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ISO 13485 certified companies: motives for implementation, benefits, disadvantages and association with Lean Tools.

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Master in Business Administration

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BUSINESS
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Department of Marketing, Operations and General Management

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Dedication and acknowledgements

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Resumo

Atualmente sociedade e empresas estão em constante transformação tecnológica o que origina a necessidade de melhorar os processos de gestão e organização. Devido a este fator, a certificação *ISO 13485:2016* tem ganho relevância nas empresas por todo o mundo. A implementação do *lean* e de um sistema de gestão de qualidade que segue as regras *ISO* pode ser considerado uma vantagem competitiva.

Este estudo teve como objetivos, investigar se os benefícios associados à certificação do sistema de gestão de qualidade dos dispositivos médicos através das normas *ISO* reportados na literatura são realmente sentidos pelas empresas. Analisar também se o uso conjunto de sistemas de gestão da qualidade de acordo com as regras *ISO 13485:2016* e ferramentas ou metodologias *lean* potência os benefícios esperados da certificação do sistema de gestão da qualidade.

Os dados foram coletados por meio de um questionário aplicado a uma amostra de empresas com ISO 13484:2016, em todo o mundo. Foi considerada uma amostra de 199 empresas fabricantes e de serviços de dispositivos médicos em todo o mundo, de uma amostra-alvo de 8.899 empresas (2.4 % taxa resposta).

Os resultados revelam e confirmam que benefícios e deficiências relatados na revisão de literatura associada à *ISO 13485:2016* foram confirmados em empresas certificadas. Em relação ao *lean*, foi possível observar que *Root Cause Analysis, KPIS* e *PDCA* foram as ferramentas que mais impactaram e influenciaram as empresas certificadas *ISO 13485:2016*. O correto alinhamento entre as ferramentas *lean* e a certificação *ISO 13485:2016* pode melhorar o desempenho das empresas.

Palavras-chave: *ISO 13485:2016; Lean*, Sistema de Gestão; Empresas Certificadas

Sistema de Classificação JEL:

I18 - Política de Governo • Regulação • Saúde Pública

M11 - Administração de Empresas: Gestão da Produção

Abstract

Nowadays society and companies are in constant technological change, which leads to the necessity of improving organizational and management processes. Due to this factor, ISO 13485:2016 certification has gain relevance in companies worldwide. Implementing lean and a Quality Management System following ISO standards can be considered a competitive advantage. Lean tools were developed to create added value by using less resources, and there is some evidence in literature that it can reinforce ISO benefits.

This study aims to investigate whether the benefits associated with the certification of the quality management system of medical devices by ISO standard reported in the literature are really felt in companies. Also analyze if the joint use of quality management systems, in accordance with the ISO 13485:2016 standard, and lean tools or methodologies enhances the expected benefits of quality management system certification.

Data was collected using a questionnaire applied to a sample of companies with ISO 13484:2016, worldwide. A sample of 199 manufacturing and services firms of medical devices worldwide from target sample 8899 companies (2.4 % of response rate), were considered.

Findings reveal and confirm that benefits and short comes reported in literature review associated to ISO13485:2016 were confirmed in certified companies. Regarding lean, it was possible to observe that Root Cause Analysis, KPIS and PDCA were the tools that most impacted and influence ISO 13485:2016 certified companies. The correct alignment between lean tools and ISO 13485:2016 certification can enhance companies performance.

Keywords: ISO 13485:2016, Lean, Management System; Certified Companies

JEL Classification System:

I18 - Government Policy • Regulation • Public Health

M11 - Business Administration: Production Management

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Glossary of Acronyms

APCER - *Associação Portuguesa de Certificação* (Portuguese Certification Association)

CEO - Chief executive officer

COO - Chief Operating Officer

CQO - Chief Quality Officer

CTO - Chief Technology Officer

EUDAMED - European Database on Medical Devices

ISO - International Standard Organization

JIT - Just-in-time

KPI - Key Performance Indicators

MD – Medical Device

OEE - Overall Equipment Effectiveness

PDCA - Plan, Do, Check, Act

QMS - Quality Management System

SMED - Single Minute Exchange of Die

SMEs - Small and Medium-sized Enterprises

TPM - Total Productive Maintenance

Chapter 1: Introduction

1.1. Problem Stating

From a business point of view, to be competitive on both a national and a global basis it is each day more difficult. Organizations must adopt a forward-thinking approach to improve their management strategies (Hutchens, 2007).

Today's society is in constant social and technological change, which leads to an increase of competition and organization's pressure to have a production of fundamental products that respect consumer health & safety (Raišienė, 2011).

Hutchens (2007) defended that, to do so, it was important that leaders in organizations developed new ways to improve organizational activity and management processes to successfully push forward companies. It requires long-term united efforts to ensure the fluency of the running stages of planning management system integration, preparing documentation, implementing and realizing integrated management system (Raišienė, 2011).

The commitment to provide quality services and produce quality products while safeguarding the environment is becoming a very important part of strategy and image for organizations that pursue long-term growth (Raišienė, 2011). Providing special attention to these areas, organizations aim to take responsibility for the outcomes of their work. In that way, organizations seek to increase the trust and loyalty of their partners and consumers (Jorgensen et al., 2006).

Government policies or consumer organizations are easily related through consumer protection, however, standards enhance an extra protective environment that lies beyond the perception of most consumers, assuring that products and services provided are fitted for purpose and safe (IRENA, 2013).

Raišienė (2011) defended that the optimization of management using requirements of international standards makes the pinpoint of a solution for this problem a bit easier. Standards ensure that companies that follow such principles have a well-documented and organized management system, which leads to a higher quality and security in the products and services provided.

A quality management system (QMS) is identified as the structure, polices, processes, procedures, and resources of the organization required to implement quality management (Stravinskiene & Serafinas, 2020).

Schönreiter (2018), defended that a process-oriented quality management system involves, manages, and directs all the activities in the organization. Process management is an integral part of a model quality system. In such models, different areas in the company apply quality management to manage processes and ensure the quality of products and services (Stravinskiene & Serafinas, 2020).

A quality management system requires standardized processes. Process standardization is defined as "the unification of business processes and forming the foundation for actions among different departments or locations in an organization" (Stravinskiene & Serafinas, 2020, p.8).

Gutiérrez et al. (2010) state that the most common way to obtain a Quality Management System (QMS) is through the implementation of ISO standards. Without these, it is almost impossible to compete in the global market. These standards represent an important initial step for companies seeking a QMS, as they involve a lower initial level of commitment to their principles (Gutiérrez et al., 2010).

The goal of ISO standards is to help an organization to better control its procedures and, consequently, its products as they are the outcomes from processes (ISO, 2016).

ISO, despite its strong administrative burden, provides standardization, which is a highly needed characteristic of any management system. Once processes are methodically implemented, consistency is achieved to support the maintenance of quality at an elevated level (Stravinskiene & Serafinas, 2020). This characteristic is in divergence with uncontrolled processes, which is the primary cause of quality problems (Stravinskiene & Serafinas, 2020).

Supported on ISO 9001 "Quality management systems", ISO 13485:2016 "Quality Management: Medical Device Compliance" recognizes that an organization has the ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements applicable to them (ISO, 2016).

According to Geremia (2018), Medical Devices (MD) are currently more and more important in the healthcare industry and the related processes for worldwide regulation and certification are a topic of great interest and importance.

By applying ISO 13485:2016 requisites for a quality management system, the organization demonstrates its ability to provide medical devices and related services that consistently meet consumer safety, and the applicable regulatory obligations (Abuhav, 2018).

International Standard 13485 has the goal to guide the organization to establish, design, and implement a quality management system (QMS) for organizations that are involved in one or more stages of the life-cycle of MD, and such activities include design and development, production, storage and distribution, installation or servicing of a medical device (Abuhav, 2018).

Outside the organization, ISO 13485 can also be implemented by suppliers or external partners that provide services, processes, materials or components for the MD area (Abuhav, 2018).

According to Zgirskas et al. (2021), organizations that give emphasis to the implementation of quality improvements and address organizational needs accomplish higher benefits from their quality management system (QMS) implementation in areas like quality and operational improvement, when compared to those organizations that implement and pursue certification of their QMS for external motives, for instance, image or customer requirements. Therefore, a QMS implemented based upon external necessities tends to provide emphasis more on compliance and control and less on organizational effectiveness.

There is evidence of superb outcomes through the implementation of ISO standards on monetary overall performance (Corbett et al., 2005; Naser et al., 2004), operational overall performance (Mann & Kehoe, 1994; Naveh & Marcus, 2005), and consumer satisfaction (Gutiérrez et al., 2010).

There is however some controversial reporting in literature regarding ISO benefits. Zgirskas et al. (2021) revision of literature shows innumerous benefits for ISO implementation, although the authors could not claim all listed benefits, they could not defend that they do not exist, do not occur, and/or have not been achieved in the organization. This shows that there is no consensus regarding the benefits of ISO application, an aspect that leaves a gap in the current literature.

According to Kaganov (2021), lean approaches are helpful for the development and maintenance of documentation compliance with ISO Management System Standards (MSS).

Some authors argue that simultaneously implementing lean tools and its methodologies align with a QMS that follows ISO standards, and it can become an important source of profits for any company (Micklewright, 2010).

According to George (2003), through the application of lean is possible to observe what are the steps of the essential processes and the inherent costs and delays that can be reduced or removed. The author believes that it is possible to see the difference between important practices for creating value and those that only bring expenses and do not add value to customers thought the implementation of lean tools and methodologies.

However, different researches have criticized ISO norms on several reasons, which includes their excessive cost, immoderate paper-work or insufficient consumer or supplier focus (Brown et al., 1998; Motwani et al., 1996). In fact, the downfall results of ISO certification on organizational overall performance have additionally been tested (Beirão & Sarsfield Cabral, 2002); Corbett et al., 2005; Gutiérrez et al., 2010). Some studies even posit that some companies aim to obtain certification just for the promotion of their business without really getting involved with quality management (Gutiérrez et al., 2010; Sousa & Aspinwall, 2010)

Through his long consulting and auditing career, Kaganov, kept on finding, the same problem: management systems are over documented and there are few companies applying Lean techniques to their management and documentation systems. These observations were common despite the size, country or type of industry (Kaganov, 2020)

According to Kaganov (2020), Lean approaches are beneficial for the development and maintenance of management systems compliant with the ISO 13485 standard. The author defends that the implementation of both lean and ISO together is the solution for the problem stated above since it can help reducing an excessive number of documents, over-detailed and over-decorated standard operating procedures that are ineffective and costly. The excessive documentation lead to procedures that are wordy and long, difficult to read, navigate and understand. The same author argues that, on the contrary, well-written and structured procedures can lead an organization to a more efficient Lean management system.

1.2. Research Objective

In line with the context and research gap disclosed previously, this study intends to verify whether the motives, benefits, disadvantages associated with the certification of the quality management system of medical devices by ISO standard reported in the literature are really experienced in companies, and also analyze if the joint use of quality management systems, in accordance with the ISO 13485:2016 standard, and lean tools or methodologies enhances the expected benefits of quality management system certification.

1.3 Research Questions

Considering the objective of this study, it is intended to answer to the following research questions:

RQ 1 – Do ISO 13485 certified companies experience the benefits and short comes attributed in the literature to the certification of a quality management system of medical devices?

SQ 1.1: What is the relevance of each of the factors described in literature in a company's decision to implement standard ISO 13485:2016?

SQ 1.2: What are the advantages that companies experienced from implementing the ISO 13485:2016?

H_1= Companies certified for more years have more expressive benefits

H_2= Larger companies see more expressive benefits

SQ 1.3: What are the disadvantages that companies experienced from implementing the ISO 13485:2016?

SQ 1.4: What is the overall perceived value for the companies for investing in ISO 13485:2016 certification?

RQ 2 – Does the use of lean tools by ISO 13485 certified companies enhance the benefits from certification of the quality management system in companies producing medical devices?

SQ 2.1: What is the influence of the use of lean tools during the certification process for ISO 13485:2016?

SQ 2.2: What is the impact of the use of lean tools on the advantages the companies experienced with getting ISO 13485:2016 certification?

1.4. Methodology

To meet the general objective of the present investigation, a questionnaire will be developed, based on literature review (on the motives, benefits, and disadvantages attributed to quality management systems in certified ISO 13485 companies, and its influence and advantages on tools and/or methodologies that fit in lean thinking). This questionnaire will be sent to ISO 13485

certified companies in all continents, for posterior analysis and answer to the research questions.

1.5. Scope of the Study

The scope of this study includes worldwide manufacturing companies certified by the EN ISO 13485:2016 standard from EUDAMED - European Database on Medical Devices.

1.6. Thesis Outline

This thesis was dived in five chapters to answer the research questions described:

1. Introduction: contextualization and definition of the research question and clarification of its importance and relevance.
2. Literature Review: comprehends the theoretical contextualization of the existent literature concerning numerous research concerning the fundaments of the benefits of ISO implementation and connection to lean tools.
3. Methodology: this chapter describes hypotheses, research and sub research questions, the data collecting tool and procedure, the target population and sample, and data analysis procedure.
4. Findings and Discussion: upon characterization of the sample the results obtained are described and their analysis and discussion are carried out according to the hypotheses and questions formulated.
5. Conclusion: The last chapter covers the conclusion of the study in relation to the proposed objective and the research questions formulated, indicating limitations to the results obtained and providing indications for future research.

Chapter 2: Literature Review

2.1 ISO

Quality management has facilitated innovation and raised standards through the years. For several decades, corporates have been identifying, defining and in some cases standardizing their business processes by putting in place quality management systems and quality management models to minimize the difficulty of the processes involved in day-to-day life (Gutiérrez et al., 2010; Stravinskiene & Serafinas, 2020).

According to Gutiérrez et al. (2010), quality control may be identified as one of the stages in Quality Management evolution. Such term appeared in manufacture industry around 1931, when W.A. Shewhart published *Economic control of quality of manufactured product*. This author spoke about the importance of statistical control of quality, as a way to detect goods produced in the same factory by the same process however quality different (Shewhart, 1931 cited by Gutiérrez et al., 2010).

According to Slack et al. (2016), quality management should be customer-centric, customer satisfaction should be measured through surveys, while quality performance should be measured by processes to assure quality throughout of the operation chain.

Quality management should be improvement driven, that is why is important that top management demonstrates their commitment to maintain a continually improved management system. Is important that top management: (1) communicates to employees the value of meeting customer need and quality system requirements; (2) establish a quality policy and quality objectives; (3) conducts management reviews to ensure the adherence to quality policies; and (4) ensures the availability of the necessary resources to maintain quality systems (Gutiérrez et al., 2010; Mann & Kehoe, 1994; Slack et al., 2016).

One way to apply quality control inside the organizations is through ISO standards. The use of these standards is not mandatory, but it is a way to establish compliance with the regulatory requirements (Carmelo et al., 2018). Its purpose when it was first framed was to provide an assurance to consumers, that such products or services were produced taken into account regulatory obligations (Gutiérrez et al., 2010).

The International Standardization Organization (ISO) is a nongovernmental association that develops and publishes a wide range of proprietary, industrial, and commercial standards. Standards are considered to be the “distilled wisdom of people with expertise in their subject

matter and who know the needs of the organizations they represent – people such as manufacturers, sellers, buyers, customers, trade associations, users or regulators" (ISO, n.d.).

Standards have an impact of an estimated 80 % world commodity trade. ISO has the possibility to have one partner per country, and its membership comes with rights, benefits, good practice and obligations, one major advantage is that ISO country members have the opportunity to decide on how standards are set (ISO, 2018).

ISO standards represent an international agreement for good quality management practices (ISO, 2016). These principles are very important inside their sectors since they give to all range of different parties the same base ideas, they are written in a way that is easily repeatable, standardized, approved, and documented. It consists of guidelines related to quality management systems (Slack et al., 2016).

2.2 ISO 13485:2016

2.2.1 ISO 13485 Overview

According to INFARMED (2016), Portuguese national authority for medicines and health products, Medical Devices (MD) are considered important healthcare instruments, frequently used by healthcare professionals or by lay people, whose impact on health and healthcare costs is increasingly significant.

Based on the above-mentioned definition of MD, it can be concluded that the use of MD have a meaningful role and can have a direct risk for the user. For this purpose, it is important to ensure that the medical device placed on the market is safe and meets the manufacturer's performance requirements (Ziarkiewicz & Górna, 2020).

As such, nowadays, processes for worldwide regulation and certification of MD are a topic of great interest and actuality (Geremia, 2018).

The ISO 13485 – Quality Management: Medical Device Compliance, recognizes that an organization has the ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements with effectiveness (ISO, 2016).

ISO 13485 was first presented in 1996 as a quality management standard for medical device companies endorsed by ISO 9001. It was first published in two categories, one for manufacturers: ISO 13485 Original Equipment Manufacturers (OEM) and other for suppliers: ISO 13488. In 2003 some modifications were made to join both documents into a single quality standard that could be generally applied to medical device industry. In 2016 a final revision was made, in advance of the new European Union Medical Devices Regulations (EU MDR) (ISO,

2016). According to a global research conducted by the ISO in 2016, the number of certifications between 2004 and 2016 increased 91% in Europe (Beuzelin et al., 2018; ISO, 2016).

According to the Introduction of ISO 13485:2016 "This International Standard is intended to facilitate global alignment of appropriate regulatory requirements for quality management systems applicable to organizations involved in one or more stages of the life-cycle of a medical device" (ISO, 2016 p. viii).

Comparing to ISO 9001, ISO 13485 includes additional requirements that are specific to the medical device manufacturing industry to assure an accurate quality performance and maintain effectiveness of QMS (Carmelo et al., 2018). It is applied in all country members, which include 165 countries over the five continents (APCER, 2019; ISO, 2016).

This standard imposes on different stakeholders (policy makers & competent authorities, standard makers, manufacturers & distributors, investors & fiscal support, verification & auditing, users of the products & services). Table 2.1 represents a set of obligations that must be respected, as well as a set of procedures that must be observed by the adopting organizations (Abuhav, 2018; IRENA, 2013).

Table 2.1 - Stakeholders Requirements from standards

Source: adapted from IRENA (2013)

Policy Makers & Competent Authorities	Standard Makers	Manufacturers & Distributers	Investors & Fiscal Support	Verification & Auding	Users of the Products & services
• Supporting; • Compliance to regulations and legislation;	• Facilitating trade; • Facilitation communication and understanding;	• Common performance specifications; • Testing samples and materials; • Quality assurance; • Quality control;	• Confidence & trust in what is being funded; • Ability to clearly specify what is being funded; • Ability to verify and audit investment;	• Clear Process, procedures & specs to audit against; • Consistency; • Harmonized approach; • Protocols establish;	• Confidence; • Trust; • Consistency; • Understanding (performance, safety, etc)

2.2.2 The structure of ISO 13485

The ISO 13485 standard is organized into the eight sections: (1) Scope; (2) Normative references; (3) Terms and definitions, (4) Quality requirements, (5) Management responsibility, (6) Resource management, (7) Product realization, (8) Measurement, analysis and improvement. The main clauses and subclauses are illustrated in Figure 2.1 (ISO, 2016).

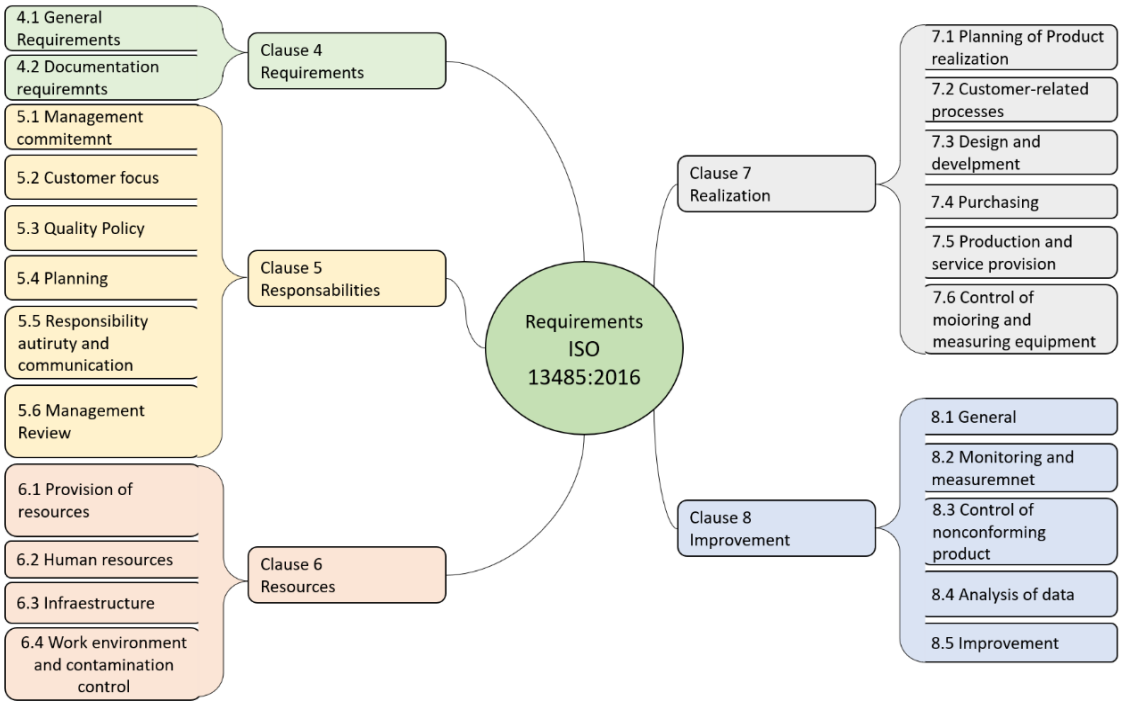


Figure 2.1 - ISO 13485:2016 Structure

Source: Based on ISO (2016)

2.2.3 Motives, Benefits and Critics of ISO implementation

The data for the elaboration of Tables 2.2, 2.3 and 2.4 was collected from Web of Science, SCOPUS, B-On and ProQuest data bases in August 2022 by using the search keywords “ISO 13485”, “ISO”, “ISO13485 AND motives”, “ISO13485 AND benefits”, “ISO13485 AND critics”. The research considered peer-reviewed academic journals available with full text, in English or Spanish, that were published from 2007 until the present. The results yielded a total of 375 articles. The articles that were repeated or did not fit the scope of this research were excluded. This protocol led to a total of 102 articles analyzed.

According to Gutiérrez et al. (2010), ISO standards lead to high levels of implementation of QMS elements, however employee involvement and employee work attitude have created some controversy.

Zgirskas et al. (2021), defended that the type of motivation for implementing a quality management system impacts the implementation of such system. According with the author, groups that focus on actual quality progresses and organizational requirements, accomplish higher benefits from ISO implementation in departments like quality and operational improvement, compared to those companies that implement and pursue certification of their QMS for external motives, for example, marketing purposes, pressure from customers or just to gain competitive advantage. Consequently, a QMS established on external requirements is biased to concentrate more on accomplish necessary obligations to pass certification and less on organizational efficiency (Zgirskas et al. 2021).

Gotzamani & Tsiotras (2002) defend that the main part regarding the efficacy of standards is linked to their ability to actually improve quality (both internal and external) and customer satisfaction.

A revision of literature was made to better understand the motives leading to ISO certification and they were divided in internal and external motives. Internal motives are the ones focused on topics that emerged within the company, whereas external motives are topics that emerge from the outside of the company - by consumers, suppliers, competitors, government/legal authorities.

During literature review it was repeatedly found sixteen (16) motives that led to ISO certification. Such motives and corresponding authors are described in table 2.2: (1) Zgirskas et al. (2021); (2) Corbett et al. (2005); (3) Slack et al. (2016); (4) Dick et al. (2010); (5) Pinar & Ozgur (2007); (6) Häversjö (2000);(7) Lo & Chang (2007); (8) Jang & Lin (2008);(9) Weerasinghe & Jayasooriya (2020); (10) Martins da Fonseca et al. (2017); (11) Martínez-Costa et al. (2008); (12) Fonseca et al. (2017); (13) Gal et al. (2020); (14) Casadesús & Karapetrovic (2005); (15) Chiarini (2019); (16)Wolniak (2016); (17) Gómez-López et al. (2016); (18) Casadesús et al. (2000); (19) Kasperavičiūtė-Černiauskienė & Serafinas (2018); (20) Kammoun & Aouni (2013); (21) Iatridis & Kesidou (2018); (22) Nair & Prajogo (2009); (23) Guo et al. (2018); (24) Iatridis et al. (2016); (25) Hussain et al. (2020). Other articles that were related with ISO but did not contain the motives for certification were excluded from this analysis.

Table 2.2 - Motives for ISO implementation

Motives		Author																								
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25
Internal	Decision of the highest authority	■			■			■						■												
	Improvement of quality of products and/or services	■	■	■	■	■		■	■		■		■	■	■		■	■				■	■	■	■	
	Improvement of processes and procedures	■		■	■			■	■		■			■	■		■	■	■	■	■	■	■	■		■
	Reduction in incidents, rejections, and complaints	■		■	■	■		■	■						■				■		■					
	Used as a basis for reducing internal costs	■		■	■		■	■	■		■		■	■	■	■	■	■	■			■	■	■	■	
	Improvement of communication in the organization	■		■				■	■					■		■	■	■	■	■	■	■	■	■	■	
	Improvement of management–employee relations	■							■					■		■	■	■	■		■		■			
External	Used as a promotional and/or marketing tool	■		■		■			■	■		■		■	■		■	■	■		■					
	Maintaining and/or increasing the market share	■	■		■	■		■	■		■			■	■		■	■	■		■	■	■	■	■	■
	Demand and/or pressure of customers	■		■	■	■			■	■	■	■	■	■	■	■	■	■	■		■	■	■	■	■	■
	Competitive advantage	■			■	■	■	■	■			■	■	■					■	■	■	■	■	■	■	■
	Condition to compete in the sector	■			■	■			■				■	■		■	■	■	■		■		■	■	■	
	Direct way to a new market	■						■	■		■		■		■		■	■	■			■	■	■	■	■
	To be a good example for suppliers	■						■	■						■	■	■	■			■		■	■		
	Improvement of public image of the organization	■		■		■			■		■		■	■	■		■	■	■	■		■	■	■	■	■
	At the request of the Government /Legal authority	■				■				■	■		■			■	■	■	■			■	■		■	

As is possible to observe in Table 2.2. the main motives regarding ISO implementation found in the research are related with: "*Demand and /or pressure of costumers"* (external); "*Maintaining and/or increasing the market share"* (external); "*Used as a basis for reducing internal costs"* (internal)*; "Improvement of processes and procedures"* (internal)*; "Improvement of quality of products and/or services"* (internal)*; "Competitive advantage"* (external)*; "Improvement of public image of the organization"* (external). The motives least repeated were: "*Decision of the highest authority"* (internal)*; "Reduction in incidents, rejections, and complaints"* (internal)*; "Improvement of management–employee relations"* (internal) and *"To be a good example for suppliers"* (external).

There are many potential benefits and some possible drawbacks from integrated management system through ISO implementation for organizations that seek to improve their management process. Table 2.3 results from the juxtaposition of the contribution of the authors with the benefits: (1) Corbett et al. (2005); (2) Jorgensen et al. (2006); (3) Kheng (2006); (4) Lie et al. (2020); (5) Zgirskas et al. (2021)(6) Karthi et al. (2012); (7) Gutiérrez et al. (2010); (8) Armeanu et al. (2017); (9) Bayati & Taghavi (2007); (10) Benner & Veloso (2008); (11) Calisir (2007); (12) Dick et al. (2010); (13) Feng et al. (2008); (14) Han et al. (2007); (15) Jang & Lin (2008); (16) Lo & Chang (2007); (17) Magd (2008); (18) Martínez-Costa & Martínez-Lorente (2007); (19) Martínez-Costa et al. (2008); (20) McGuire & Dilts (2008); (21) Pinar & Ozgur (2007); (22) Singh (2008); (23) Terziovski & Power (2007); (24) Zaramdini (2007); (25) Tarí et al. (2012); (26) Fonseca et al. (2017); (27) Gal et al. (2020); (28) Ociepa-Kubicka et al. (2021); (29) Casadesús & Karapetrovic (2005); (30) Chiarini (2019); (31) Wolniak (2016); (32) Casadesús et al. (2000); (33) Lundmark & Westelius (2006); (34) Kasperavičiūtė-Černiauskienė & Serafinas (2018); (35) Kammoun & Aouni (2013); (36) Iatridis & Kesidou (2018); (37) Guo et al. (2018); (38) Pop & Socaciu (2013); (39) Iatridis et al. (2016); (40) Hussain et al. (2020); (41) Ruževičius (2008). Other articles related to ISO but which did not convey the benefits associated with certification were excluded from this analysis.

Table 2.3 shows ISO implementation benefits and associated articles found in literature. "*Profitability"* and *"Productivity and/or efficiency"*, both internal benefits, were the most noticed benefits related in the study revision. Followed by "*Clarification of processes and procedures", "Customer satisfaction", "Expansion into international markets* and *Quality/safety of MD".* Conversely, the three benefits least highlighted are reduction of "*Paperwork"*, increased "*Quality of suppliers"* and reduction on the *"Number of incidents, rejections, and complaints".*

However, is it important to have into account that such benefits may vary over time or company size. According to Fonseca et al. (2017), time is considered to be an important variable to take into account, as some benefits can be achieved on the short term (e.g. customer satisfaction) while others only on the long term (e.g. corporate image on the market).

Regarding company size Pacana & Ulewicz (2020), reported that, at that time, the largest number of companies that were certified were Small and Medium-sized Enterprises (SMEs). Complementing this idea, Lo & Chang (2007) argued that bigger dimension certified organizations may have greater chances for success with ISO certification due to the fact that they have higher level of resources available to them to pursue the implementation process, on

the other hand, researchers also found that small businesses desire to implement ISO mostly due to pressure by their customers.

Based on these arguments two hypotheses are formulated and will be analyzed in chapter 4:

H_1= Companies certified for more years have more expressive benefits

H_2= Larger companies see more expressive benefits

Table 2.3 - Benefits from ISO implementation

	Benefits	Author																																									
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41
Internal	Quality/safety of MD	■	■	■	■	■			■			■	■				■	■					■		■	■	■	■		■		■		■		■	■	■	■			
	Performance of MD			■	■	■			■				■														■	■				■			■			■				
	Number of incidents, rejections, and complaints				■	■							■																	■			■			■						
	Productivity and/or efficiency		■		■	■			■	■		■	■	■	■	■	■	■		■			■	■	■	■	■	■		■		■	■				■		■	■	■	
	Internal costs		■	■	■	■							■													■	■	■		■	■	■	■	■		■	■	■	■			
	Profitability	■			■	■	■				■	■	■			■	■	■	■	■	■	■	■	■	■	■	■	■		■		■	■		■		■					■
	Employee motivation and retention					■	■			■		■		■		■	■	■		■					■	■	■			■	■	■	■	■		■						
	Employees understanding of quality					■			■																	■	■	■			■	■	■	■	■	■						
	Clarification of processes and procedures		■		■	■				■		■	■	■		■	■	■					■		■	■	■			■		■	■	■	■	■	■	■			
	Paperwork				■	■							■														■				■											
	Working environment					■																			■	■	■			■	■	■	■			■		■				
External	Customer service					■							■														■			■		■	■		■	■	■	■				
	Customer satisfaction				■	■				■			■		■	■	■	■		■			■		■	■	■	■		■	■	■	■		■	■	■	■				
	Expansion into international markets			■	■		■					■		■	■	■	■			■			■		■	■	■			■		■	■	■		■	■	■	■	■	■
	Competitive advantage				■	■	■							■			■								■	■	■	■		■			■	■		■	■	■		■		■
	ISO as a promotional and/or marketing tool					■																			■	■	■	■		■		■	■	■	■						
	Quality of suppliers					■																								■			■				■					
	Mutual cooperation with suppliers					■											■	■							■					■	■	■				■		■				
	Corporate image at the market			■		■	■					■		■			■	■							■	■	■	■		■		■	■	■	■		■	■	■			

Nevertheless, standardizing management systems with common documentation is difficult due to the variety of organizational goals and characteristics and the uncertainty of management, which is influenced by a changing external environment (Gutiérrez et al., 2010).

Some authors less enthusiastic with the ISO implementation argue that business only aim to achieve certification to benefit their business without really committing themselves to a QMS (Gutiérrez et al., 2010).

Even now, ISO certification is not seen as benefit by all authorities and is still subject to some discussion. Table 2.4 shows the link of such found disadvantages on companies certification and the related articles found in the literature: (1) Corbett et al. (2005); (2) Kheng (2006); (3) Karthi et al. (2012); (4) Slack et al. (2016); (5) Armeanu et al. (2017); (6) Dick et al. (2010); (7) Pinar & Ozgur (2007); (8) Jang & Lin (2008); (9) McGuire & Dilts (2008); (10) Weerasinghe & Jayasooriya (2020); (11) Martínez-Costa & Martínez-Lorente (2007); (12) Gal et al. (2020); (13) Kasperavičiūtė-Černiauskienė & Serafinas (2018); (14) Kammoun & Aouni (2013); (15) Lo & Chang (2007); (16) Guo et al. (2018). Other articles that were related with ISO but did not contain critics associated with certification were excluded from this analysis.

Table 2.4 - Disadvantages of ISO implementation

Criticism	Author															
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
It involves high level of documentation and administration effort	■	■	■	■	■				■		■		■	■	■	
It requires significant cost and time	■	■	■	■		■			■	■	■		■	■	■	
It is not a variable system			■	■	■		■		■							
It is doubtful that ISO certification as a single system would yield better performance.			■				■				■					■
The ISO certified companies make use of only the standard tools and techniques.		■	■													
The motive for obtaining ISO certifications is more external than internal			■				■	■			■					■
The ISO standard is general.	■	■	■						■			■				
In case of research and development, ISO promotes an increased stress on documentation			■	■					■		■		■	■	■	
Internal audits conducted as a part of ISO certification cannot audit everything because the audits are based on sampling. This results in weak validity of the audit findings.	■		■													
ISO standard can be a mere promoter of the organization rather than serving its important criteria of continual improvement		■	■				■				■				■	■

Analyzing table 2.4 the most common disadvantages presented at the revision of literature were the "*High level of documentation and administration effort"* and the *"Significant cost and time"* required for ISO certification. Whereas the least stated where *"ISO certified companies make use of only the standard tools and technique"* and *"Internal audits conducted as a part of ISO certification cannot audit everything because the audits are based on sampling. This results in weak validity of the audit findings."*

These critics can certainly be minimized and advantages of integrated management systems become even stronger if researchers and practitioners join their forces in search of methods of organizational management development (Raišienė, 2011).

According to Mentel & Hajduk-Stelmachowicz (2020), currently, standardization is not yet the powerful tool has it could be. The level of standardization should be considered as one of the marks of sustainable development in the circular economy. Standardization can strengthen the achievement of economic, ecological and social goals, leading to a sustainable development.

2.3 Lean thinking

According to Stravinskiene & Serafinas (2020), the "Quality Management" concept is a crucial topic in today's companies. According with the authors, it has emerged in the mid of the 20th century evolving in its application and tools. Nowadays, this subject is always evolving standing out specific tools and different approaches to overcome different barriers applied to each context (Stravinskiene & Serafinas, 2020)

Lean was originated in Japan. Originally, the concept was applied in manufacturing and production industries (Kaganov, 2020).

According to the Lean Enterprise Institute (2021), Lean is considered to be a way of thinking associated with the idea of creating value with fewer resources and therefore waste reduction. According with the institute this can only be achieved with continuous testing.

Lean thinking has been seen as a new paradigm of production processes and its tools are recognized for their ability to provide productivity gains, as they foster continuous quality improvement while minimizing waste (Womack & Jones, 2003).

Sugimori et al. (1977), in their research study refer that the Toyota production system and the kanban system are considered the starting point for the implementation of lean production in companies of Western World.

Further important publications without doubt contributed to lean management becoming the preferred method for driving operational efficiency, where the pressure to reduce costs and lead time while enhancing quality grows its importance each day (Roth et al., 2020).

According to Gonçalves (2019), Marin-Garcia & Bonavia (2015) and Marodin & Saurin (2013), the main results from lean implementation are positive. The most frequently mentioned benefits include: Boost of organized structure, improvement of productivity; reduction of cost; improvement of general performance; shorter lead time of delivery, better product final quality,

better adjustment of the product to the necessities of the client, increasing capacity to adjust production to meet changing demand, reduce levels of stock, increase profit, improved communication between employees, improved working conditions, increased employees autonomy and satisfaction, increased market share, improved environmental performance and profit by reducing waste leading to an increase of customer satisfaction (Table 2.5). According to Marin-Garcia & Bonavia (2015), the results found in the literature can be however misleading due to the lack of replication and homogeneity in the studies realized and also due to different market industries represented in some researches (Marin-Garcia & Bonavia, 2015).

Table 2.5 - Lean's Identified advantages according to: Gonçalves (2019), Marodin & Saurin (2013) and Main-Garcia & Bonavia (2015)

Lean Advantages	Author	Measures				
		Operational	Financial	Human	Market	Environment
Better Organized structure	Gonçalves (2019)	X				
Improves productivity	Marodin & Saurin (2013)	X				
Reduction in products /operation costs	Marodin & Saurin, (2013)		X			
Improves performance in general	Marodin & Saurin, (2013)	X				
shorter lead time	Marin-Garcia & Bonavia, (2015)Marodin & Saurin, (2013)	X				
Better product quality	Marin-Garcia & Bonavia, (2015)Marodin & Saurin, (2013)	X				
Adaptation of the product to the characteristics requested by the client	Marin-Garcia & Bonavia, (2015)Marodin & Saurin, (2013)				X	
Capacity to adjust production to meet fluctuating demand	Marin-Garcia & Bonavia, (2015)Marodin & Saurin, (2013)				X	
Reduced stock levels, especially WIP, regardless of the product type (An excessively high or low inventory has a negative impact on operational performance)	Marodin & Saurin, (2013)	X				
Increase in profits	Marodin & Saurin, (2013)		X			
Improved communication between employees	Marodin & Saurin, (2013)			X		
Improved working conditions, regardless of work intensification and increased pressure exerted by supervisors to meet production targets. (Stress levels are	Marodin & Saurin, (2013)			X		
Increased employees autonomy and satisfaction	Marodin & Saurin, (2013)			X		
Increased market share in premium brands	Marodin & Saurin, (2013)				X	
More efficient use of natural resources and environmental performance	Marodin & Saurin, (2013)					X
Improved environmental performance, due to reduction of waste and pollution	Marodin & Saurin, (2013)					X
Increased profit margins by reducing waste and improving efficiency	Marodin & Saurin, (2013)		X			
Increasing customer satisfaction	Marodin & Saurin, (2013)				X	

Lean thinking has an open framework that allows for individual selection and alignment of methods/tools according to the specific needs and circumstances of the organization in question (Gonçalves, 2019). Among the concepts commonly associated with lean thinking there are various tools such as, for example, Kaizen, Kanban, the 5S program, Single Minute Exchange of Die (SMED) and Total Productive Maintenance (TPM) Bottleneck analysis, Continuous flow, Gemba, Heijunka, Hoshin kanri, Jidoka, Just-in-time (JIT), Key Performance Indicators(KPI), Muda, Overall equipment effectiveness (OEE), Plan, Do, Check, Act (PDCA), Poka-yoke, Root cause analysis, Six big losses, Smart goals, Standardized work, Takt time, Value stream mapping, Visual factory. The meaning of each tool can be found in Annex A.

2.4 ISO and Lean

The philosophy of lean production and its distinct models has become a reality in our times. With an increase of population, increases the necessity to satisfy its specific needs (Hallgren & Olhager, 2009). Consequently, is expected some degree of implementation of lean manufacturing (LM) practices in any sector with strong competition (Marin-Garcia & Bonavia, 2015).

Usually, manufacturing is supported on structured quality process systems and procedures (Marin-Garcia & Bonavia, 2015). A study conducted by the Lean Enterprise Research Centre showed that 60% of production activities in a typical manufacturing company are considered waste. Some of the typical weaknesses in procedures found were: (1) Documents are too voluble and too sweeping; (2) Poorly written; (3) Have complex content; (4) Were repeated; and (5) Outdated (Kaganov, 2021).

According with Micklewright (2010), ISOs based on quality management system (QMS) tend to be slow moving and bureaucratic, with an abundance of useless documents, contrary to what is desired, to be effective and efficient (Micklewright, 2010). That is why Kaganov (2021) defended that Lean methodologies are beneficial for the development and maintenance of documentation in accordance with ISO Management System Standards.

According to Stravinskiene & Serafinas (2020), lean has an outstanding reputation for its focus on process efficiency and effectiveness. Lean thinking provides principles and practices intended to renew innovation capacity (Stravinskiene & Serafinas, 2020).

When compared, ISO 9001:2015 and ISO 13485:2016 have the same base fundaments, however, ISO 13485:2016 is more focus on the medical device area and lacks continuous

improvement vision and there is where a complementarity between ISO 13485 and Lean Thinking can lead to an improvement of companies performance (ETQ, 2021).

According with Micklewright (2010), there is no conflict between lean and an ISO 9001 based quality management system. In fact, the two are, or should be, complementary to each other, if developed with knowledge and wisdom.

A strategic quality management systems usually involves, or should involve a systematic approach, focusing on elimination of waste and continuous improvement, involving people in the process in order to meet customer demands and pursuit of perfection (Micklewright, 2010).

In section 5.5.1 from ISO 13485:2016 entitled – responsibility and authority - it is stated: "Top management shall document the interrelation of all personnel who manage, perform and verify work affecting quality and shall ensure the independence and authority necessary to perform these tasks" (ISO, 2016 p.10). According to Cappelli & Neumark (2001) perspective, employee involvement is the main concept behind work systems and organizational performance. Micklewright (2010) defended that the best way to measure "Process performance" is through lean metrics, in order to control cycle times, output or inventory.

However according with Bacoup et al., (2018) and Micklewright (2010), there is an lack of consensus in the fact that QMS and Lean are both intended to improve the production processes of the firm though, in reality, they are two parallel systems operated by two different departments, resulting in wasted resources because they are not completely associated.

In order to attend each companies' specific needs, Bacoup and his team started introducing the term "Lean Normalization" a more complete methodology which combines the advantages of both ISO standards and Lean Management. Firstly design for ISO 9001 standard, its generic structure can be applied to other standards (Bacoup et al., 2015). This approach leads manufacturing or service companies to certification without creating more documentation. It has the goal to guarantee agility and flexibility in the day-to-day management of the company, reducing expenses and time (Bacoup et al., 2018).

The interrelationship between ISO and Lean are growing each day its importance, that is why some countries like France created a guideline that facilitates the integration of both ISO 9001 and Lean thinking simultaneously at the company: FDX 50-819:2011 (Bacoup et al., 2018). FDX 50-819, seeks to cross-reference ISO 9001 requirements with Lean principles and tools. The main purpose of this document is to emphasize the most appropriate tools in Lean for a complimentary interaction with each clause of the ISO 9001 standard (Bacoup et al., 2018).

2.5 Summary

The literature review carried out in chapter 2 aimed to build a conceptual basis to support the answer to the research questions. The main conclusions drawn from this review are:

- Medical Devices importance are increasing worldwide, its regulation and certification are a topic of great interest and actuality (Geremia, 2018).
- Standards have an impact of an estimated 80 % worldwide commodity trade (ISO, 2018).
- There are many potential benefits and some possible drawbacks of integrated management systems for organizations that seek to improve management process. Its benefits are described in Table 2.2.3.2 and critics for the implementation of a quality management system based on ISO are present in Table 2.2.3.3.
- ISOs based on QMS tend to be slow moving and bureaucratic, with an abundance of useless documents, contrary to what is desired, to be effective and efficient (Micklewright, 2010). However, according with Kaganov (2021), when ISO is implemented together with lean methodologies it can be beneficial for the development and maintenance of documentation;
- According with some authors, QMS and Lean are both intended to improve the production processes although sometimes they are not correctly associated (Bacoup et al., 2018; and Micklewright 2010).

Chapter 3: Methodology

In this chapter, the methodology used to answer the research questions is disclosed, namely, the data collection procedure and methodology for processing the collected data.

To meet the general objective of this research, it was developed a quantitative analysis through a questionnaire based on a literature review. The goal was to explore the motives and possible benefits, or critics attributed to Quality Management Systems (QMS) in Medical Device companies, and, at the same time, understand the relation between its tools or methodologies that fit in lean thinking, while looking for references of complementarity between the ISO 13485 standard and Lean tools or methodologies.

3.1 Research questions

In chapter 1 research questions were defined as such:

RQ 1 – Do ISO 13485 certified companies experience the benefits and short comes attributed in the literature to the certification of a quality management system of medical devices?

The literature review made it possible to identify the motives, benefits and critics that literature associates with certification by the ISO 13485 standard. From the conclusions of this review (subchapter 2.2.3.) it was found that previous reviews carried out by authors identified in Tables 2.2. 2.3 and 2.4 resulted in the identification of several motives, benefits and critics associated with ISO certification. These factors were identified in previous studies, but there is no evidence of their adherence to the 13485:2016 worldwide reality. In this sense, these sub question arises:

SQ 1.1: What is the relevance of each of the factors described in literature in a company's decision to implement standard ISO 13485:2016?

SQ 1.2: What are the advantages that companies experienced from implementing the ISO 13485:2016?

Considering the arguments of Fonseca et al. (2017) and Lo & Chang (2007) a detail analysis to this sub question is fundamental to understand the impacts of company's dimension and its years of certification on its identified benefits. This led to two research hypotheses.

H_1= Companies certified for more years have more expressive benefits

H_2= Larger companies see more expressive benefits

SQ 1.3: What are the disadvantages that companies experienced from implementing the ISO 13485:2016?

SQ 1.4: What is the overall perceived value for the companies for investing in ISO 13485:2016 certification?

RQ 2 – Does the use of a lean approach or lean tools in ISO 13485 certified companies enhance the certification of the quality management system of medical devices?

The literature review presented in subchapters 2.3 and 2.4 aimed to obtain references of complementarity between lean and ISO 13485 and the possible complementary or synergistic effects that they may have.

According with Micklewright (2010), there is no conflict between lean and an ISO based quality management system. In fact, the two are, or should be, complementary to each other, if developed with knowledge and wisdom. From this proposition emerge de sub research questions:

SQ 2.1: What is the influence of the use of each lean tool during the certification process for ISO 13485:2016?

SQ 2.2: What is the impact of the use of lean tools on the advantages the companies experienced with getting ISO 13485:2016 certification?

3.2. Data collection tool and procedure

The tool (questionnaire) for collecting the data needed to analyze the propositions and test the formulated hypotheses was built based on three groups of questions.

The first group of questions includes questions about the company's characterization, such as the year witch the company starts working, year of obtaining the ISO 13485:2016 certification, the country where they were based on, answerers role at the company, company's sales volume, the number of employees in the company and what were companies' main costumers.

The second group of questions is related with the ISO 13485:2016 certification. Namely, the motives for implementation the standard, the level of agreement of its benefits and critics and the overall perceived value.

The 16 motives leading for the implementation of quality management systems are mentioned in Table 2.2, the benefits identified in Table 2.3 and the critics disclosed in Table 2.4, all according with the revision of literature in chapter 2. For each factor it was used a Likert like scale with 7 categories; Very Negative (1); (2); (3); Neutral (4); (5); (6); (7) Very Positive.

The first and second groups of questions are intended to collect data to answer RQ 1.

The third group of questions concerns the use or not of lean tools and methodologies in conjunction with certification. If companies use lean tools or methodologies, they must indicate, using a qualitative scale similar to the one used in the second group of questions, the influence of the use of each tool during the process of certification. For such identified tool, it was also defined their impact on the advantage of certification with ISO 13485:2016. This third group of questions is intended to collect data for answering RQ 2.

The full questionnaire can be found in Annex B.

A pre-test of the questionnaire was carried out with five people, of which some questions were simplified to improve interpretation.

3.3 Target population and sample

The target comprised 8899 manufacturing and service firms of MD worldwide. The firms contacted were derived from EUDAMED database between January and May of 2022. The procedure for data collection consisted of sending a letter by email explaining the research project to the CEO, Quality Department (CQO) or Operations Department (COO). After explaining the reasons for and purposes of the research, the letter included a direct link to a questionnaire available online. Having clicked that link, that directed to QualtricsXM®, respondents could access the questionnaire, fill it online and send it automatically to a central computer, where all responses were saved. Four hundred and forty-six (446) replies were received. Two hundred and forty-seven (247) were unusable because they empty. Finally, we had one hundred and ninety-nine (199) usable surveys, 2.24% response rate.

3.4 Data Analysis

The data collected will be analyzed using Microsoft Excel 365® for the characterization of the sample, RQ1 and RQ2 and Python™ for the Hypothesis analysis. To test hypothesis, the

normality of the distribution (using the Kolmogorov-Smirnov test) and the homogeneity of variances (using the Levene test) will be investigated in order to confirm the assumptions of the conditions for performing the One-Way ANOVA test, if the assumptions are not confirmed it will be used Kruskall Wallis. As for the analysis of the significant results it will be used a pos-hoc test: Tukey.

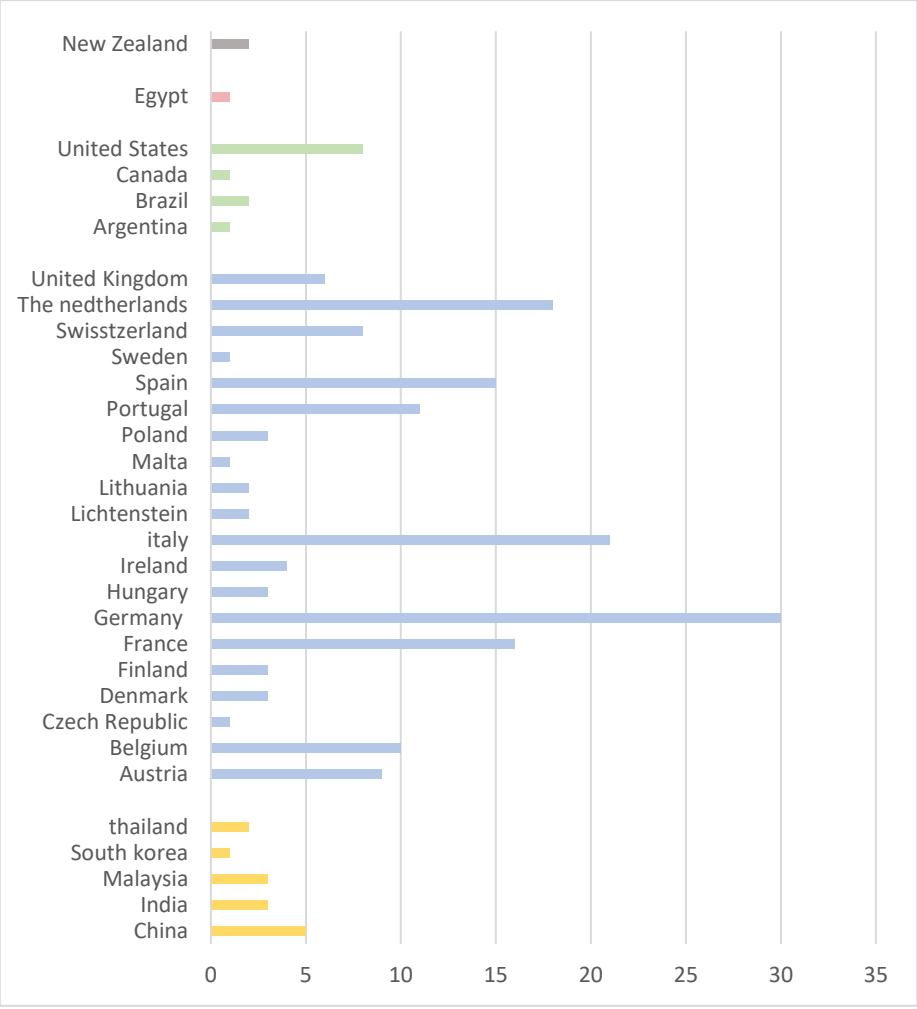
In the next chapter, the findings obtained through the analysis of the data collected will be presented. First it will be characterized the sample. Next, the results obtained are discussed in order to respond the Research Question 1 (RQ1) and its sub-research questions and hypotheses H_1 and H_2. In the next section, it will be presented the results for Research Question 2 (RQ2) regarding the use of a lean approach or lean tools in ISO 13485:2016 certified companies.

Chapter 4: Findings and Discussion

4.1 Sample demographics

Replies came from 32 countries worldwide: Argentina, Austria, Belgium, Brazil, Canada, China, Czech Republic, Denmark, Egypt, Finland, France, Germany, Hungary, India, Ireland, Italy, Lichtenstein, Lithuania, Malaysia, Malta, New Zealand, Poland, Portugal, South Korea, Spain, Sweden, Switzerland, Thailand, The Netherlands, United States and United Kingdom. Germany (15.08%), Italy (10.55%), The Netherlands (9.05%), France (8.04%), Spain (7.54%) and Portugal (5.53%) were the countries where more responses came from (Graphic 4.1).

Analyzing by continent, Europe had a predominance of 85.43% of answers, followed by Asia (7.04%), America (6.03%), Oceania (1.01%) and Africa (0.50%) (Figure 4.1). Martínez-Costa & Martínez-Lorente (2007) found that other non-European firms are more likely to seek ISO certification when they have high levels of exports to Europe, there is why most respondents are from Europe, other countries just certify their companies if necessarily.



Graphic 4.1 - Number of answers by country

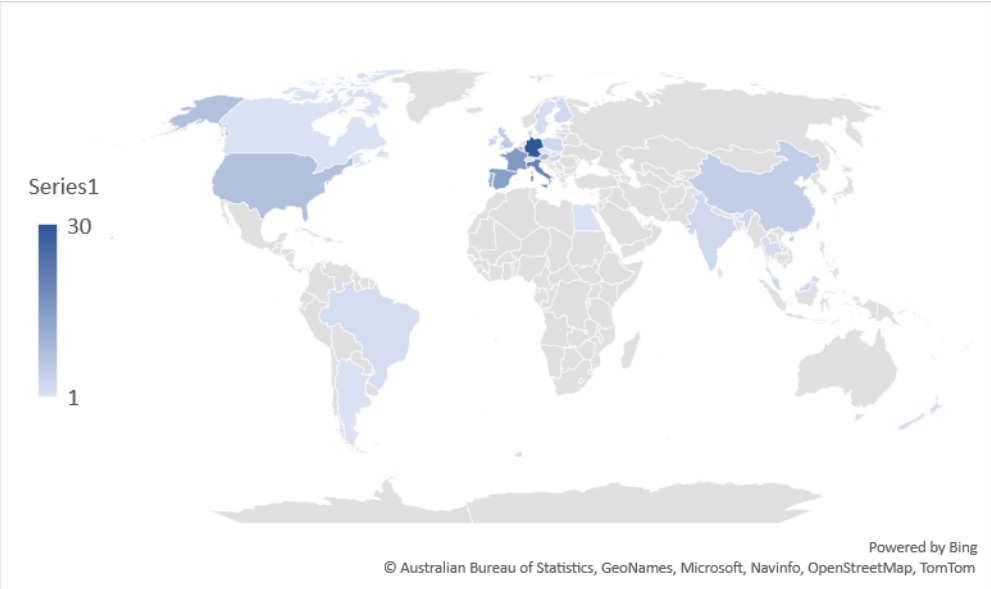
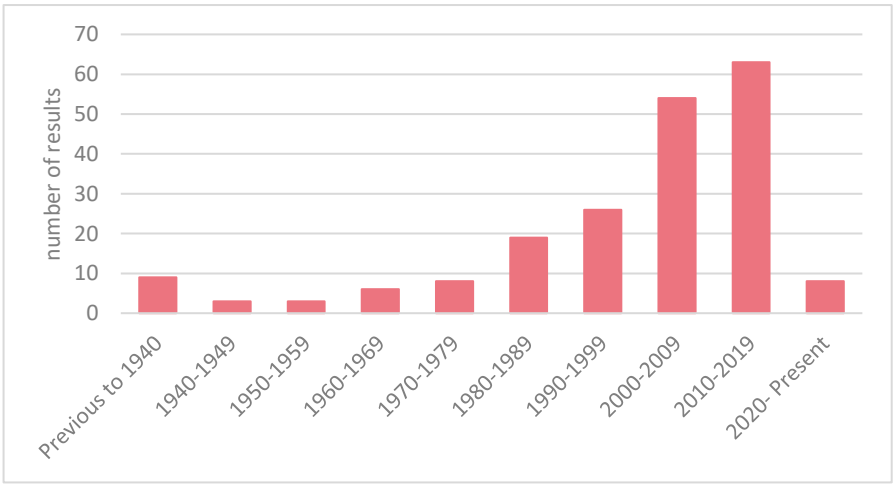


Figure 4.1 – Answers distribution worldwide

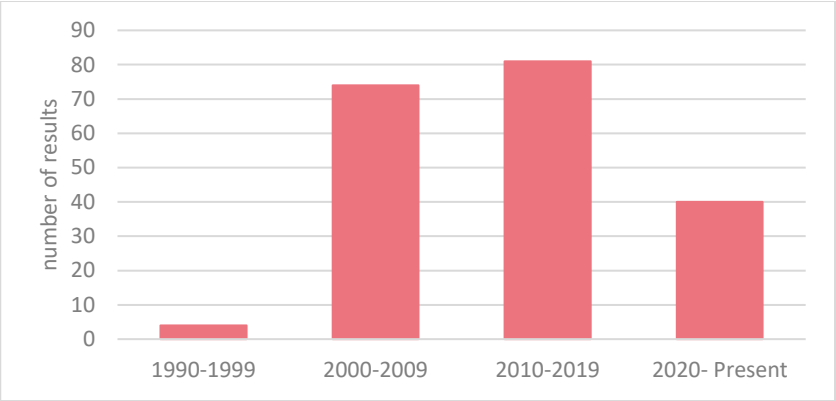
From the sample collection was possible to observe that the inquired companies were mostly founded in the last decade's 2010-2019 (31.66%), 2000-2009 (27.14%), 1990-1999 (13.07%), 1980-1989 (9.55%) and 2020-Present (4.02%) (Graphic 4.2). This shows a sample with a tendency to more recent certifications. It should be taken into consideration that the pressing market competition and legal constraints to be in the market may contribute to this phenomenon.



Graphic 4.2 - Business startup year

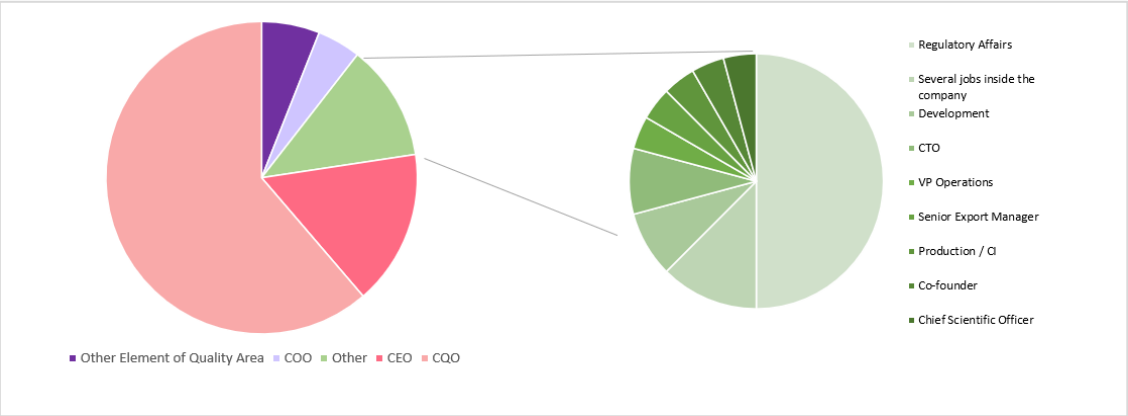
Regarding the year of ISO 13485 certification, most inquired companies refer that they got their certification between 2010-2019 (40.70%) and 2000-2009 (37.19%). Besides analyzing just 2 years, the present decade (2020-Present) has already higher values (20.10%) of ISO

certification inquired than 1990-1999 (2.01%), showing an increased tendency in certification (Graphic 4.3).



Graphic 4.3 - Year of ISO 13485 Certification

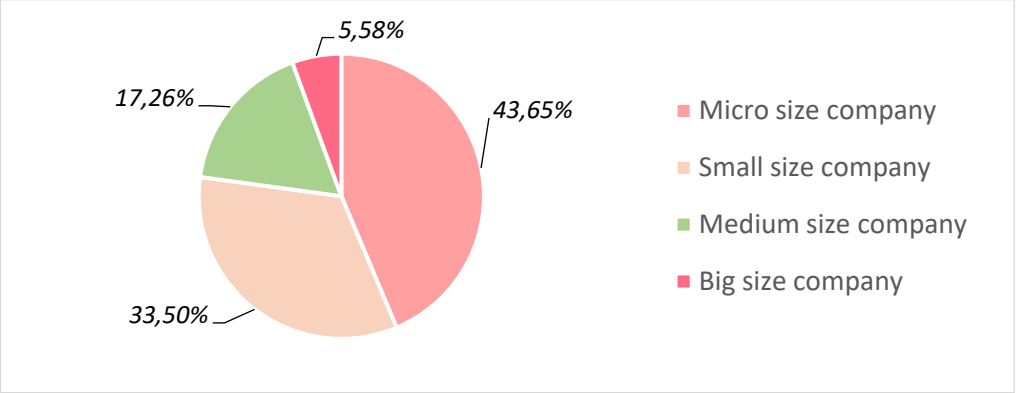
When asked about their role in the company, 61.31% respondents answered that they are CQO, 16.08% CEO, 12.06% had other roles that were not listed, 6.03% worked in quality area but were not CQO and 4.52% were COO. The respondents who wrote that they worked in other areas, the most common were regulatory affairs, several jobs inside the company and development area (Graphic 4.4).



Graphic 4.4 - Role at the company

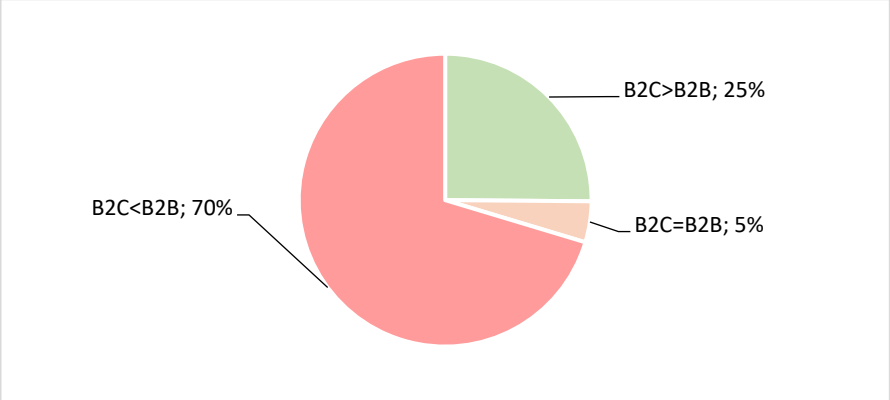
Approximately 22.61% of the firms in the sample have 10 or fewer employees, 44.72% of the firms employed between 10 and 49 workers, 23.62% of the firms had 50 to 249 employees, and 9.05% of the firms had more than 250 employees. Regarding companies' annual sales volume, about 39.70% of the firms reported annual sales of 2 million euros or less, and

29.15% of the firms had annual sales between 2 million and 10 million euros. The firms that had annual sales between 10 million and 50 million euros comprised about 21.11% of the final sample, and approximately 8.54% of the firms had annual sales of more than 50 million euros. This information shows that predominantly the inquired companies have a micro dimension (43.65%), followed by small sized companies (33.50%), medium (17.26%) and big companies (5.58%) (Graphic 4.5). This variable was categorized according to the classification on the COMPETE website (2013).



Graphic 4.5 - Company Size

When asked about what the main costumers of their business were, 70% of the respondents answer that they sell more to other Business than to the Final consumer, 25% answered that they sell more to the final consumer and just 5% say that they sell the same to both groups (Graphic 4.6).



Graphic 4.6 – Inquired Main Costumers

4.2 Approach to Research Question (RQ1)

In order to analyze research question 1. the benefits and short comes attributed in the literature to the certification of a quality management system of medical devices with ISO 13485:2016 four (4) sub questions were made.

SQ1 - What was the relevance of each of the factors described in literature in a company's decision to implement standard ISO 13485:2016?

Table 4.1 presents the median, mean and standard deviation of the classification obtained in relation to the impacts for each factor described in the literature review. Graphic 4.7 shows an illustrative comprehension of the sum obtained for such motives in relation with the best possible sum. The scale used was a Likert like scale of 7 points.

Table 4.1 – Identified relevance of the factors in company's decision to implement standard ISO 13485:2016

		Sum all values	Best possible Sum	Median	Average	Standard Deviation	Total Answers
Internal	Decision from company's CEO or Head Office	1081	1393	6	5.43	1.76	199
	Improvement of quality of products and/or services	1065	1393	6	5.35	1.66	199
	Improvement of processes and procedures	1041	1393	6	5.23	1.63	199
	Reduction in incidents, rejections, and complaints	916	1393	5	4.60	1.89	199
	Basis for reducing internal costs	688	1393	4	3.46	1.83	199
	Improvement of communication in the organization	805	1393	4	4.05	1.85	199
	Improvement of management–employee relations	730	1393	4	3.67	1.86	199
External	Used as a promotional and/or marketing tool	944	1393	5	4.74	1.77	199
	Maintaining and/or increasing the market share	1014	1393	6	5.10	1.78	199
	Demand and/or pressure of customers	950	1393	5	4.77	2.06	199
	Source of competitive advantage	996	1393	5	5.01	1.86	199
	Condition to compete in the sector	1176	1393	6	5.91	1.44	199
	Direct way to a new market	971	1393	5	4.88	1.94	199
	To set a good example for suppliers	812	1393	4	4.08	2.03	199
	Improvement of corporate image of the organization	989	1393	5	4.97	1.79	199
	At the request of the Government /Legal authority	1085	1393	7	5.45	2.08	199

Graphic 4.7 – Identified relevance of the factors in company's decision to implement standard ISO 13485:2016

The results show that there is a general positive average in the factors presented, that is, the average impacts felt by worldwide inquired 13485:2016 companies are positive, although the expression of these motives is relatively variable.

Despite *Request of the "Government /Legal authority"* achieved the highest median and mean, the standard deviation of answers is 2.08 meaning the answers are very discrepant. "*Condition to compete in the sector"* is the strongest motive, at the same time that it is the one with the least variability among the companies in the sample. This result is a bit surprising since Zgirskas et al. (2021) and other sources described in Table 2.2 found that *"Demand and/or pressure of customers"* was the most common motive found in the literature and in this research, it only had a mean of 4.77 being one of the least recognized motives by the inquired. Since the standard deviation was 2.06 it means that the agreement of the respondents is quite uneven, that is, while for some respondents it is a relevant reason, for others it is not.

According with Martínez-Costa et al. (2008), external motivation is present when companies motive to implement ISO are linked to the external perception of the firm and internal motivation is visible when companies want to have an impact inside their business.

When analyzing the results, "*Request of the government/ legal authorities" (*External), "*Decision from company's CEO or Head Office"* (Internal), "*Improvement of quality of products and /or services"* (Internal) and "*Improvement of processes and procedures"* (Internal) are the main motives presented. On the other end, "*Basis for reducing internal costs"* (Internal), "*Improvement of management-employee relations"* (Internal), "*Improvement of communication in the organization"* (Internal), "*Set a good example for suppliers"* (External) and "*Reduction in incidents, rejections and complaints"* (Internal) are the least rated motives.

Internal motives were mainly the ones who developed more positive or negative influence between the factors presented. Corroborating with Martins da Fonseca et al. (2017), internal motivations can foster organizational and process improvements which may contribute to better "*Quality of products and /or procedures"*. However, disagreeing with Martins da Fonseca et al. (2017) study, customer satisfaction *(used as "Reduction of complaints")* and *"Reducing of internal costs"*, are not found in this research as the main internal motives. External motivation factors described by Martins da Fonseca et al. (2017), are also do not corroborate by the findings in this study. According with the authors, the main motives were related with satisfy customer requirements, *("Demand and/or pressure of costumers"*) or enhance the organization image (used as "*Promotional and/or marketing tool"*).

Martínez-Costa et al. (2008) defend that companies applying ISO that consider just external motivation achieve fewer benefits from certification than those companies that were convinced of ISO possibilities to improve management practices and, consequently, performance. Therefore, it was interesting to understand from this study that an external factor such as: "*Condition to compete in the sector",* was the most recognized motive for implementation and the least recognized motive was internal: "*Basis for reducing internal costs"*. This finding's lead to the question: Are companies truly experiencing the advantages from ISO certification?

SQ 2 - What were the advantages that companies experienced from implementing the ISO 13485:2016?

Table 4.2 presents the median, mean and standard deviation of the classification obtained in relation to the advantages from implementing ISO 13485:2016 described in the literature review. Graphic 4.8 shows an illustrative comprehension of the sum obtained for such advantages in relation with the best possible sum.

Table 4.2 - Identified impacts of implementing ISO 13485:2016 certification

		Sum all values	Best possible Sum	Median	Average	Standard Deviation	Total
Internal	Quality/safety of MD	1123	1393	6	5.64	1.11	199
	Performance of MD	1034	1393	5	5.20	1.35	199
	Number of incidents, rejections, and complaints	980	1393	5	4.92	1.34	199
	Productivity and/or efficiency	925	1393	5	4.65	1.33	199
	Internal costs	746	1393	4	3.75	1.55	199
	Profitability	820	1393	4	4.12	1.51	199
	Employee motivation and retention	814	1393	4	4.09	1.38	199
	Employees understanding of quality	1016	1393	5	5.11	1.29	199
	Clarification of processes and procedures	1107	1393	6	5.56	1.19	199
	Paperwork	749	1393	4	3.76	1.85	199
	Working environment	888	1393	4	4.46	1.29	199
External	Customer service	1001	1393	5	5.03	1.18	199
	Customer satisfaction	1036	1393	5	5.21	1.23	199
	Expansion into international markets	1100	1393	6	5.53	1.37	199
	Competitive advantage	1044	1393	5	5.25	1.39	199
	ISO 13485:2016 as a promotional and/or marketing tool	1008	1393	5	5.07	1.46	199
	Quality of suppliers	960	1393	5	4.82	1.28	199
	Mutual cooperation with suppliers	935	1393	5	4.70	1.37	199
	Corporate image at the market	1028	1393	5	5.17	1.31	199

Graphic 4.8 - Identified impacts of implementing ISO 13485:2016 certification

When asked to identify the impact of implementing ISO 13485:2016. "*Quality/safety of MD"* was the most valued benefit with a total sum of 1123, average impact of 5.64 and standard deviation of 1.11 followed by *"Clarification of processes and procedures"* and "*Expansion into international markets*". Contrarily, the least identified benefits were the reduction of internal

cost reduction of "*Paperwork*", *"Employee motivation and retention"* and "*Profitability*". Despite some least beneficial factors, all factors presented a positive mean. Mostly of these results were not surprising, since they are aligned with the findings in the revision of literature (Table 2.3), just "*Profitability*" was described in the revision of literature as one of the most observed benefits however in this research is one of the least valued benefits by the respondents.

These results are aligned with Lundmark & Westelius (2006)'s study. The authors also found that one of the most common benefits regarding ISO certification were transparency regarding responsibilities and obligations and transparency regarding work procedures *("Clarification of processes and procedures"*). Following the referred authors research, quality awareness comes in second from the seventeen benefits studied while in present study employees understand of quality is in the middle of the table*. "Qualiy and safety of MD"* is the benefit with the highest average in this study,but is in ninth place of Lundmark & Westelius (2006)'s study.

According with Tarí et al. (2012), in general terms, the benefits of ISO certification may be classified into internal and external ones. The authors posit that the three main benefits found in the literature are improved Efficiency *("Productivity and/or efficiency"),* "*Improved customer satisfaction*" and improvements in relations with employees *("Employee motivation and retention" / "Work environment").* According to the finding of the present study, these were not the least nor the most desired benefits. Showing only a slight positive impact in respondents perspectives it can be found: *Productivity and/or efficiency* (925 sum of all values - 4.65 average impact); *Employee motivation and retention* (814 sum of all values - 4.09 average impact); *Work environment* (888 sum of all values – 4.46 average), which is contrary Tarí et al. (2012)'s findings. Just customer satisfaction was in accordance with the authors top three research on the benefits with a total sum of 1036 and 5.21 average score advantage. Nonetheless, it is not on the top identified advantages by the author, Product Quality was also one benefit stated.

According to Fonseca et al. (2017) and Pacana & Ulewicz (2020), factors like time or company dimension may decrease or enhance companies benefits. Accordingly, two research hypotheses were formulated.

H_1= Companies certified for more years have more expressive benefits

Within the scope of this research was the assessment of how the benefits promoted by ISO 13485:2016 certification were perceived by companies that were certified in different time periods. The data collected about how old companies have been certified it was used to produce a variable with 3 categories: companies certified between 1997-2008; companies certified between 2009-2017 and companies certified between 2018-2022. To test these hypotheses, the normality of the distribution and the homogeneity of variances were investigated to confirm the assumptions of the conditions for performing the One-Way ANOVA test (Marôco, 2018).

Analyzing the results from the normality of distribution (Kolgomorov-Smirnov test) (Annex C and D), it can be concluded that in all cases the null hypothesis was rejected, meaning that it cannot be concluded the normality of the distribution. As for the homogeneity of variances (Levene test), since the p-value was superior to the significance level (p=0.05), it cannot be reject the null hypothesis and can, therefore, assume that the groups have equal variances (Annex E). Since normal distribution of data was not verified, a non-parametric test was used: Kruskal Wallis (Table 4.3), for the analyses of the significant results presented it was used the pos-hoc test Tukey's Honest Significant Difference (HSD)(Annex F and G) (Marôco, 2018).

Table 4.3 - Kruskal Wallis test for H1

	Benefits	***P-Value***
1	Quality/safety of MD	*0.032685
2	Performance of MD	0.112249
3	Number of incidents, rejections, and complaints	0.976186
4	Productivity and/or efficiency	0.660976
5	Internal costs	0.299893
6	Profitability	*0.031231
7	Employee motivation and retention	0.660327
8	Employees understanding of quality	0.405135
9	Clarification of processes and procedures	0.295427
10	Paperwork	0.240332
11	Working environment	0.432522
12	Customer service	0.734068
13	Customer satisfaction	0.905410
14	Expansion into international markets	0.900865
15	Competitive advantage	0.157483
16	ISO 13485:2016 as a promotional and/or marketing tool	*0.005312
17	Quality of suppliers	0.439522
18	Mutual cooperation with suppliers	0.248529
19	Corporate image at the market	0.051583

Analyzing the results in Table 4.3 is possible to conclude that the probability related with the Kruskal Wallis test value in benefits: *"Quality/safety of MD", "Profitability", "ISO 13485:2016 as a promotional and/or marketing tool",* is lower than the default significance level (0.05), taking into account a confidence level of 95% we reject the null hypothesis in such cases and conclude that there is a statistical significance.

In order to assess the significance of differences of each benefit within the group of years it was used the post hoc test: Tukey (Annex F and G). Analyzing Tukey's results is possible to observe that the mean difference between the companies certified for more years (1997-2008) and the companies certified at least time (2018-2022) has achieve higher results in all stated benefits. Between the three benefits, *"ISO 13485:2016 as a proportional and /or marketing tool"* is the benefit that achieved higher values, followed by *"Profitability"* and last *"Quality /safety of MD".*

Following Fonseca et al. (2017) research, time is an important variable to be considered, as some benefits can be achieved on the short term while others only on the long term.

According with Wolniak (2016), frequently, certified companies lack awareness about how much effort it would take to implement the standard in the business and submit it for certification. In the authors perspective, this awareness comes over time when the benefits start emerging.

Taking into account Tuckey's results and arguments presented, H_1 is partially confirmed, it could be concluded that companies certified at more time (since 1997 until 2008) have more expressive benefits from companies certified at less time (since 2018 until 2022) (Annex F and G) regarding the benefits: *"ISO 13485:2016 as a proportional and /or marketing tool", "Profitability"* and *"Quality /safety of MD".* These conclusions are in line with the results obtained by Margaça (2013), which state that the certificate's age can influence the expression of the benefits felt.

H_2= Larger companies see more expressive benefits

The focus of this hypothesis was to investigate how the benefits promoted by ISO 13485:2016 certification was perceived by the companies with different dimensions. Companies were divided in 4 groups: micro-sized, small-sized, medium-size and big-size companies. To test this hypothesis, the normality of the distribution (Annex H and I) and the homogeneity of variances (Annex J) were investigated, to confirm the assumptions for the conditions for

performing the One-Way ANOVA test (Marôco, 2018). Since the normal distribution of the data was not verified, a non-parametric test was used: Kruskal Wallis (Table 4.4).

Table 4.4 - Kruskal Wallis Test for H2

	Benefits	***P-value***
1	Quality/safety of MD	0.99949
2	Performance of MD	0.73384
3	Number of incidents, rejections, and complaints	0.84655
4	Productivity and/or efficiency	0.96757
5	Internal costs	0.45951
6	Profitability	0.51370
7	Employee motivation and retention	0.57749
8	Employees understanding of quality	0.47354
9	Clarification of processes and procedures	0.99935
10	Paperwork	0.25656
11	Working environment	0.86547
12	Customer service	0.61046
13	Customer satisfaction	0.43245
14	Expansion into international markets	0.37604
15	Competitive advantage	0.25780
16	ISO 13485:2016 as a promotional and/or marketing tool	0.26728
17	Quality of suppliers	0.90398
18	Mutual cooperation with suppliers	0.98808
19	Corporate image at the market	0.48871

Analyzing the results in Table 4.4 is possible to conclude that there was no rejection of the null hypotheses taking into account a significance level (0.05), and a confidence level of 95%. It can be concluded that Kruskal Wallis results did not show statistically significant differences between the company groups, regarding the benefits.

According to Chiarini (2019), when making research it is important to have into account the company dimension since the size of the company can bias the individual factors for a successful ISO implementation, such as employee and management contribution as well as economic investments; these factors could differ from micro companies to larger companies.

Following Fonseca et al. (2017), studies, financial performance is more focused on firm's short term financial outcomes, while some quality aspects are more long-term oriented leading

to non-financial indicators such as (customer satisfaction, corporate image, reputation, employees' motivation and retention at the company, quality of products and services).

Lo & Chang (2007) defend that company size may have an outcome on the benefits obtained from certification. According with their research, a larger certified organization may have greater success with ISO certification since they have higher level of resources available to pursue the implementation process. In the other hand most of small sized companies get certification just for external motives (customer pressure) and not from their desire to improve.

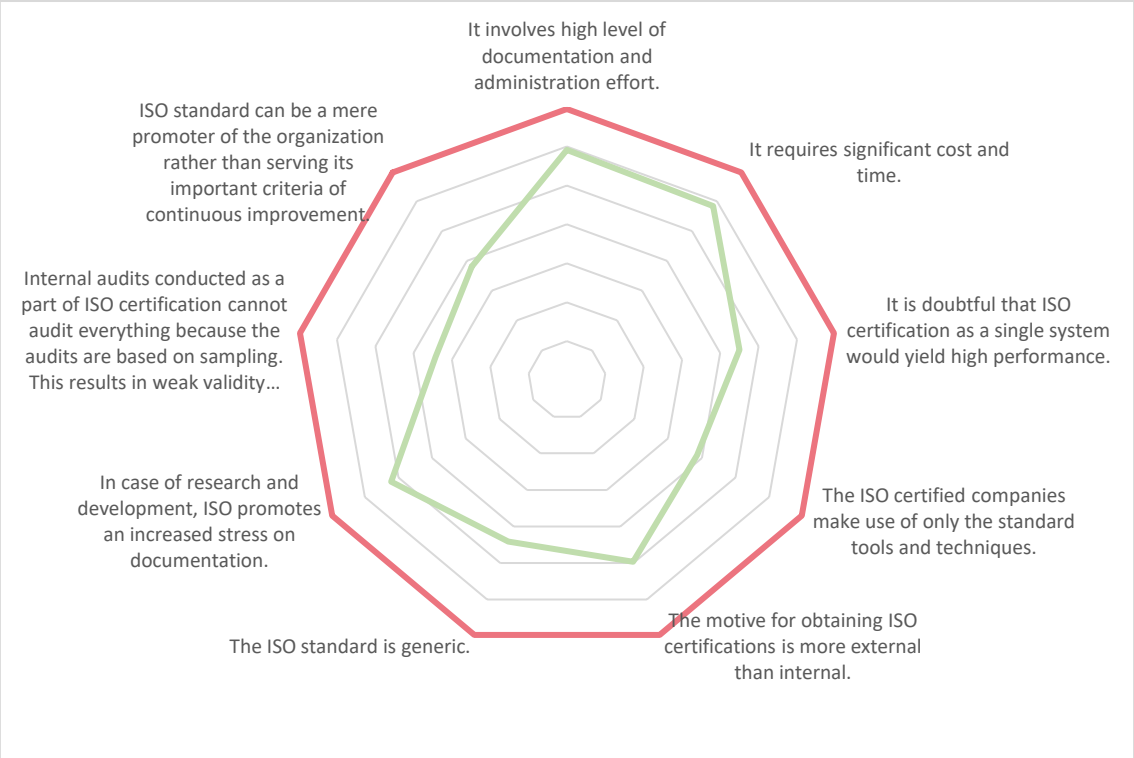
However, in this research, for the companies in the sample, taking into account the results obtained and the arguments presented, H_2 cannot be confirmed, meaning that it could not be concluded that larger companies see more expressive benefits than small companies.

SQ 3- What were the disadvantages that companies experienced from implementing the ISO 13485:2016?

Table 4.5 presents the median, mean and standard deviation of the classification obtained in relation to the disadvantages for each factor described in the literature review. Graphic 4.9 shows an illustrative comprehension of the sum obtained for such disadvantages in relation with the best possible sum.

Table 4.5 - Identified level of agreement regarding ISO 13485:2016 certification

	Sum all values	Best possible Sum	Median	Average	Standard Deviation	Total
It involves high level of documentation and administration effort.	1183	1393	6	5.94	1.19	199
It requires significant cost and time.	1168	1393	6	5.87	1.20	199
It is doubtful that ISO certification as a single system would yield high performance.	900	1393	5	4.52	1.68	199
The ISO certified companies make use of only the standard tools and techniques.	772	1393	4	3.88	1.40	199
The motive for obtaining ISO certifications is more external than internal.	993	1393	5	4.99	1.72	199
The ISO standard is generic.	882	1393	4	4.43	1.53	199
In case of research and development, ISO promotes an increased stress on documentation.	1043	1393	6	5.24	1.52	199
Internal audits conducted as a part of ISO certification cannot audit everything because the	686	1393	4	3.45	1.75	199
ISO standard can be a mere promoter of the organization rather than serving its important	762	1393	4	3.83	1.64	199



Graphic 4.9 - Identified level of agreement regarding ISO 13485:2016 certification

When asked to analyze the level of agreement with some identified statements regarding ISO 13485:2016 certification disadvantages, most inquired agree that *"It involves high level of documentation and administration effort"* and *"It requires significant cost and time"*. When asked to classify from 1 (completely disagree) to 7 (completely agree). The average of agreement was 5.94 and 5.87 with a standard deviation of 1.19 and 1.20 respectively, meaning that the inquired agree with these statements. These results are in harmony with the revision of literature (Table 2.4), the more stated by the authors are also the more agreed by the interviewed and the least stated are also the least agreed.

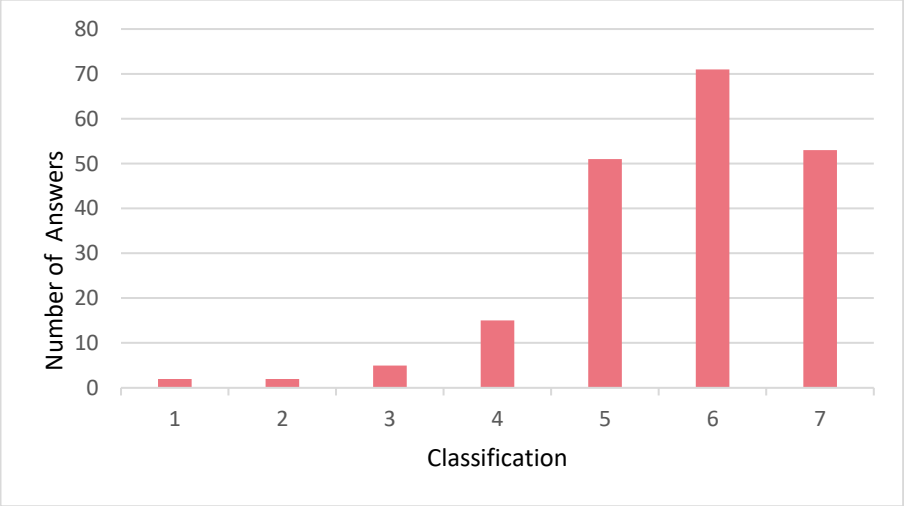
Kasperavičiūtė-Černiauskienė & Serafinas (2018) state that the implementation of the standard can take more than a year and is considered to be time-consuming, resulting in an overload of work and expenses.

Kammoun & Aouni (2013) found the same results, the process is too expensive and time consuming, companies should ensure that they plan implementation by having adequate human and material resources since it requires an enormous effort in documentation

In accordance with this study, Slack et al. (2016) defends that even now, ISO certification is not seen as beneficial by all authorities and is still subject to some specific criticisms. These includes the continued use of standards and procedures encouraging over-systematized decision making, also, in accordance with this study and authors findings, the whole process involved with ISO certification is considered to be expensive and time consuming.

Stated as the least agreeable fact *"Internal audits conducted as a part of ISO certification cannot audit everything because the audits are based on sampling. This results in weak validity of the audit findings"* being the only factor that had an average of agreement below the average and the highest standard deviation meaning that inquired do not agree with this statement besides. Also, in the revision of literature made it was difficult to find many authors agreeing with this statement. Corbett et al. (2005) and Karthi et al. (2012) were the only authors found that agree with this ISO disadvantage.

SQ4 - What is the overall perceived value for the companies for investing in ISO 13485:2016 certification?



Graphic 4.10 – Distribution of the perceived value for the companies with ISO13485:2016 certification, per point of scale

Graphic 4.10 shows the overall perceives value of certification for respondent companies (companies that have ISO 13485:2016 certification). To assess the perceived value with the standard, respondents were asked to rate on a seven-point scale 1 (very low value) to 7 (very high value). The overall perceived value for this ISO certification is positive. The average answer was 5.7 with a standard deviation of 1.17.

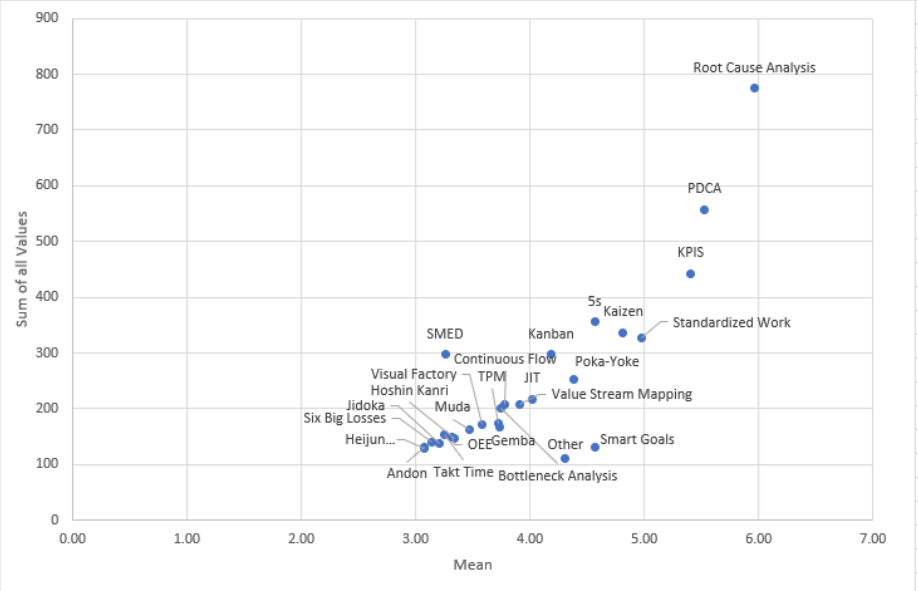
Despite in this research it is being inquired the perceived value, when comparing with Lundmark & Westelius (2006) research about ISO 9001 level of satisfaction, is possible to observe likewise positive results in their findings.

4.3 Approach to Research Question (RQ2)

In order to analyze Research Question 2, if the use of a lean approach or lean tools in ISO 13485 certified companies enhance the certification of the quality management system of medical devices, two (2) sub questions were made.

SQ 1 -What is the influence of the use of each lean tool during the certification process for ISO 13485:2016?

When asked to identify which lean tools facilitate more during the certification process, *"Root Cause Analysis"* was the tool that achieved a highest response rate (130 total answers) with a response rate of 65.33%, an average score of 5.96, standard deviation of 1.07 and total sum of values of 775. *"PDCA"* and *"KPIS"* were next, with respectively a response rate of 50.75% and 41.21%, combined with an average of 5.52 and 5.40 in a Likert-like scale of influence in facilitation (Graphic 4.11 and Table 4.6).



Graphic 4.11 – Influence of the use of Lean Tools in ISO13485:2016 companies

Table 4.6 – Influence of the use of Lean Tools in ISO13485:2016 companies

	№ Answers	Mean	Standard Deviation	Sum of all Values
5s	78	4.56	1.71	356
Andon	43	3.07	1.62	132
Bottleneck Analysis	54	3.74	1.84	202
Continuous Flow	55	3.78	1.87	208
Gemba	45	3.73	2.07	168
Heijunka	42	3.07	1.76	129
Hoshin Kanri	44	3.34	1.94	147
Jidoka	43	3.21	1.83	138
JIT	54	4.02	1.99	217
Kaizen	70	4.81	1.76	337
Kanban	71	4.18	1.82	297
KPIS	82	5.40	1.70	443
Muda	47	3.47	1.91	163
OEE	45	3.31	1.99	149
PDCA	101	5.52	1.58	558
Poka-Yoke	58	4.38	1.84	254
Root Cause Analysis	130	5.96	1.07	775
Six Big Losses	42	3.14	1.79	140
Smart Goals	65	4.57	1.91	132
SMED	43	3.26	1.90	297
Standardized Work	66	4.97	2.02	328
Takt Time	47	3.26	1.84	153
TPM	47	3.72	2.00	175
Value Stream Mapping	53	3.91	1.94	207
Visual Factory	48	3.58	1.99	172
Other	26	4.31	2.26	112

"Standardized Work", "Kaizen", "Smart Goals", "5s", "Poka-Yoke", "Other", "Kanban", "JIT", "Value Stream Mapping", "Continuous Flow", "Bottleneck Analysis", "Gemba", "TPM" and *"Visual Factory"* followed such positive tendency, achieving a positive mean.

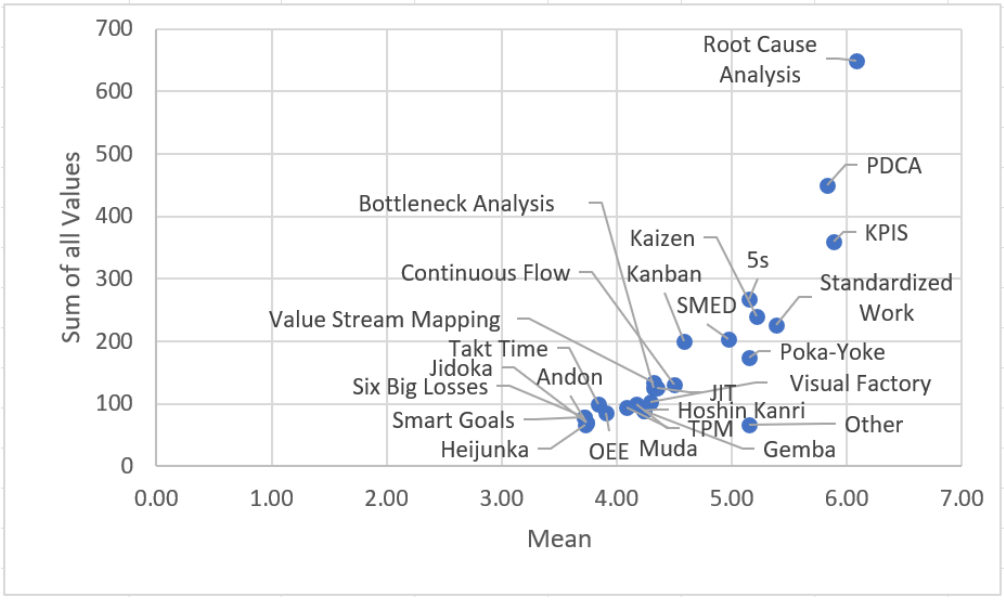
"Andon" was described as the tool that least facilitated ISO 13485 certification with a mean of 3.07, standard deviation of 1.62 and a total sum of 132 values. *"Heijunka", "Six Big Losses", "Andon", "Jidoka", "SMED", "Hoshin Kanri", "OEE"* and *"Gemba"* were labeled as the least used and with a low average.

Besides having the lowest total sum of values, due to the low number of answers, the category "others" achieved a high mean. The tools in the context of lean more applied by the inquired were: Qualio, Process Management, Failure Mode and Effect Analysis (FMEA), Eight disciplines problem solving (8D), Ishikawa diagram, 5Ws, JIRA, Atlassian suite, Agile Sprint, GAP analysis, Agile Scrum and Taguchi.

When analyzing the influence of each lean tool by country, European answerers reported that the tools that most impacted ISO 13485 certification were *"Root cause Analysis"* (mean of 5.95 and standard deviation of 1.11) followed by *"PDCA"* (mean of 5.53 and standard deviation of 1.52) and *"KPIS"* (mean of 5.39 and standard deviation of 1.68). In America the tools that achieved the highest means were *"Root cause Analysis"* (mean of 6 and standard deviation of 1), *"PDCA"* (mean of 5.75 and standard deviation of 1.28) and *"KPIS"* (mean of 5.5 and standard deviation of 1.05), while Asian responders reported that *"Root cause analysis"* (mean of 6 and standard deviation of 0.76), *"Standardizes work"* (mean of 5 and standard deviation of 2.55) and *"PDCA"* (mean of 4.89 and standard deviation of 2.26), were the tools with most influenced certification.

SQ 2 - What is the impact of the use of lean tools on the advantages the companies experienced with getting ISO 13485:2016 certification?

From the tools that were reported previously as the ones applied inside the company, the respondents were asked to classify their impact inside their organizations. Like in the previous question, when asked to classify about their influence, the answers that achieved a highest mean were again: *"Root Cause Analysis", "KPIS"* and *"PDCA"*. With a respective mean and standard deviation of: *"Root Cause Analysis"* 6.08 (mean) 0.96 (Std. Deviation); *"KPIS"* 5.89 (mean) 1.29 (Std. Deviation); *"PDCA"* 5.83 (mean) 1.23 (Std. Deviation) (Graphic 4.12 and Table 4.7).



Graphic 4.12 – Influence of the use of Lean Tools in ISO13485:2016 companies

Table 4.7 – Influence of the use of Lean Tools in ISO13485:2016 companies

	Nº Answers	Mean	Standard Deviation	Sum of all Values
5s	52	5.15	1.27	268
Andon	53	3.74	1.85	71
Bottleneck Analysis	53	4.32	1.63	125
Continuous Flow	53	4.50	1.60	130
Gemba	53	4.24	2.12	89
Heijunka	53	3.72	1.99	67
Hoshin Kanri	52	4.24	1.87	89
Jidoka	52	3.74	2.05	71
JIT	52	4.34	1.67	126
Kaizen	52	5.22	1.62	240
Kanban	52	4.58	1.47	201
KPIS	52	5.89	1.29	359
Muda	51	4.09	2.02	94
OEE	51	3.91	2.11	86
PDCA	51	5.83	1.23	449
Poka-Yoke	51	5.15	1.79	174
Root Cause Analysis	50	6.08	0.96	650
Six Big Losses	49	3.71	2.03	78
Smart Goals	49	3.71	1.79	78
SMED	49	4.98	1.69	204
Standardized Work	48	5.38	1.72	226
Takt Time	48	3.84	1.97	100
TPM	47	4.17	1.90	100
Value Stream Mapping	47	4.32	1.83	134
Visual Factory	47	4.29	1.78	103
Other	46	5.15	2.12	67

All listed tools achieve a mean above the average regarding its impact. *"SMED"* was the tool that achieved the highest increase compared with previous question, with a mean of 4.98 and standard deviation of 1.69.

When analyzing the impact of each tool by country, European answerers reported that the tools that most impacted ISO 13485 certification by order were *"Root cause Analysis"* (mean of 6.10 and standard deviation of 0.97) followed by *"KPIS"* (mean of 6.02 and standard deviation of 1.11) and *"PDCA"* (mean of 5.89 and standard deviation of 1.17). In America the tools that achieved the highest means were *"Root cause Analysis"* (mean of 6.14 and standard deviation of 0.89), *"Kaizen"* (mean of 5.75 and standard deviation of 0.96) and *"PDCA"* (mean of 5.67and standard deviation of 1.97), while Asian responders reported that *"5S"* (mean of 5.67 and standard deviation of 0.82), *"Root cause analysis"* (mean of 5.57 and standard deviation of 0.98),

"Kanban" (mean of 5.50 and standard deviation of 2.12) and *"Standardizes work"* (mean of 5.50 and standard deviation of 3) were the tools with most impact in certification. When comparing the findings of the impacts and influence of Lean Tools and ISO 13485 it can be considered that the results were quite similar in both questions in each continent, the most influencing tools, were in majority also the most impacting tools.

Chapter 5: Conclusion

Aiming at the proposed objective, this chapter presents the conclusions of the study by answering the research questions defined in Chapter 1. Next, the limitations of the presented results are described and, finally, guidelines for future investigations related to the present study.

5.1 Research Questions Analysis

This sub-section is intended to summarize the findings related with the motives, benefits and disadvantages described by ISO 13485:2016 certified companies and the influence and impact of lean tools in such certified companies.

For this purpose, a questionnaire was designed to obtain data that would allow answering the defined research questions and the associated propositions and hypotheses. This questionnaire was sent to 8899 manufacturing and service firms of MD worldwide from EUDAMED database 199 valid responses were obtained.

The first research question (RQ1) on this investigation focused on the benefits and short comes associated with ISO 13485 certification and relation to what is reported in the literature. For research purposes, sub questions and hypotheses were defined. Their discussion and testing are summarized below.

The sub-question SQ1 stated the relevance of each factor that motivated for ISO 13485 certification felt among 32 different countries. From the 16 motives founded in literature and comparing with the results obtained, the results found in this research, are not fully aligned with results demonstrated by scientific evidence since: *"Condition to compete in the sector"; "At the request of the government /legal authorities"; "Decision from company's CEO or Head Office"; "Improvement of quality of products and/or services"* and *"Improvement of processes and procedures"* were the top five most common answers from company's representatives inquired. Whereas in literature review were found: *"Demand and/or pressure of customers"; "Maintaining and/or increasing the market share"; "Used as a basis for reducing internal costs"; "Improvement of processes and procedures"; "Improvement of quality of products and/or services"; "Competitive advantage"* and *"Improvement of public image of the organization"* were the most representative findings. Just "*Improvement of processes and procedures"* and *"Improvement of quality of products and/or services"* were both found in the literature review

and in findings of this research as the main motives. However, the results obtained confirmed that, on average, the recognition felt by certified companies was positive by the respondents. A positive average was felt by all categories, excluding "*Basis for reduction internal costs"*. As so, in this context, we can conclude that partially, SQ1 results were positive.

Regarding ISO benefits, SQ2 was formulated. According with this research 19 benefits were acknowledged by 41 different authors achieving the conclusion that the most reported benefits were *"Profitability"* and *"Productivity and/or efficiency*", both internal benefits. Followed by *"Clarification of processes and procedures", "Customer satisfaction", "Expansion into international markets"* and *"Quality/safety of MD".* Some of these benefits were also the most reported by ISO 13485 users: *"Clarification of processes and procedures", "Expansion into international markets"; "Quality/safety of MD".* In the other hand, *"Paperwork", "Increased quality of suppliers" and "Reduction on the number of incidents, rejections, and complaints"* were the least reported benefits. According with this research, *"Paperwork"* was also reported as one of the least impacted benefits among with *"Internal costs", "Employee motivation and retention"* and *"Profitability"*. The impact of this last benefit is controverse since it can be found on the top mentioned benefits in the literature and at the same time is considered by its respondents in this research as one of the benefits that least impact ISO 13485 certification. Despite some not very strong scores as beneficial factors, all factors presented a positive mean regarding SQ2.

According with Wolniak (2016) and Lo & Chang (2007), factors like time or company dimension may decrease or enhance companies benefits, taken that into account two research hypotheses were formulated. After analysis it could be concluded that companies certified for more years (since 1997 until 2008) have more expressive benefits from companies certified at less time (since 2018 until 2022), regarding the benefits: *"ISO 13485:2016 as a proportional and /or marketing tool", "Profitability"* and *"Quality /safety of MD"* leading to partially confirmation of H_1. Regarding company size, for the companies in the sample, it could not be concluded that companies with bigger dimension have more expressive benefits, leading to rejection of H_2.

To clarify the disadvantages that companies experienced from implementing the ISO 13485:2016, SQ3 was formulated. It was concluded that the level of agreement with stated disadvantages was on average mostly positive. Analyzing the disadvantages within the literature review the two more quoted were: *"The level of documentation and administrative effort";* and *"The significant cost and time"* that it takes to get ISO certification. These results were in

harmony with the findings of this study. At the same time, the least stated disadvantages were the least agreed by ISO 13485 users.

Regarding the overall perceived value of ISO 13485:2016 implementation (SQ4), in the user's perspective, its investment is very positive. With an average answer of 5.7 in a seven-point scale.

In response to the first research question (RQ1), we can say that certified companies feel the benefits and short comes attributed in the literature to the certification of a Quality management system by the ISO 13485 standard. However, it could not be demonstrated a positive relation between company dimension and time of certification and its benefits.

Lastly, in order to answer the second research question (RQ 2) regarding the use of a lean approach or lean tools in ISO 13485 certified companies and its association with the certification of the quality management system of medical devices two sub research questions were formulated.

When asked about the influence of the use of each lean tool during the certification process for ISO 13485:2016 (SQ1), it was concluded that the most used tool was "*Root Cause Analysis"* followed by *"PDCA"* and *"KPIS"*. "*Andon*" was described as the tool that least facilitated ISO 13485 certification. Most tools achieved a positive mean *("Visual Factory", "TPM", "Gemba", "Bottleneck Analysis", "Continuous Flow", "Value Stream Mapping", "JIT", "Kanban", "Poka-Yoke", "5s", "Smart Goals", "Kaizen", "Standardized Work", "KPIS", "PDCA", "Root Cause Analysis*"). It can be concluded that these tools have a positive influence on the benefits of ISO 13485 certification.

Regarding ISO 13485 impact (SQ2*), "Root Cause Analysis", "KPIS"* and *"PDCA"* were the tools that stand out from interviewees perspective. It can also be concluded that all tools achieved a positive mean, meaning that their influence is considered to be positive by its users.

Answering to the second research question, the study allowed us to understand the type and frequency of use of some lean tools reported in literature.

To summarize, it is believed that the aim proposed in this research has been accomplished. The methodology allowed a validation crossing data from literature review and results obtained. This can lead to consider that the combined use of ISO 13485:2016 standard and lean tools or methodologies, enhances the benefits felt with the certification.

5.2. Limitations of the Results Obtained

Limitations found in this research were firstly regarding the number of answers. It was not very high, and was mainly focused in European companies, therefore could have been a more representative sample. Nonetheless, it is also European companies that mainly seek this certification. Secondly was aimed to achieve more responses from countries outside Europe, that were not so represented. However, these results are consistent with those found in literature.

5.3. Future Lines of Investigation

Considering the lack of published studies on ISO 13485:2016, it would be important to carry out studies considering:

- Bigger sample with more countries from different continents in order to better represent ISO users and its realities.
- Different ISO standards and its correlation with lean tools and /or methodologies.
- Performance of lean tools and /or methodologies inside ISO 13485:2016 companies - Case study Approach.

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Annex A – Lean's Tools

5S	The 5S program is one of the most suitable tools for introducing change in employees' attitudes to encourage their involvement in improvement activities in the workplace. The 5S designation comes from the first letter of five Japanese terms (Seiri, Seiton, Seiso, Seiketsu, Shitsuke), whose names can be translated as: sort, (remove everything that is not used daily); set on order (arrange the tools used daily in order to facilitate their access); shine (clean and care for the workspace); standardize (develop procedures to ensure program compliance) and sustain or maintain (motivate and commit to daily compliance with procedures). Among the organizational approaches suitable for continuous improvement processes, 5S is one of the most widespread methodologies, especially because it provides immediate results for its application and because it has a close connection with activities related to Kaizen (Gapp et al., 2008; Gonçalves, 2019).
Andon	The Andon System consists of a system of notifications triggered by the line operators to signal the presence of an anomaly and the need help to solve it. One main benefit is the empowerment of the operators while taking care of problems in the real time process (Castro, 2016).
Bottleneck Analysis	With bottleneck analysis it is identified which part of the manufacturing process limits the overall performance of the process such performance can be improved by strengthening the weakest link in the manufacturing process (Slack et al., 2016).
Continuous Flow Consists	Continuous flow consists in a technique where work in process has minimal or no barriers between the process (Slack et al., 2016).
Gemba	The philosophy behind Gemba is that is important to get out of the office and spend time were the actions actually happen, understanding the problems and restrictions around the process (Micklewright, 2010).
Heijunka	Heijunka consists in scheduling orders in a repetitive pattern in order to smooth day-to-day variations in total orders to correspond to longer-term demand (Womack & Jones, 2003).
Hoshin Kanri	Hoshin kanri is a strategic decision-making tool for a firm's executive team. This tool focuses resources on the initiatives necessary to accomplish the business objectives by unifying and align the resources and establishes clearly measurable targets. It can also be called Policy Development (Womack & Jones, 2003).
Jidoka	Jidoka consists in the automation of the process; by doing so, errors can be easily found while workers monitor multiple tasks, leading to a reduction of labor costs and improvement of quality (Slack et al., 2016).

Just-In-Time (JIT)	Just-in-time (JIT) production is based on actual demand instead of projected demand. Is very effective in reduction of inventory levels (Womack & Jones, 2003).
Kaizen	The term Kaizen is from Japan and is composed of "kai" (change) and "zen" (better) and introduces the idea of continuous improvement, based on the principle of reducing or eliminating waste as well as activities that do not add value (Kaizen Institute, 2021). This concept aims to improve productivity, reduce waste, eliminate unnecessary effort and humanize the workplace (Gonçalves, 2019).
Kanban	The term Kanban means “visual sign”. The Kanban system proposes the use of cards on a board, so that, with the least allocation of resources, it is possible to indicate and monitor the progress of production flows in a visual and practical way (Gonçalves, 2019).
KPIS	KPIS, also known as key performance indicators, are metrics that guide towards the organization’s goals. They analyze if implemented quality management system provides the added value that are expected before the QMS implementation (Zgirskas et al., 2021).
Muda	Muda means "waste". It is present in any human activity in the process that absorbs resources but creates no value in the customer’s perspective (Womack & Jones, 2003).
OEE	Overall equipment effectiveness (OEE) has the goal to measure productivity loss for a given manufacturing process (Slack et al., 2016).
PDCA	Plan, Do, Check, Act (PDCA) discipline is an efficient way of implementing improvements in processes (Abuhav, 2018).
Poka-Yoke	Poka-yoke is designed for error detection and prevention at production processes with the objective of achieving zero flaws (Womack & Jones, 2003).
Root Cause Analysis	Root cause analysis is a problem-solving practice that focuses on the resolution of the problem instead of applying quick solutions that only treat direct symptoms of the problem (Womack & Jones, 2003).
Six Big Losses	Six big losses are six categories that provide a framework for productivity loss: break- downs; setups and adjustments; reduced speed; minor stoppages; defects and rework :startup loss (Micklewright, 2010).
SMART	SMART goals are an acronym for Specific, Measurable, Achievable, Realistic, Timely. This are the key statements to pursue an objective and achieve a goal according to this theory (Islam et al., 2019).

SMED	Single Minute Exchange of Die, also known as SMED, is used in small batch production and stock reduction. This tool helps to dramatically reduce the time it takes to complete equipment changeovers. The essence of the SMED system is to convert as many changeover steps as possible to "external" (performed while the equipment is running) and to simplify and streamline the remaining steps (Slack et al., 2016).
Standardized Work	Standardized work consists on a sequence of processes. It is important to standardize in order to control inventory on hand and to achieve a consistent work. Standardized work should be a cooperative effort between the foreman and the worker (Micklewright, 2010).
Takt Time	Takt time it is the time between items developed from the process, it aligns production with the customer demand (Slack et al., 2016).
Total Productive Maintenance	Total Productive Maintenance, also known as TPM, is an industrial strategy. It is based on the idea that is necessary to ensure that every machine in a production process is always prepared to perform its required functions so that production is never disturbed, (Slack et al., 2016; Womack & Jones, 2003)
Value Stream	Value stream mapping is an activity that is typically done on an already existing process that has abundant waste. It is oftentimes the first step in trying to identify and eliminate waste in order to improve performance (Micklewright, 2010).
Visual Factory	Visual factory has the goal to provide change in an environment in demand for information exchange, revision and update. The system provides a positive thrust in business continuous improvement. Consequently, the method proposed can serve as an inter-functional tool facilitating the job of workers and top managers (Bilalis et al., 2002).

Annex B - Questionnaire

This questionnaire is under the scope of an academic study that aims to understand the impact of having ISO 13485:2016 certification on the company's operation and the influence of the use of Lean tools on that impact.

It will take about 7 minutes to answer the questionnaire.

All data collected will be used only for academic purposes. The answers are completely anonymous and will not be analyzed individually. If you have any questions regarding the questionnaire, please contact: sjgcs@iscte-iul.pt

Thank you in advance, your answer is very important for this research!

1. In what year did your company start working?
2. In which year your company got its ISO 13485 certification?
3. In which country is your company based on?
4. What is your role at the company?

- CEO
- Head of quality area (CQO)
- Other element of quality area
- Head of operations area (COO)
- Other element of operations area
- Other. Which role?

5. What was the sales volume of your company in 2021?

- 2 million euros or less
- more than 2 million euros but not more than 10 million euros
- more than 10 million euros but not more than 50 million euros
- more than 50 million euros

6. What is the number of employees at your company?

- Less than 10 employees
- 10 to 49 employees
- 50 employees to 249 employees
- 250 employees or more

7. What are the main customers of your company? B2C (Business to Customer) B2B (Business to Business) Note: Total must be 100%

	B2C	B2B	Total
Main customers	0 %	0 %	0 %

8. On a scale from 1 (not relevant) to 7 (very relevant), identify the relevance of each of the following factors in your company's decision to implement standard ISO 13485:2016.

	Not Relevant			Neutral			Very Relevant
	1.	2.	3.	4.	5.	6.	7.
At the request of the Government /Legal authority	☐	☐	☐	☐	☐	☐	☐
Improvement of corporate image of the organization	☐	☐	☐	☐	☐	☐	☐
To set a good example for suppliers	☐	☐	☐	☐	☐	☐	☐
Direct way to a new market	☐	☐	☐	☐	☐	☐	☐
Condition to compete in the sector	☐	☐	☐	☐	☐	☐	☐
Source of competitive advantage	☐	☐	☐	☐	☐	☐	☐
Demand and/or pressure of customers	☐	☐	☐	☐	☐	☐	☐
Maintaining and/or increasing the market share	☐	☐	☐	☐	☐	☐	☐
Used as a promotional and/or marketing tool	☐	☐	☐	☐	☐	☐	☐
Improvement of management–employee relations	☐	☐	☐	☐	☐	☐	☐
Improvement of communication in the organization	☐	☐	☐	☐	☐	☐	☐
Basis for reducing internal costs	☐	☐	☐	☐	☐	☐	☐
Reduction in incidents, rejections, and complaints	☐	☐	☐	☐	☐	☐	☐
Improvement of processes and procedures	☐	☐	☐	☐	☐	☐	☐
Improvement of quality of products and/or services	☐	☐	☐	☐	☐	☐	☐
Decision from company's CEO or Head Office	☐	☐	☐	☐	☐	☐	☐

9. On a scale of 1 (very negative) to 7 (very positive), identify what was the impact of implementing ISO 13485:2016 certification at your company, in each of the following factors:

	Very Negative			Neutral			Very Positive
	1.	2.	3.	4.	5.	6.	7.
Quality/safety of MD	☐	☐	☐	☐	☐	☐	☐
Performance of MD	☐	☐	☐	☐	☐	☐	☐
Number of incidents, rejections, and complaints	☐	☐	☐	☐	☐	☐	☐
Productivity and/or efficiency	☐	☐	☐	☐	☐	☐	☐
Internal costs	☐	☐	☐	☐	☐	☐	☐
Profitability	☐	☐	☐	☐	☐	☐	☐
Employee motivation and retention	☐	☐	☐	☐	☐	☐	☐
Employees understanding of quality	☐	☐	☐	☐	☐	☐	☐
Clarification of processes and procedures	☐	☐	☐	☐	☐	☐	☐
Paperwork	☐	☐	☐	☐	☐	☐	☐
Working environment	☐	☐	☐	☐	☐	☐	☐
Customer service	☐	☐	☐	☐	☐	☐	☐
Customer satisfaction	☐	☐	☐	☐	☐	☐	☐
Expansion into international markets	☐	☐	☐	☐	☐	☐	☐
Competitive advantage	☐	☐	☐	☐	☐	☐	☐
ISO 13485:2016 as a promotional and/or marketing tool	☐	☐	☐	☐	☐	☐	☐
Quality of suppliers	☐	☐	☐	☐	☐	☐	☐
Mutual cooperation with suppliers	☐	☐	☐	☐	☐	☐	☐
Corporate image at the market	☐	☐	☐	☐	☐	☐	☐

10. On a scale of 1 (completely disagree) to 7 (completely agree), identify what is your level of agreement with each of the following statements, regarding ISO 13485:2016 certification:

	Completely Disagree			Neutral			Completely Agree
	1.	2.	3.	4.	5.	6.	7.
ISO standard can be a mere promoter of the organization rather than serving its important criteria of continuous improvement.	☐	☐	☐	☐	☐	☐	☐
Internal audits conducted as a part of ISO certification cannot audit everything because the audits are based on sampling. This results in weak validity of the audit findings.	☐	☐	☐	☐	☐	☐	☐
In case of research and development, ISO promotes an increased stress on documentation.	☐	☐	☐	☐	☐	☐	☐
The ISO standard is generic.	☐	☐	☐	☐	☐	☐	☐
The motive for obtaining ISO certifications is more external than internal.	☐	☐	☐	☐	☐	☐	☐
The ISO certified companies make use of only the standard tools and techniques.	☐	☐	☐	☐	☐	☐	☐
It is doubtful that ISO certification as a single system would yield high performance.	☐	☐	☐	☐	☐	☐	☐
It requires significant cost and time.	☐	☐	☐	☐	☐	☐	☐
It involves high level of documentation and administration effort.	☐	☐	☐	☐	☐	☐	☐

11. On a scale of 1 (very low value) to 7 (very high value), Identify what was the overall perceived value for your company for investing in ISO 13485:2016 certification.

1.Very Low value			4.Neutral			7.Very High Value
☐	☐	☐	☐	☐	☐	☐

12. Consider the following list of tools. For those tools that are used at your company, identify the influence of the use of each tool during the certification process for ISO 13485:2016, on a scale of 1 (limited heavily) to 7 (facilitated highly). Note: just answer for the tools you use. If you do not use any please proceed to next question.

	Limited Certification Process Heavily			Neutral			Facilitated Certification Process highly
	1.	2.	3.	4.	5.	6.	7.
5s	☐	☐	☐	☐	☐	☐	☐
Andon	☐	☐	☐	☐	☐	☐	☐
Bottleneck Analysis	☐	☐	☐	☐	☐	☐	☐
Continuous Flow	☐	☐	☐	☐	☐	☐	☐
Gemba (The Real Place)	☐	☐	☐	☐	☐	☐	☐
Heijunka (Level Scheduling)	☐	☐	☐	☐	☐	☐	☐
Hoshin Kanri (Policy Deployment)	☐	☐	☐	☐	☐	☐	☐
Jidoka (Autonomation)	☐	☐	☐	☐	☐	☐	☐
Just-In-Time (Jit)	☐	☐	☐	☐	☐	☐	☐
Kaizen (Continuous Improvement)	☐	☐	☐	☐	☐	☐	☐
Kanban (Pull System)	☐	☐	☐	☐	☐	☐	☐
Kpis (Key Performance Indicators)	☐	☐	☐	☐	☐	☐	☐
Muda (Waste)	☐	☐	☐	☐	☐	☐	☐
Overall Equipment Effectiveness (Oee)	☐	☐	☐	☐	☐	☐	☐
Pdca (Plan, Do, Check, Act)	☐	☐	☐	☐	☐	☐	☐
Poka-Yoke (Error Proofing)	☐	☐	☐	☐	☐	☐	☐
Root Cause Analysis	☐	☐	☐	☐	☐	☐	☐
Single-Minute Exchange Of Die (Smed)	☐	☐	☐	☐	☐	☐	☐
Six Big Losses	☐	☐	☐	☐	☐	☐	☐
Smart Goals	☐	☐	☐	☐	☐	☐	☐
Standardized Work	☐	☐	☐	☐	☐	☐	☐
Takt Time	☐	☐	☐	☐	☐	☐	☐
Total Productive Maintenance (Tpm)	☐	☐	☐	☐	☐	☐	☐
Value Stream Mapping	☐	☐	☐	☐	☐	☐	☐
Visual Factory	☐	☐	☐	☐	☐	☐	☐
Other? Please specify	☐	☐	☐	☐	☐	☐	☐

13. Note: Please ignore this question if you did not select any tools in the previous question. If you had, identify their impact on the advantages your company

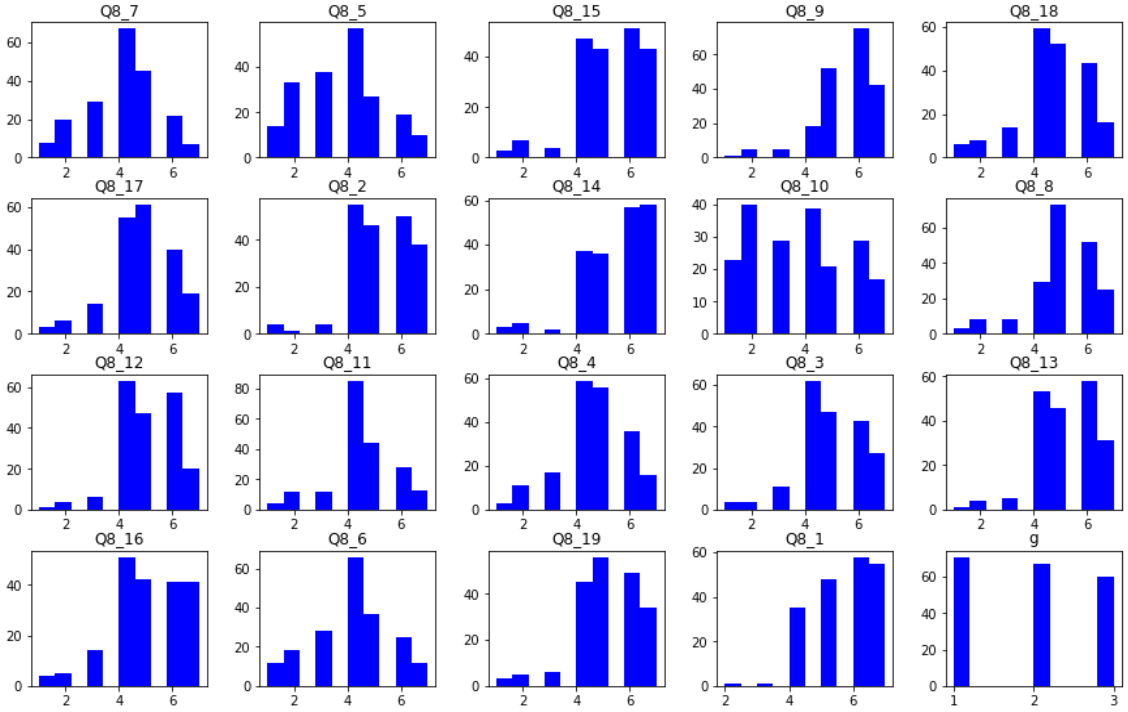
experienced with getting ISO 13485:2016 certification, on a scale of 1 (very negative impact) to 7 (very positive impact).

	Very Negative Impact			Neutral			Very Positive Impact
	1.	2.	3.	4.	5.	6.	7.
5s	☐	☐	☐	☐	☐	☐	☐
Andon	☐	☐	☐	☐	☐	☐	☐
Bottleneck Analysis	☐	☐	☐	☐	☐	☐	☐
Continuous Flow	☐	☐	☐	☐	☐	☐	☐
Gemba (The Real Place)	☐	☐	☐	☐	☐	☐	☐
Heijunka (Level Scheduling)	☐	☐	☐	☐	☐	☐	☐
Hoshin Kanri (Policy Deployment)	☐	☐	☐	☐	☐	☐	☐
Jidoka (Autonomation)	☐	☐	☐	☐	☐	☐	☐
Just-In-Time (Jit)	☐	☐	☐	☐	☐	☐	☐
Kaizen (Continuous Improvement)	☐	☐	☐	☐	☐	☐	☐
Kanban (Pull System)	☐	☐	☐	☐	☐	☐	☐
Kpis (Key Performance Indicators)	☐	☐	☐	☐	☐	☐	☐
Muda (Waste)	☐	☐	☐	☐	☐	☐	☐
Overall Equipment Effectiveness (Oee)	☐	☐	☐	☐	☐	☐	☐
Pdca (Plan, Do, Check, Act)	☐	☐	☐	☐	☐	☐	☐
Poka-Yoke (Error Proofing)	☐	☐	☐	☐	☐	☐	☐
Root Cause Analysis	☐	☐	☐	☐	☐	☐	☐
Single-Minute Exchange Of Die (Smed)	☐	☐	☐	☐	☐	☐	☐
Six Big Losses	☐	☐	☐	☐	☐	☐	☐
Smart Goals	☐	☐	☐	☐	☐	☐	☐
Standardized Work	☐	☐	☐	☐	☐	☐	☐
Takt Time	☐	☐	☐	☐	☐	☐	☐
Total Productive Maintenance (Tpm)	☐	☐	☐	☐	☐	☐	☐
Value Stream Mapping	☐	☐	☐	☐	☐	☐	☐
Visual Factory	☐	☐	☐	☐	☐	☐	☐
Other? Please specify	☐	☐	☐	☐	☐	☐	☐

Annex C - Kolmogorov-Smirnov test (H1)

Benefit	1997-2008	2009-2017	2018-2022
Quality/safety of MD	8.53E-132	1.07E-192	2.19E-270
Performance of MD	2.18E-88	1.07E-192	4.59E-107
Number of incidents, rejections, and complaints	3.09E-92	2.97E-120	1.10E-84
Productivity and/or efficiency	3.09E-92	1.66E-110	1.10E-84
Internal costs	2.98E-69	4.86E-73	2.44E-63
Profitability	1.17E-78	3.41E-68	1.03E-68
Employee motivation and retention	1.05E-84	7.51E-79	1.70E-75
Employees understanding of quality	5.09E-97	1.66E-110	1.10E-84
Clarification of processes and procedures	3.20E-102	2.97E-120	5.25E-99
Paperwork	5.70E-57	4.86E-73	1.17E-48
Working environment	3.09E-92	1.66E-110	1.70E-75
Customer service	4.83E-129	1.66E-110	4.38E-105
Customer satisfaction	4.43E-117	1.66E-110	4.38E-105
Expansion into international markets	4.43E-117	1.66E-110	8.58E-78
Competitive advantage	4.43E-117	7.89E-96	8.58E-78
ISO 13485:2016 as a promotional and/or marketing to	4.43E-117	4.05E-86	5.11E-88
Quality of suppliers	3.20E-102	2.57E-101	5.25E-99
Mutual cooperation with suppliers	3.09E-92	2.57E-101	1.70E-75
Corporate image at the market	4.43E-117	4.05E-86	4.38E-105

Annex D – Histogram Plots for all variables (H1)



Annex E – Levene's Test (H1)

Benefit	P-Value
Quality/safety of MD	0.255566974
Performance of MD	0.302325195
Number of incidents, rejections, and complaints	0.676423456
Productivity and/or efficiency	0.406188021
Internal costs	0.752213841
Profitability	0.428860988
Employee motivation and retention	0.384587019
Employees understanding of quality	0.442795098
Clarification of processes and procedures	0.473988213
Paperwork	0.309050086
Working environment	0.876197148
Customer service	0.751877472
Customer satisfaction	0.933319912
Expansion into international markets	0.941744484
Competitive advantage	0.355844368
ISO 13485:2016 as a promotional and/or marketing tool	0.523885218
Quality of suppliers	0.778850758
Mutual cooperation with suppliers	0.773774523
Corporate image at the market	0.60582652

Annex F – Tukey's Test (H1)

H1_1

Multiple Comparison of Means - Tukey HSD, FWER=0.05

group1	group2	meandiff	p-adj	lower	upper	reject
T_1997_2008	T_2009_2017	0.2922	0.264	-0.1492	0.7336	False
T_1997_2008	T_2018_Present	0.5056	0.025	0.0512	0.9601	True
T_2009_2017	T_2018_Present	0.2134	0.5187	-0.2472	0.674	False

H1_6

Multiple Comparison of Means - Tukey HSD, FWER=0.05

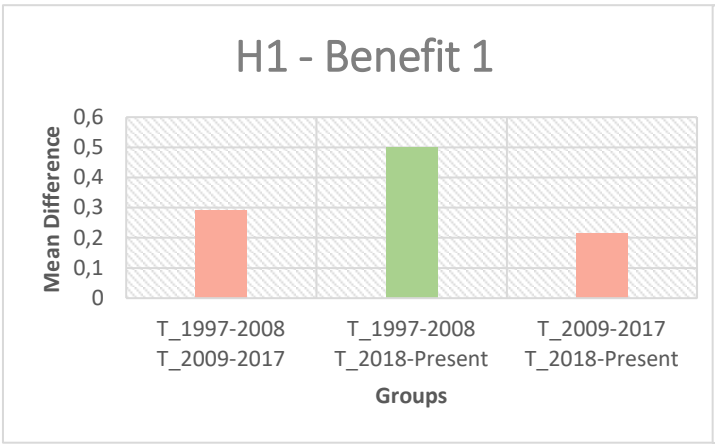
group1	group2	meandiff	p-adj	lower	upper	reject
T_1997_2008	T_2009_2017	0.2735	0.5323	-0.3288	0.8758	False
T_1997_2008	T_2018_Present	0.6357	0.0431	0.0156	1.2558	True
T_2009_2017	T_2018_Present	0.3622	0.3635	-0.2664	0.9907	False

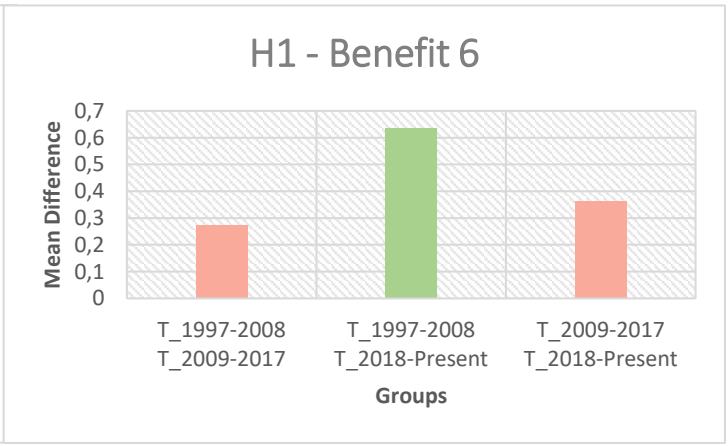
H1_16

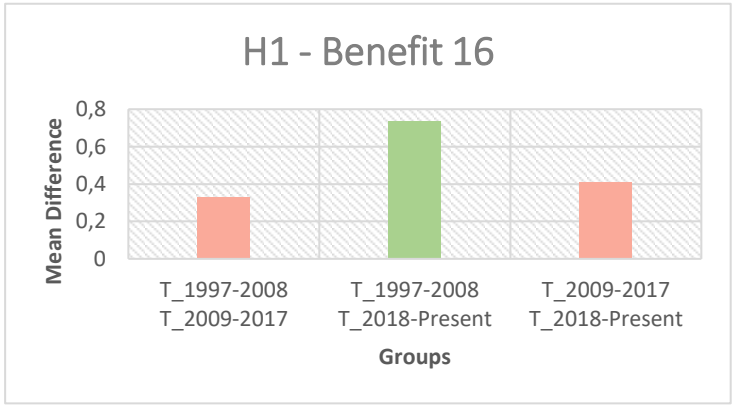
Multiple Comparison of Means - Tukey HSD, FWER=0.05

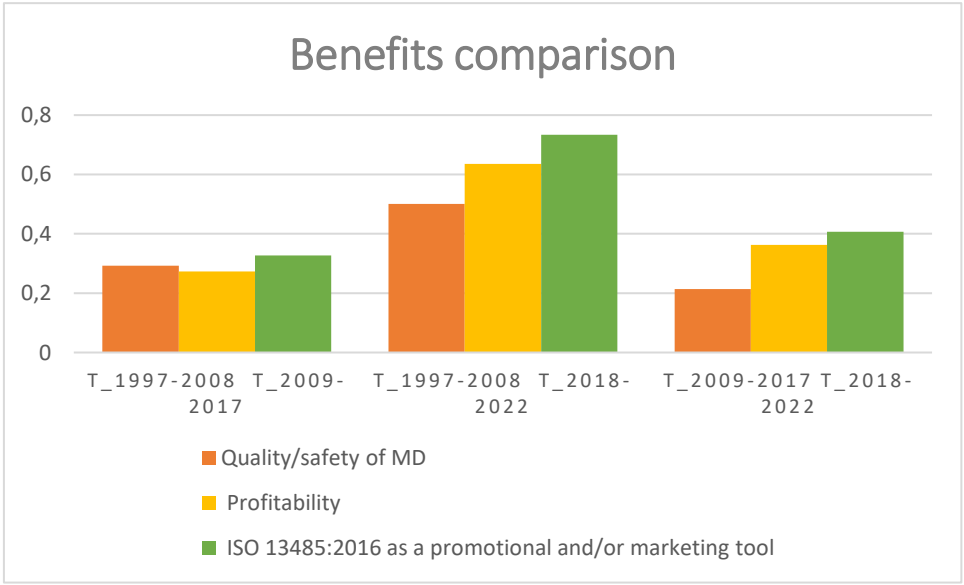
group1	group2	meandiff	p-adj	lower	upper	reject
T_1997_2008	T_2009_2017	0.3273	0.3762	-0.2507	0.9053	False
T_1997_2008	T_2018_Present	0.7343	0.0111	0.1392	1.3294	True
T_2009_2017	T_2018_Present	0.407	0.2509	-0.1962	1.0101	False

Annex G – Tukey's Test (H1) – Graphic Results





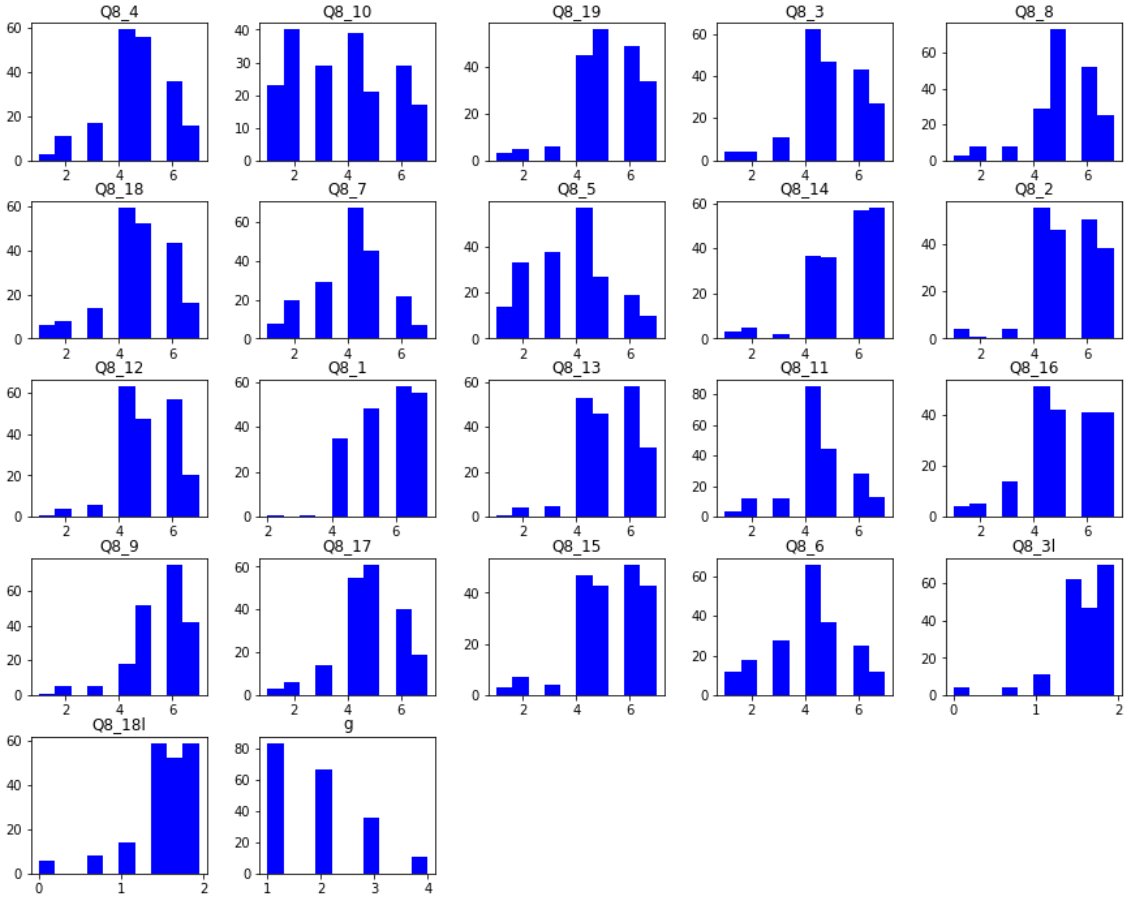




Annex H – Kolmogorov-Smirnov test (H2)

GROUP	Small	Micro	Medium	Large
Quality/safety of MD	7.01E-302	5.73E-162	9.81E-104	6.43E-50
Performance of MD	2.57E-101	1.24E-120	9.81E-104	5.42E-32
Number of incidents, rejections, and complaint	2.57E-101	5.25E-104	9.81E-104	5.42E-32
Productivity and/or efficiency	2.57E-101	4.38E-123	1.42E-59	1.69E-18
Internal costs	4.96E-64	2.37E-78	1.42E-59	1.69E-18
Profitability	4.96E-64	1.53E-91	4.25E-47	1.69E-18
Employee motivation and retention	7.89E-96	1.31E-86	4.25E-47	1.69E-18
Employees understanding of quality	2.57E-101	2.59E-112	1.42E-59	5.42E-32
Clarification of processes and procedures	2.97E-120	1.94E-138	1.42E-59	6.43E-50
Paperwork	4.42E-57	2.57E-67	4.25E-47	1.69E-18
Working environment	7.89E-96	5.25E-104	1.42E-59	1.69E-18
Customer service	1.07E-192	4.38E-123	1.42E-59	5.42E-32
Customer satisfaction	1.07E-192	4.38E-123	1.42E-59	5.42E-32
Expansion into international markets	7.89E-96	5.92E-122	1.42E-59	5.42E-32
Competitive advantage	1.66E-110	5.25E-104	1.42E-59	6.43E-50
ISO 13485:2016 as a promotional and/or marketi	2.97E-120	1.56E-102	1.42E-59	1.69E-18
Quality of suppliers	1.07E-192	5.25E-104	9.81E-104	1.69E-18
Mutual cooperation with suppliers	1.07E-192	3.03E-97	3.07E-45	1.69E-18
Corporate image at the market	2.97E-120	1.80E-110	1.42E-59	5.42E-32

Annex I – Histogram Plots for all variables (H2)



Annex J – Levene's Test (H2)

Benefit	P-Value
Quality/safety of MD	0.287438251
Performance of MD	0.621747208
Number of incidents, rejections, and complaints	0.014698408
Productivity and/or efficiency	0.069420205
Internal costs	0.196933859
Profitability	0.566342381
Employee motivation and retention	0.224788308
Employees understanding of quality	0.381825975
Clarification of processes and procedures	0.402621208
Paperwork	0.150393586
Working environment	0.660313663
Customer service	0.484336713
Customer satisfaction	0.825321725
Expansion into international markets	0.952841558
Competitive advantage	0.884869988
ISO 13485:2016 as a promotional and/or marketing	0.457459802
Quality of suppliers	0.187120729
Mutual cooperation with suppliers	0.033054284
Corporate image at the market	0.20483617