.

III. PROJECT

16 OPTIMISATION OF QMS

The final part of the thesis describes the practical use of the analysis findings. As the gap analysis will be used during a recertification audit, it is imperative to prepare a functional solution that will best suit the company Dina-Hitex spol. s r.o. to implement. At first, the findings are compiled into a coherent issue, and then solutions are offered and evaluated. In the end the best version is picked for practical implementation.

16.1 Summarisation of the findings

Because the findings (as seen in chapter 14) from the gap analysis are all concerning the same issue – a missing procedure - they are and defined and compiled as:

- Missing an explicit strategy for regulatory compliance
- Missing communication with regulatory authorities
- Missing description of procedures, which fulfil obligations of MDR 2017/745.
- Missing requirements and documents that are to be shared with NB.

16.2 Corrective actions for the findings

Findings can be corrected by implementing corrective actions. Defined steps show how the non-conformities can be corrected to show full compliance with the regulation:

- Create a new procedure describing the regulatory requirements set by the MDR. The procedure must overview how Dina-Hitex shows compliance with the regulation and description of responsibilities concerning the notified body. The procedure must include a strategy for regulatory compliance, a responsibility matrix, and specific steps taken to show compliance throughout the certification period. Presented must be the specific reports and documents prepared for the auditing process and therefore ensuring the quality and safety of the devices produced under the QMS.
- Create a process map for processes and their outputs necessary for regulatory compliance and implement it into the Quality Manual, as it is the main document describing the state of the QMS of the Dina-Hitex.

16.3 Evaluation of the solutions of non-conformities

As mentioned previously, because the optimisation of the QMS lies in documentation, its solutions are limited. This is due to the restrictions set by the nature of internal QMS and limited solutions. There are two options: include external sources or do it with internal sources.

16.3.1 External sources

Using a third party and outsourcing the corrective action is possible using a consulting agency or a freelancer. Dina-Hitex has an agreement with such a company, so it is possible to outsource the corrective action.

Table 11Evaluation of the external solution

Evaluation of external solution	
Costs	Dina-Hitex`s consultants have an hourly rate of 1500 CZK per hour spent on working on QMS processes and documentation. If presumed, that the external consultant needs time to understand the internal working of Dina-Hitex (3h) and then the creation of the procedure document (5h) and creation of process map with outputs (5h) the total hours spent working on it is 13 hours costing 19 500 CZK.
Benefits and risks	Using external sources has the biggest benefit of saving time for the Quality and Regulatory department. Other than that, it is presumed that external sources can have added expertise to the problem. Resulting in better general coverage and understanding of the requirements of the regulation. However, the benefit of the bigger expertise can be a burden because the internal understanding of the company can be smaller and therefore lacking. At the same time, a possibility of a mistake made by the external party is not high but needs to be considered.
Time investment	The company must inquire the project, spent time explaining the requirements and demands, then receive the project, understand it and implement it on its own, as the QMS is still managed internally.

	And then train the responsible people in their responsibilities.

16.3.2 Internal sources

Using internal sources is the way how most issues are resolved in Dina-Hitex. Employees responsible for regulatory compliance must keep the QMS effective and up to date, and their job is to implement corrections.

Table 12 Evaluation of the internal solution

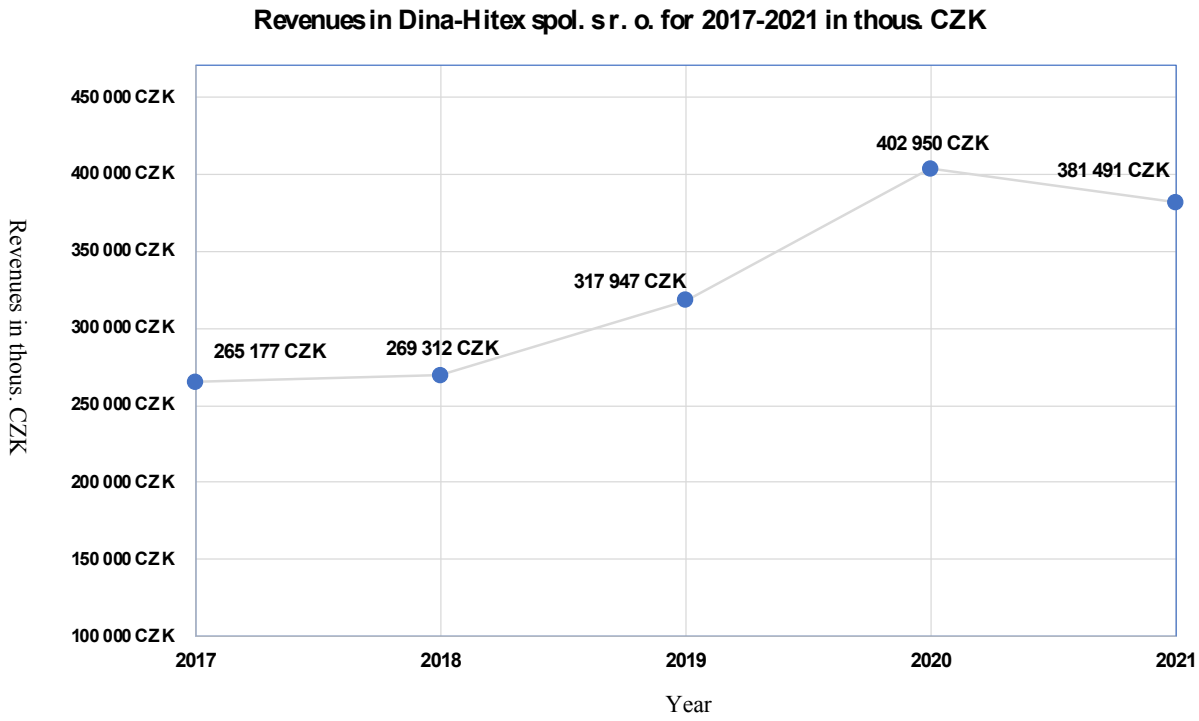
Evaluation of internal solution	
Costs	Internal costs for the company for the solution are the time spent by responsible people. This means the time of the Quality and Regulatory manager. As the employees know the system, the presumed time is 8 hours for the Quality Manager and 8 hours for the regulatory manager. That means 16 hours of work by full-time employees, therefore two working days spending creating a new process.
Benefits	The biggest benefit is that internal employees know the QMS because they are responsible for its compliance and effectiveness. With this benefit also lies the threat of not understanding the requirements specifically as it is a completely new process, which needs to be set up. However, a large benefit is that the obtained knowledge during the creation of the process stays inside the company and can be used to further develop the process.
Time investment	Work of the employees is spent on studying the requirements, creating the process and implementing it with training the responsible employees.

16.3.3 Return on investments

As the optimisation result is passing the audit to stay on the market, a return on investment is not counted as an important factor for the thesis. Either Dina-Hitex manages to update the QMS, correct the findings, ensure compliance, and stay on the market, or it fails and

therefore is forced to cease production. This conclusion seems harsh, however, as the MDR 2017/745 states that a QMS with these requirements is necessary for the production of medical devices in the EU.

Because of this, return on investments is counted as a prediction of future sales based on previous earnings and the company's growth. The available public data from 2017-2021 show growth, as seen in picture 2. For this trend to end, there are no available data. The medical devices market is growing. Due to the requirements and limitations set by the new regulation MDR, the competition will shrink; therefore, simply staying on the market will have a large return on investments.



Picture 2 Revenues in Dina-Hitex spol. s r.o. for 2017-2021 (source Dina-Hitex documentation)

16.3.4 Choosing the solution

As this project needs to be used, the decision for the choice was presented to the company's management. Both versions were discussed. However, what was chosen by the management was the internal solution. This was done mainly because of the price and time it would take to implement the external party. Responsible employees, the Quality and Regulatory manager, were tasked to implement these changes to ensure compliance is in their job description. However, what was considered and planned for the end of June 2023,

was using the external party to perform an independent audit of the QMS to ensure that all relevant parts of the system and requirements were fulfilled.

16.4 Implementation plan of the chosen internal solution in Dina-Hitex spol. s r. o.

Dina-Hitex spol. s r.o. will have its recertification audit for ISO 13485:2016 and its CE mark by MDR 2017/745 for its devices in the summer of 2023. Because of this, the issue needed to be dealt with. The gap analysis was performed in February of 2023. And at the end of February, the findings were presented to the company management. They have chosen the internal solution, and the work by the Quality and Regulatory manager started.

In March 2023, all necessary documents were created. Requirements set by the MDR were extracted to a separate document, G23 Regulatory compliance with NB. Every point of the regulation, which needed to fill in, was divided into sections and described how the system fulfils the requirements. Because most of the processes were done, but they were not described, it was shown that the project was faster than anticipated. Then it was necessary to devise a strategy for how the processes affect regulatory compliance. A process map was created based on data from the management review and its inputs and outputs because the conditions are similar. The process map was implemented into the Quality Management and document G23, as it needs to be part of the core documentation set. Another part of the optimisation project was implementing new risks into the risk management system and the QMS FMEA. New risks in the section regulatory compliance named RC01, RC02 and RC03 were identified and updated in the risk analysis.

The last part was training the responsible people with the documentation. This was done at the beginning of April 2023. With this, the optimisation project was done and can now be audited by either audit on demand by a third party, or the recertification audit by NB.

17 SUMMARY OF THE PROJECT OPTIMISATION

First, the solutions need to be prepared. The non-conformities of the QMS were specified and summarised. This showed that the optimisation lies in covering a procedure relating to the compliance strategy and notify body relationship with the manufacturer Dina-Hitex spol. s r.o.

Two solutions were prepared – one of an external consultant company, which would create and implement the document, and the second one of an internal solution. The solutions were evaluated on costs, benefits, and time. Both were viable solutions which would be possible. However, they were presented to the company's management, and it was decided that the internal sources would focus on dealing with the non-conformities. Quality and Regulatory managers were chosen to ensure regulatory compliance and QMS certification for Dina-Hitex. However, it was decided that after implementation by internal resources, an external company can do a “mock” audit of the QMS to ensure compliance before the actual recertification audit, which is coming in the summer of 2023. Because of this, the optimisation project is viewed as a success.

CONCLUSION

The diploma thesis aimed to optimise the quality management system in the company Dina-Hitex spol. s r.o. and prepare the system for the upcoming recertification audit.

The theoretical part of the thesis was done by literature research, which provided a necessary background for better orientation in quality management systems, medical devices, and the required legislation. Focus is put on the Medical Device Regulation 2017/745 and the ISO 13485:2016. At the end of the theoretical part, analysis methods were described, which are used in the analysis part of the thesis.

At the beginning of the analysis Dina-Hitex spol. s r.o. is introduced. Then it is further explored through SWOT, PESTLE, and Porter's Five Forces analysis. The core of the analysis is describing the current state of the organisation's quality management system as it is then used for the gap analysis of ISO 13485:2016 A11 and MDR 2017/745 to the current situation of the QMS. The gap analysis is then evaluated and summarised as findings were identified and summarised.

The last part of the thesis focuses on the optimisation of the QMS. Two solutions were explored and presented to the top management of Dina-Hitex spol. s r.o., and it was chosen that internal sources will be used for the optimisation process. The implementation was then done in practice in the company.

The thesis aimed at identifying non-conformities, which then need to be corrected. The thesis was created to be used during the audit, and the analysis part managed to fulfil this objective. As this gap analysis specified the differences between the current and new state of the QMS, it will be used during an audit as proof of a working quality management system. The gap analysis has shown that a missing process needs to be implemented and established in the current QMS. Because the process was established and corrected, it is presumed that Dina-Hitex spol. s r.o. is now prepared for its certification audit. Therefore, the goal of the thesis is complete.

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LIST OF ABBREVIATIONS

CE – CE mark (conformité européenne)

DoC – Declaration of Conformity

EMS – Environmental system

G - Guidance

IP – Internal procedure

ISO – International Organisation for Standardization

MDD Second abbreviation – Medical Device Directive 93/42/EEC

MDR – Medical Device Regulation 2017/745

NB – Notify Body

PDCA – Plan-do-check-act

PMFC – Post-Market Clinical Follow-Up

PMS – Post-Market Surveillance

QMS First abbreviation – Quality Management System

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