An investigation into the impact of the MDR Clinical Data Requirement for Legacy Devices & Transitional Provisions set out in Regulation EU 2023/607 on Medical Device manufacturers.

Dissertation submitted in partial fulfilment of the requirements for M.Sc. in Medical Device Technology & Business (QQI)

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Candidate Declaration

I hereby certify that this material, submitted for assessment on the programme of study leading to the award of M.Sc. in Medical Device Technology & Business, is my own; based on personal study and research, and I have acknowledged all material and sources used in this dissertation. I also certify that I have not copied or otherwise plagiarised the work of anyone else, including other students, and have not used AI tools or third-party writing websites in the preparation of this dissertation.

Signed: 

Student

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Lists of Abbreviations

510(k)	US FDA Premarket Submission to demonstrate safe & effective device
AIMDD	Active Implantable Medical Device Directive
ASR	Articular Surface Replacement
BSI	British Standards Institution – British Notified Body
CE	European Conformity marking
CPME	Standing Committee of European Doctors
DG SANTE	EU Commission's Directorate-General for Health and Food Safety
EU	European Union
FDA	Food and Drug Administration
HPRA	Health Products Regulatory Authority
IVDR	In Vitro Diagnostic Regulation
MDCG	Medical Device Coordination Group
MDD	Medical Device Directive
MDR	Medical Device Regulation
MHRA	Medicines and Healthcare products Regulatory Agency
NB	Notified Body
NSAI	National Standards Authority of Ireland
PIP	Poly Implant Prothèse
PMA	US FDA Premarket Approval
SME	Small and Medium sized Enterprise
US	United States

Abstract

An investigation into the impact of the MDR Clinical Data Requirement for Legacy Devices & Transitional Provisions set out in Regulation EU 2023/607 on Medical Device manufacturers.

Manus Duggan

OBJECTIVE: This study investigated the impact of the Medical Device Regulation requirement of clinical evidence for legacy devices and the transitional timelines on medical device manufacturers in Ireland. The MDR legislation which came in force on 26th May 2021, sets out the legal regulatory framework for medical device manufacturers, who wish to place their product on the EU market. Four key objectives were identified; firstly, to establish the current status regarding obtaining CE mark certification for medical devices. Secondly, to determine the status of products needing re-certification under MDR. Thirdly, to determine if the manufacturer in their opinion considers the transitional provisions set out under Regulation (EU) 2023/607 is sufficient. And finally, to obtain recommendations from industry as to improvements needed to improve the process of MDR certification.

METHODS: Secondary research was conducted of peer-reviewed journals, books, newspaper articles, and organisational websites, using the terms MDR, clinical data, medical device, and legacy medical devices. Primary research was conducted by means of a survey questionnaire, which was answered by 27 people with significant knowledge of medical devices in Ireland. One of the survey respondents worked in academia. Interviews took place with two individuals one from academia, and the other with a regulatory background in a medical device company.

RESULTS: In this study it was found that the introduction of the MDR legislation has had a negative impact on the medical device industry. Start-up and SMEs have been severely impacted by the requirements of the MDR, particularly the financial cost of clinical trials and access to Notified Bodies for MDR assessment. The clinical evidence requirement is ambiguous and impacts even the larger companies. Access to Notified Bodies, and the time taken by Notified Bodies to assess devices is taking much longer than under previous legislation. There have been device shortages and withdrawals warning from industry sources, but the consequence of this is unclear, and close monitoring of the situation is needed. Orphan and paediatric device shortages have already happened in the EU.

CONCLUSIONS: In this study, the author found that the primary research data broadly corresponded with what was found in the secondary research data. Clinical evidence is causing the most issues for companies. The EU have not been pro-active in their response to issues encountered by the medical device industry. The primary research sample size was limited, and warrants further study with a larger sample size.

Chapter One Introduction

1.1 Medical Device Regulation

From the 1990's to 2021, the regulations in Europe governing medical devices and active implantable medical devices were the Medical Device Directive 93/42EEC (MDD) and the Active Implantable Medical Devices Directive 90/385/EEC (AIMDD) (Behan, et al., 2017).

Following several high-profile medical device cases, such as the Poly Implant Prothèse (PIP) scandal in 2010-2011 in which non-medical silicone was used to manufacture breast implants, this led to calls for a high-level review of the MDD to minimise the risk of reoccurrence (Frumento, 2017) (Nussler, 2023).

The most recent Medical Device Regulations (MDR EU2017/745), specified a 4-year timeframe for medical devices to transition from the previous Medical Device Directive (MDD 93/42 EEC) and Active Implantable Medical Device Directive (AIMDD 90/385 EEC).

Medical devices certified under the old MDD & AIMDD, and placed on the market prior to 26th May 2021 are termed legacy devices. Under the MDR certain classes of legacy devices need sufficient clinical evidence to receive certification from designated bodies termed Notified Bodies (NB), and allowed to be placed on the market.

Notified bodies are government approved bodies designated under the Medical Device Regulation (MDR 2017/745). The role of these bodies is to assess the conformity of the medical device and the manufacturer against the regulation requirements, in order to obtain a CE marking and allowed to be marketed within the EU. All devices whether already on the market (so called legacy devices), or new devices now require a conformity assessment from a Notified Body except for Class I devices i.e. those having the lowest risk to human health. Individual European member states are responsible for the assessment and designation of a Notified Body located in their jurisdiction (Schröttner & Baumgartner, 2023).

Figure 1 Simplified outline of activities of a Notified Body from application to post-market surveillance (Schröttner & Baumgartner, 2023)

1.2 Industry Concerns

Medical device industry representatives indicated to the EU (Kaule, et al., 2020) that given the limited resources of the Notified Bodies to handle the number of legacy devices needing re-certification in the short timeframe of 4 years, possible device shortages would occur.

(McKernan & McDermott, 2022) in a research study state that significant issues are being encountered by medical device manufacturers due to the requirements placed on the companies by the MDR, mainly the need for fresh clinical trials for the products already on the market. Of the estimated 500,000 medical devices certified for the European market, they believe 20% of the certified devices under the previous MDD and AIMDD will not get market certification under MDR. Other factors highlighted in the article to add to this situation are, the increase in the average time of device approval and the reduction of Notified Bodies (NB), 51 NB assessed devices for MDD, whereas only 25 are designated for MDR.

1.3 EU solutions to industry concerns

In March 2023, the EU granted further time extensions to the transition of certain classes of medical devices from the old MDD and AIMDD to the newer MDR, ranging from 2026 to 2028 (HPRA, 2023).

For medical devices issued with a certificate or a declaration of conformity before 26th may 2021, the extended transition period according to risk class of the device will be as follows;

- Class III custom -made implantable devices – 26th May 2026.
- Class III devices and Class IIb implantable medical devices, but excluding sutures, dental crowns, braces, dental braces, dental fillings, plates, screws, wedges, wires, clips, pins and connectors – 31st December 2027.
- Other Class IIb products, Class IIa products, and Classes Is (sterile), Im (measuring), Ir (re-usable surgical instruments) – 31st December 2028.

These extension dates apply only to products where the manufacturer has taken action to convert to MDR certification by 26th May 2024 and has a contractual agreement with a Notified Body by 26th September 2024. The sell-off period for existing devices has been abolished to allow devices already on the market to be made available beyond the May 2025 date previously specified under the MDR legislation (TÜV SÜD, 2023).

1.4 Ireland as a global Medical Technology (medtech) Hub

Ireland is home to several clusters of medical device industries (MedTech Europe, 2023), (McKernan & McDermott, 2022). Employing more than 40,000 and the second-largest employer of Medical Technology (Medtech) professionals per capita in Europe (McDermott, et al., 2022). By their very nature and application medical devices are amongst the most highly regulated industry sector (MedTech Europe, 2023). Medical technologies can be defined as solutions, products and services that diagnose, treat, prevent, monitor, and care for people, and somewhere in the region of 500,000 medical technologies are in homes, hospitals, and care facilities across Europe in the form of medical devices, in vitro diagnostics, and digital health (MedTech Europe, 2023).

Medical Devices range from a simple tongue depressor or plaster at one end of the scale to stents and large diagnostic equipment at the other end. With a turnover of €100 billion the European market accounts for 25% of the global medical device market (Bianco, et al., 2017)

1.5 Aims and objectives of the research

The author wishes to investigate from an Irish medical device industry perspective, the resource burden associated with legacy device MDR certification, and if the current extension timeframe is sufficient to transition the medical devices needing MDR certification and to do so in the time specified to avoid device shortages or discontinuation.

The key objectives are:

1. To establish the current status regarding obtaining certification for medical devices.
2. To determine the status of products needing re-certification under MDR.
3. To determine if the manufacturer in their opinion considers the transitional provisions set out under Regulation (EU) 2023/607 is sufficient.
4. To obtain recommendations from industry as to improvements needed to improve the process of MDR certification.

1.6 Outline of dissertation chapters

1. Chapter One Introduction: sets out to give the reader a short introduction and background of the topic under review. It also outlines the aims and objectives to be explored as part of the research.
2. Chapter Two Literature Review: Provides a comprehensive review of the secondary research carried out. It sets out to investigate the actual effect on certain companies in complying with the new MDR regulations, the issues surrounding transitional provisions and sufficient clinical evidence.
3. Chapter Three Research Methodology: describes the research design and mixed-method approach to obtaining the primary research data.
4. Chapter Four Findings & Analysis: The primary research data obtained is presented along with any discussion and analysis of the data.
5. Chapter Five Conclusions & Recommendations: This chapter outlines the conclusions of the research, limitations encountered and recommendations. It sets out to explore to what extent the primary research data linked back to what was outlined in the Literature Review chapter.

Chapter Two Literature Review

2.1 The need for the new Medical Device Regulation

The Medical Device Regulation EU 2017/745 (MDR), replaced the Medical Device Directive 93/42EEC (MDD) and the Active Implantable Medical Devices Directive 90/385/EEC (AIMDD). The Directives provided the regulatory framework for medical devices and active implantable devices since the 1990's and sets out a minimum of regulatory requirements on the two types of medical devices, namely general medical devices and active implantable medical devices. The provisions within the Directives had no legal standing within the EU member states, and had to be written into the national law of each member state, leading to variations in how each member state interpreted the provisions (Behan, et al., 2017).

(Carl & Hochmann, 2023) point to, the need for an overhaul of the regulatory framework has partly come about from the advances in medical technology (medtech) and some high-profile scandals involving unsafe medical devices. (Huusko, et al., 2023) argue that in light of the device scandals, the need arose to establish a robust, transparent, and sustainable framework that aimed to provide safe and effective medical devices, ensured internal market functionality, support innovation, and competitiveness of the medical device industry. The scandals highlighted concerned breast and hip implants. The breast implant scandal in 2010-2011, involved a French company Poly Implant Prothèse, using non-medical grade silicone in the manufacture of breast implants. The serious safety issues of these implants were, with a higher rate of rupture, the implants posed a serious health risk with leakage of industrial-grade silicone into the surrounding body tissue. Another scandal in 2010 involved the recall of articular surface replacement (ASR) hip implants manufactured by DePuy. The high rate of revision of these implants gave rise to the recall and it was later revealed the metal-on-metal ASR, produced metal fragments which destroyed the surrounding tissue, causing considerable pain and disability in patients receiving them.

(Pitkanen, et al., 2020) states that the medical device directives had been complemented by additional legislation and guidance documents. In 2007 an extensive amendment to the medical device directives occurred due to the pace of innovation in the medical device sector, but even after this, concerns were raised by the occurrence of severe incidents concerning implantable medical devices. These incidents highlighted the shortcomings in the

manufacturing processes of certain companies and also with the performance of certain Notified Bodies as the irregularities should have been flagged during conformance assessments carried out by the Notified Bodies concerned.

In light of these shortcomings the EU came under pressure to strengthen the legislation regarding the regulation of medical devices. This in turn led to the EU Commission drafting a new piece of legislation the MDR, which came into force on 26th May 2021, replacing the MDD and AIMDD.

2.2 LEGACY DEVICES

The MDR (Medical Device Regulation 2017/745) was written into law on 26th May 2017 with a transition period of 4 years to 26th May 2021, under which medical devices lawfully placed on the market before and after the May 2021 date, could continue to be made available under valid MDD and/or AIMDD CE certification if certain criteria were met until 26th May 2025 (MED Institute, 2020).
(Vergani & Francisco Marin Barrios, 2023) outline the comprehensive documentation surrounding the Medical Device Regulation containing 123 articles, and the Medical Device Coordination Group (MDCG) has published numerous guidance documents, to accompany the legislation in clarifying certain aspects of the MDR, since 2017. This compares to the 23 articles contained in the Medical Device Directive.

Medical devices placed on the market under MDD and AIMDD certification are termed 'Legacy Devices'. Under the MDD, certain devices were exempt from meeting certain requirements under the Directive and allowed access to the market, this process is generally termed 'grandfathering'. The term originated in the United States and refers to devices placed on the market prior to May 1976 when the FDA came into being, and have no significant changes made to the current device and so do not require a premarket submission to prove the device is safe and effective. The MDR does not provide for such 'grandfathering' (MED Institute, 2020) (U.S. Food & Drug Administration, 2024).
(Ladd, 2023), points out that as the Medical Device Regulation does not confer 'grandfathering' rights on medical devices already on the market, having already gained CE certification under the Medical Device Directive. It is necessary therefore for all devices existing or novel to undergo clinical testing in order to gain CE certification under the MDR legislation.

2.3 The impact of Medical Device Regulation (2017/745) on Medical Device certification

The European medical device industry quickly realised these changes posed significant difficulties to existing and new device certification after the transition period.

Kaule and colleagues (2020) outlines the EU's proposal to extend the initial transition period due to the significant challenges posed by COVID-19 on all stakeholders involved in transitioning devices from MDD to MDR certification, and the pressure on the Notified Bodies to get devices certified and deal with the increased workload from manufacturers. They go on to state that these challenges may lead to product shrinkage in the market.

Under the MDR, manufacturers must ascertain the classification of the device, under the new regulations. Manufacturers must also obtain and evaluate sufficient clinical data defined in Article 2 par.48 & Article 61, par. 6a, and continue to monitor post-market surveillance or post market clinical follow-up (Melvin & Torre, 2019).

The need for such sufficient clinical data, places a significant resource burden on manufacturers to gain CE certification of medical devices under the new MDR, and on Notified Bodies to issue certification.

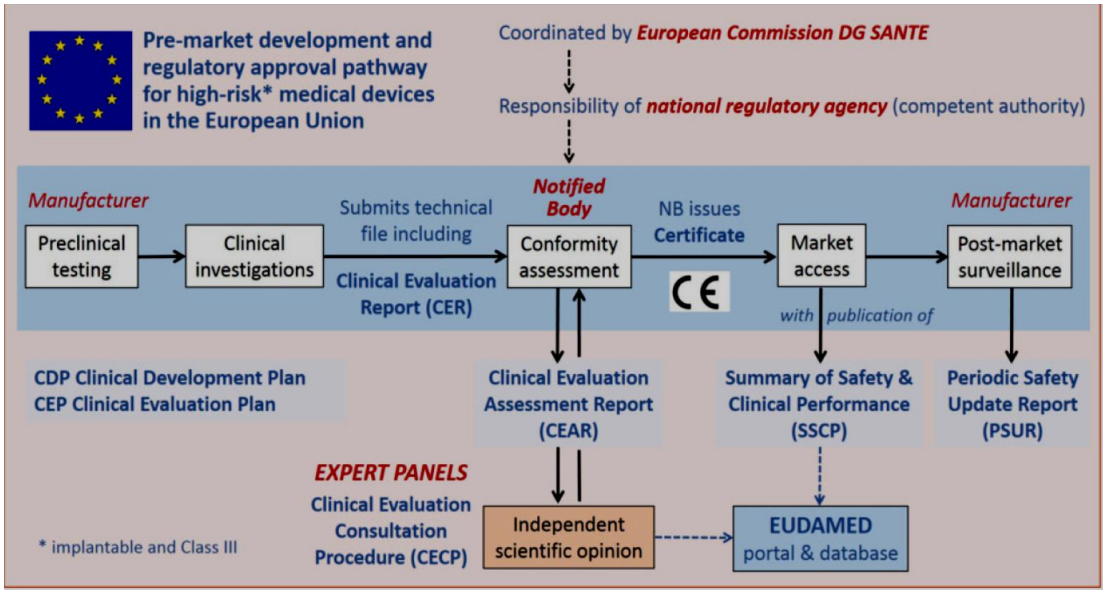

Figure 2 Approval process and Clinical Evaluation consultation Procedure for high-risk medical devices (Fraser, et al., 2020).

In a survey report by MedTech Europe (2022), some key figures from the survey of MedTech companies in Europe are highlighted.

The results of the survey show that of the estimated 500,000 devices previously certified under the MDD and AIMDD, only 15% have received certification under the MDR. It takes

somewhere between 13 -18 months for MDR Notified Bodies to issue certification, double the time under MDD. Greater than 50% of respondents planned to discontinue their devices by up to one-third, and that the impact of planned product discontinuation is spread across all product categories (MedTech Europe, 2022).

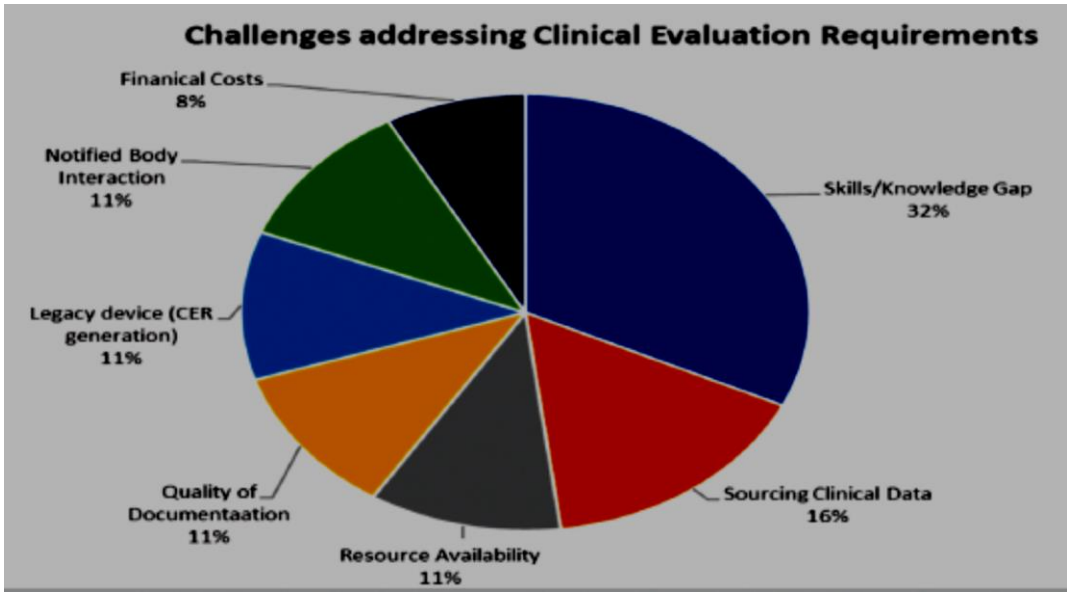

Figure 3 Common challenges faced by medical device manufactures in the preparation of a clinical evaluation report (Kearney & McDermott, 2023)

In 2022, MedTech Europe posted a document paper urging the EU institutions to take immediate and urgent action to address the imminent threat of medical devices shortages in relation to the backlog of certifications and at that time the transition date to MDR was set for 26th May 2024. They also highlight that without immediate action from the EU, the quality of healthcare to patients in Europe and around the world would be severely hampered (MedTech Europe Document Paper, 2022).

In an article on their website (VEEVA MedTech, 2024), Ernest & Young estimate it can cost medical device manufacturers somewhere in the region of between 3.5% and 5% of their total revenue to transition to the Medical Device Regulation. It follows on with a statement from Peter Gaines, a Professor at Sheffield Hallam University, in which he estimates that larger device manufacturers will halve their product portfolios, a large proportion, approximately 30% of smaller manufacturers will shut down and the amount of total medical devices withdrawn from the market will be in the region of 50%.

2.4 Competent Authority and Notified Body

The role of Competent Authority in Ireland is held by the Health Products Regulatory Authority (HPRA). Competent Authorities assess and designate Notified Bodies to carry out conformity assessments in the member state they are both located. The Competent Authority also monitors the compliance of medical devices being placed on the EU market (Schröttner & Baumgartner, 2023).

Notified Bodies assess medical device products against the applicable regulation in order to issue a CE certificate to the device. A medical device cannot be placed on the market within the EU without this certification. When a device reaches the expiry of its previous certification, the manufacturer is obliged to under the regulations to apply to a Notified Body to be assessed for a new CE certification and cannot market the product until certification is authorised (HPRA Health Products Regulatory Authority, 2024). The decrease in Notified Bodies designated for MDR, and the sheer number of devices needing re-assessment under MDR, has led to a significant backlog of products unable to be placed on the market.
At the time of writing, the National Standards Authority of Ireland (NSAI) is the sole designated Notified Body in Ireland charged with conformity assessment activities under MDR and IVDR (NSAI, 2024).
Under the Medical Device Regulation, there is increased inspection and oversight on Notified bodies by the Competent Authority and a requirement for the NB to assess conformity to the MDR. Under such circumstances some Notified Bodies designated under MDD, are no longer available to carry out conformity assessments and have not applied for MDR designation. This has led to a shortage of Notified Bodies available to carry out conformity assessments on manufacturers and devices within the medical device industry (Kearney & McDermott, 2023).

(Baines, et al., 2023) raise concerns surrounding Notified Body capacity from stakeholders in the medical device industry and including some NBs raising the very same concerns with the authors. The authors conclude that these capacity issues may be detrimental to current and future innovations.
(Vergani & Francisco Marin Barrios, 2023), state that under the MDD, the number of Notified bodies designated to carry out conformity assessments stood at 51. In comparison the number of Notified Bodies designated by Competent Authorities is 38 as of April 2023. Even allowing for 11 of the MDD Notified Bodies from the United Kingdom, no longer designated to operate

due to Brexit, it still leaves a significant shortfall of Notified Bodies, considering the volume of devices needing re-certification to comply with MDR legislation in the designated timeframe. The authors also point out that due to the shortfall of Notified bodies, the length of time for a conformity assessment to be carried out on a device and manufacturing practices has increased significantly. Some manufacturers must take some responsibility in this regard for the increased time to certification, the authors state that some 20% of documentation submitted to Notified Bodies, as part of the conformity assessment are more than 50% complete.

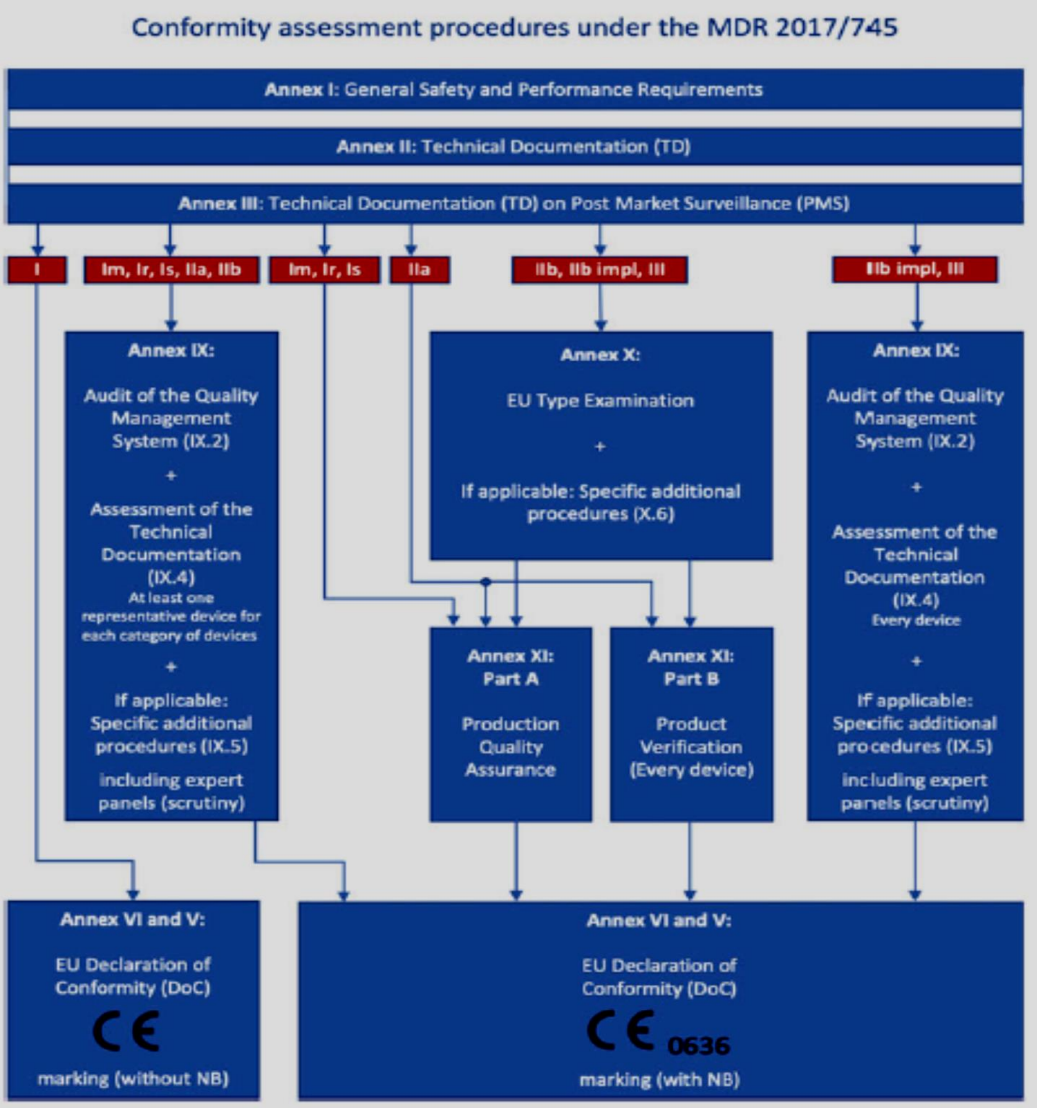

Figure 4 Medical Device Notified Body conformity assessment under MDR. No NB assessment needed for Class I devices (Schröttner & Baumgartner, 2023).

2.5 THE EU EXTENDS TIME ALLOWED TO TRANSITION DEVICES TO MDR CERTIFICATION

MedTech Europe posted a press release, welcoming the decision of the EU Commission to extend the transitional provisions of the EU MDR and the EU IVDR. The extension alleviates the pressure on Notified Bodies to grant MDR CE certification and avoid the potential scenario of legacy devices becoming discontinued (MedTech Europe, 2023).

On 20th March 2023, the Regulation (EU) 2023/607 came into force. It provides for extensions for medical device products transitioning from EU MDD to EU MDR, for Notified bodies to grant certification for such devices, whose certificate has expired after 20th March 2023 and satisfies the requirements outlined in Regulation 2023/607 (HPRA, 2023).

By allowing additional time in the transitional provisions of the MDR, the EU hopes to avoid device shortages or worst-case device discontinuation. The extension of transitional provisions in the Regulation is based on the device classification as follows;

"2026 for class III custom made devices,
2027 class III and class IIb implantable devices,
2028 other class IIb, class IIa and class Is, Im devices, and
2028 for class I up classified devices" (HPRA, 2023).

Further changes to the MDR transitional provisions set out in Regulation (EU) 2023/607 removes the sell-off period, meaning devices already on the market can continue to do so until the shelf life of the device expires or reaches the revised transition provision date, to be certified under MDR certification. The extended timelines are subject to the medical device developer or manufacturer registering with a Notified Body by 26th May 2024 and having a signed contract in place with the Notified Body by 26th September 2024 (HPRA, 2023) (BSI, 2023).

To further highlight the fact of possible device product shortages, the EU Commission's Directorate-General for Health and Food Safety (DG SANTE), commissioned a European-wide study of manufacturers and authorised representatives in December 2022 to monitor the availability of medical devices on the EU market. It also sets out to monitor shortages in medical devices and to identify the challenges of such device availability and potential solutions to alleviate shortages. The study will run until December 2025 (HPRA Health Products Regulatory Authority, 2024).

2.6 MDR effect on Small and Medium Sized Enterprises

The European medical device market is the second largest globally, with a value of US $140.07 billion in 2022 (Kearney & McDermott, 2023). It is home to some 500,000 medtech devices ranging from pacemakers & software to contact lenses and categorised into roughly 7,000 device groups (Huusko, et al., 2023).

(Carl & Hochmann, 2023), state that in Germany, Small and Medium sized Enterprises (SMEs) account for 93% of medical device manufacturers having fewer than 250 employees, and yet SMEs in particular struggle with MDR implementation. The authors conducted a survey of German orthopaedic aids manufacturers in 2021 and again in 2023. The findings indicated different risks associated with implementation of the Medical Device Regulation. 90% of the companies surveyed have already seen or anticipate an increase in costs. 46% of respondents anticipated a reduction in product portfolio, 28% indicated difficulties in bringing innovative aids to market, 18% of companies had planned to or had already reduced research & development activities and 14% of respondents indicated that job cuts were inevitable due to impact of MDR implementation. Of note is a striking risk to some of the company's existence due to the requirements placed upon the companies by the MDR. In the initial survey, 10% of 146 respondents indicated that their company was at risk due to MDR. Two years later, and two years after the Medical Device Regulation come into force, that risk had risen to 25% of 233 respondents.

The importance of small & medium sized medical device manufacturers is borne out in the fact that there is some 25,000 MedTech enterprises in Europe, with 95% of the companies classed as SMEs (Maresova, et al., 2021). The authors point to the importance of such SMEs to the medical device industry, as this is normally where innovation is the main driver of the operation. Being at the beginning of technological progress in the medical device industry, the SME company can adapt faster because of its small size. The person making the decisions of an SME is normally the inventor or innovator, and this makes it easier to assess risks and make informed decisions, unlike larger enterprises where management, leadership and research are based in different departments and different organisational structures. The challenges faced by SMEs as a result of the introduction of, and the transitioning to the Medical Device Regulation cannot be overstated and SMEs will be affected the most from such changes and may lead to reduced innovation of medical devices and in some cases, companies ceasing to trade.

(Kearney & McDermott, 2023) outline that the high costs associated with clinical investigations in an effort to gather the data needed to satisfy the sufficient clinical data requirement in the MDR, can be restrictive, and outweigh the potential return on investment of a medical device. In such cases, manufacturers may choose to discontinue the device and this can have a negative effect on the innovation of such devices and restriction of such devices for patients in the EU healthcare system.

(Huusko, et al., 2023) states that successfully passing a Notified Body conformity assessment and obtaining CE marking to place on a medical device, can be a real challenge for manufacturers, as so many of them are SMEs with limited resources. The authors cite a recent study from (Maresova, et al., 2021) which states that whilst the MDR will increase patient safety, on the other side the increased administrative burden and increased costs of MDR will have a negative effect on the innovativeness of SMEs. This may result in some companies moving to the manufacturing of non-medical products.

(Baines, et al., 2023) state in their findings that SMEs are identified as drivers of innovation, the same SME sector were frequently acknowledged to be disproportionately affected by the MDR requirements, leading to a lack of innovation and a loss of existing products.

It is estimated that 1,700 different types of medical devices made up of 50,000 separate products. The medical device industry is made up of a large number of small companies. The larger companies account for the vast proportion of sales. The early stages of innovation of medical devices are mainly carried out by small firms or individuals, whilst the later development of devices is carried out by the larger firms, sometimes through the acquisition of smaller firms (Maresova, et al., 2020).

Maggie Fick is a journalist with the Reuters news agency, she wrote a number of news articles for Reuters in 2022 and 2023 on the subject of the Medical Device Regulation, the subsequent medical device supply worries and the medical device SMEs transition issues.

In a Reuters article (Fick, 2022b), highlights the issues for medical device SMEs and the financial resources or otherwise needed to transition from MDD to MDR certification. German medical device manufacturer Osypka AG, is a small operation and has been in business since 1977 when founded by Peter Osypka. His daughter Nicola is currently in charge of the operation and the company manufactures devices for use if surgery is required on newborn babies. Up to end of 2022 the company has had to drop 5 lines of medical device products from the EU market, some of the devices had been on the market for more than 30 years. Nicola points out that company cannot afford the estimated €1.1 million for an innovative

product application, even though the product has already gone through clinical trials. She goes on to say that companies like Osypka AG, are paying the price for rogue manufacturers more than 10 years ago.

Reuters spoke to eight medical device companies about the effect MDR transition was having on their company. Getinge is a large Swedish device manufacturer and due to the extra cost to comply with the new legislation is withdrawing devices from the EU market and ceasing manufacturing of other products. The company manufactures products for surgery, intensive care and sterilisation, and has 20% of its portfolio re-certified under MDR. Getinge plans to drop about a third of its portfolio because of dwindling profits on those products but the company admits that even for a larger company like Getinge the process of re-certification was more demanding and has taken longer than expected.

Andreas Kohl's company AndraTec in Germany is a stent and catheter manufacturer, says he plans to drop two or three devices of his company's six products on the EU market as it cannot afford to re-certify all six with rising costs.

Another medical device company executive, interviewed by Reuters for the article was John O'Dea, the chief executive of Palliare, a small Irish medical device manufacturer based in Galway, Ireland. He says that in order to get his company's new laparoscopic device onto the market, the company is willing to absorb the extra costs. The device is used in surgery in the abdomen or pelvis region of the human body and has already got approval from the U.S. Food and Drug Administration (FDA), two years ago. Even with this FDA approval, Palliare still have to gather sufficient clinical evidence, which O'Dea estimates will be about €100,000, and the process has been on-going for the past year and a half. Under MDD certification a similar device would cost €15,000 and would take a few months for approval.

Some of the eight companies say that the devices they have dropped from the market will have negligible impact on patients or profits, all of the eight companies agree that the time take for re-certification is as much as two and a half years under MDR, compared to only a few months under MDD. Costs are also a significant factor and the cost for certification of a device under MDR has risen from three to ten times the MDD cost.

In January 2023, (Fick, 2023a) reported that after the EU Health Commissioner had tabled the proposal to extend the transition period from MDD to MDR. Several executives from companies highlighted in the previous article (Fick, 2022b), having issues with MDR certification, told Reuters that they did not believe that extending the transition deadline would eliminate the logjams and high costs associated with MDR certification.

(Sojka, et al., 2023) highlight a survey conducted by the German Medical Technology Association (BVMed), of its 110 members in 2021. The survey results revealed that the MDR is the biggest obstacle to future development of medical devices. Devices manufactured by small companies or individually custom-made, are strongly affected by the requirements in the MDR. 70% of the respondents called for a simplification of the re-certification process for commonly used existing devices. 35% of companies had insufficient data for the devices being re-certified according to the Notified Body report after conformity assessments had been carried out. 30% of the companies have products that will need clinical trials in the next five years to stay in the market, and of those 30% of companies nearly half face additional difficulties due to a lack of clinical trial investigators or negative evaluations by investigating ethics committees. The companies had difficulty with interpreting the requirements of the MDR, not alone with the actual legislation text, but with the amount of guidance documents, currently standing at about 100 documents. (Sojka, et al., 2023) go on to say that 66% of Swiss medical device manufacturers will be reducing their product portfolio, by 13% on average and that the average the cost of medical devices in Switzerland has increased by about 12%.

Since the introduction of the Medical Device Regulation, both the EU and the medical device industry have struggled with the concept of a highly regulated industry that is balanced enough to allow innovation to flourish. Data collected in the coming years on innovation and new device development, will answer the question on whether the MDR struck the correct balance between regulation and innovation (Vergani & Francisco Marin Barrios, 2023).

(Vergani & Francisco Marin Barrios, 2023) further state that according to MedTech Europe, 95% of medical device companies are SMEs. Those SMEs and start-ups in particular are looking to other markets other than the EU due to the increased costs, documentation and the lack of access to Notified Bodies.

The need for clinical data and post-market surveillance may hamper innovation of devices for the EU market. The extra costs and resources involved to bring products to market may lead to a slowing of availability of innovative devices. The need to divert resources away from research and development activities to fund existing devices through MDR certification, is a major concern, especially for niche or so-called orphan devices, used in paediatrics or interventional radiology with limited market demand (Ladd, 2023).

2.7 MDR CERTIFICATION AFFECTING MEDICAL SERVICES

(Fick, 2022a), outlines an interview by the European Health Commissioner Stella Kyraikides to Reuters on an impending device shortage, as doctors warned the EU Commission that shortages of lifesaving equipment is being caused by the MDR legislation.
Ms. Kyraikides said that supplies of critical medical devices such as catheters used for surgeries on newborn babies with heart conditions, were being hampered by challenges implementing the MDR. Ms. Kyraikides goes on to point out that the EU Commission has put in place the new legislation, as patients expect medical devices to be safe and effective. Challenges remain and that is why proposals are being brought before a meeting of the EU health ministers, to amend the legislation to allow for an extension to the transition period to avoid any risk of shortages. Under the original MDR legislation all medical devices on the market in the EU must be re-certified by May 2024.
Christiaan Keijzer, president of the Standing Committee of European Doctors (CPME), told Reuters that essential medical devices especially in the areas of paediatrics, cardiology and orthopaedics were at a worrying level of supply and in many cases, there is no alternative device available. Data released to the Commission ahead of the vote to extend the transition period, shows the extent of the backlog. Under the MDD certification there were 23,000 devices, whose CE certification will expire by May 2024 without an extension. 2,000 of the 8,000 submitted application by manufacturers had been approved. The Commission admit that at that pace of re-certification under the MDR only 7,000 certificates would be issued by the May 2024 original deadline.

In a report in Reuters (Fick, 2023b), the European Academy of Paediatrics have asked Brussels to amend the Medical Device Regulation, to prevent the disappearance of vital medical devices for children, from being withdrawn from the EU market. 23 medical associations wrote to Stella Kyraikides the EU Health Commissioner in June 2023 outlining their concerns. In April 2023 the EU extended the transition periods from MDD to MDR according to the device class risk. The medical associations feel that the transition extension alone will not solve the problem of shortages of vital lifesaving medical devices, because the companies manufacturing the devices are small in size and the cost of compliance is prohibitive for many of them. The report highlights the case of a company having received an invoice for €800,000 for conformity assessments for a single device that previously had been on the market for 5 years under MDD certification. The medical associations point out that the cost of €800,000 is 150 times that for the same process for the same device in the United States. The medical associations letter

urges the EU to take action to protect access for certain paediatric devices and rare diseases and to monitor medical devices that have already been dropped from the EU market. The letter also details that a shortage of dialysis machines for children with kidney disease has been reported.

The issues surrounding product shortages and discontinuation due to requirements of MDR certification not only affects manufacturers, but also medical professionals and the patients in their care. Device availability will lead to treatment difficulties and limited patient care (Sojka, et al., 2023)

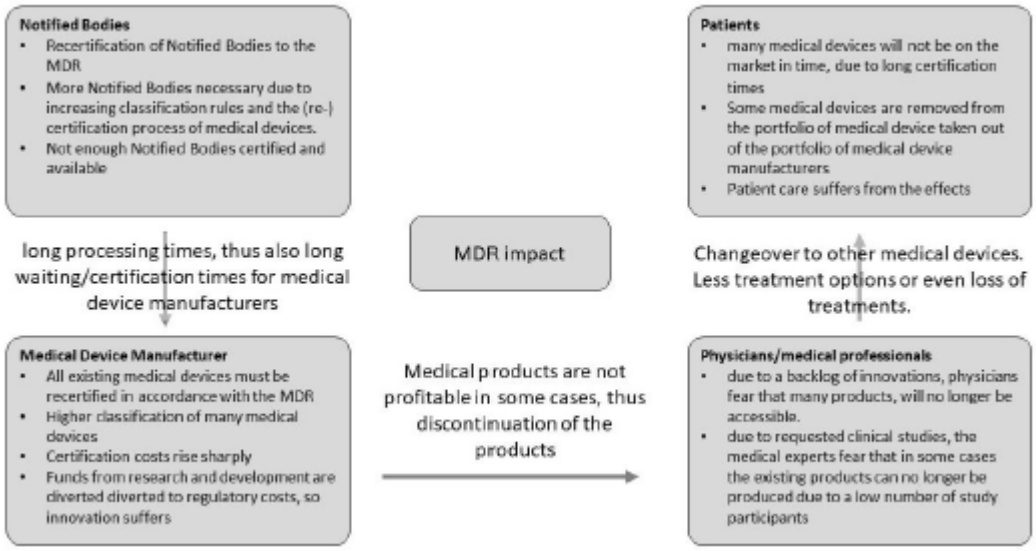

Figure 5 Impact of MDR and stakeholder interdependencies (Sojka, et al., 2023)

(Vergani & Francisco Marin Barrios, 2023), maintains that if the one of the aims of the MDR was to ensure that patients and medical device users had a high level of protection and access to devices, then the MDR is counterproductive in its approach, as the literature has shown that shortages and withdrawal of devices from the market has already occurred.

2.8 Literature Review Summary

The Regulatory framework for Medical Devices placed on the market in the EU between the 1990's and 2017 was covered by two pieces of legislation, the Medical Device Directive 93/42EEC (MDD) and the Active Implantable Medical Devices Directive 90/385/EEC (AIMDD). In light of some medical device regulatory shortcomings in the 2010's involving silicone breast implants and metal-on-metal hip implants, the EU came under pressure to strengthen the legislation regarding the regulation of medical devices. This in turn led to the drafting of a new piece of legislation the Medical Device Regulation, which on 26th May 2021, replaced the previous medical device directives.

Medical devices placed on the market under the MDD and AIMDD legislation are termed legacy devices and allowing them to continue on the market without meeting the full requirements of the new legislation is generally termed 'grandfathering'. The Medical Device Regulation does not confer 'grandfathering' rights to medical devices already on the market. It is necessary for all devices existing or new to undergo clinical testing in order to gain CE certification under the MDR legislation.

The introduction of the Medical Device Regulation has had a significant impact on the medical device industry for a number of reasons. The MDR requires new and existing medical devices to undergo significant clinical assessment before CE certification is granted by a Notified Body, in the designated timeframe laid out in the MDR. Notified Bodies are designated by Competent Authorities in each member state in the EU. Rigorous assessment of Notified Bodies by the Competent Authorities has led to a reduction in the number of Notified Bodies that carried out conformity assessments under the MDD, currently available to assess under the MDR legislation. The cost of clinical studies of the device and the conformity assessments carried out by the Notified Body contribute to a significant financial burden on device manufacturers to place new devices, and keep existing devices on the EU market.

Because of the backlog the EU has had to grant extensions to the transitional timeframe set out in the MDR to allow Notified Bodies to clear the backlog of existing devices needing MDR certification. The extensions range from 2026 to 2028 depending on the device risk type.

Innovative start-up companies and SMEs have been severely impacted by the increased resource demands as part of the requirements of the MDR. This in turn has led to a shortage or in some cases a withdrawal of a device from the market in the EU. Doctors have urged the EU to take action to prevent shortages and discontinuations of lifesaving medical devices.

Chapter Three Research Methodology

3.1 Introduction

The research question investigated was, how has the requirement of clinical data, for legacy devices set out in the Medical Device Regulation EU 2017/45, and the transitional provisions timeframe extension set out in the EU 2023/607 Regulation was impacting on medical device manufacturers in Ireland.

This study adopted mixed-methods primary research, comprising of a questionnaire survey and a series of semi-structured interviews with experienced medical device regulatory professionals.

This chapter outlines the methodological approach taken by the author in conducting the research, and justification for the way the research was carried out.

(Saunders, et al., 2007) describe one way to perceive the structure of the methodology chapter as peeling away the layers of an onion from the outside in, following a linear and logical approach to writing the chapter.

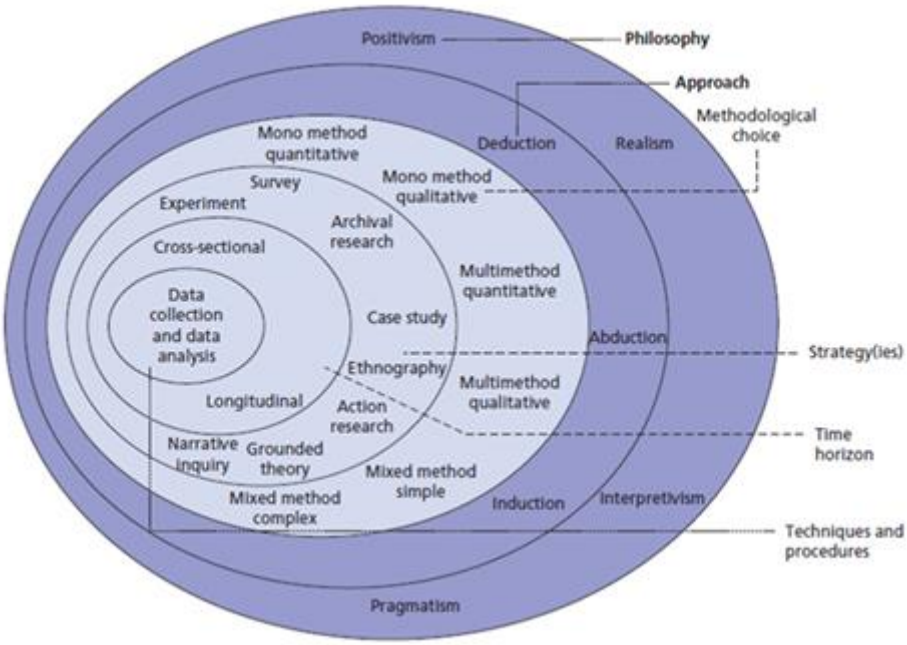

Figure 6 The Research Onion (Saunders, et al., 2007)

3.2 Conceptual Framework

Philosophy	Positivism	Interpretivism
Approach	Deductive	Inductive
Methodological choice	Mixed method (Quantitative)	Mixed method (Qualitative)
Strategies	Survey	Interviews
Methods	Questionnaire	Semi-structured

Table 1 Conceptual Framework overview of this study

3.3 Research Philosophy

(Ryan, 2018) states that the researcher's perception of truth, reality and knowledge is what governs their research philosophy. The philosophy will also shape the value and beliefs guiding the design, and how the data for a study is collected and analysed. The philosophy employed in a particular study will govern the direction of the methodology. Three common philosophy paradigms are positivism, interpretivism and pragmatism.

Two objectives of this study were to ascertain the current status regarding obtaining certification for medical devices and determine the status of products needing re-certification under MDR, this indicated a positivism philosophy. The remaining two objectives set out to determine if the manufacturer in their opinion considers the transitional provisions set out under Regulation (EU) 2023/607 is sufficient and to gain recommendations from industry as to improvements needed to improve the process of MDR certification. This suggests an interpretivism philosophy. A mixed method philosophy was undertaken to incorporate both positivism and interpretivism philosophies in this study. The combination of these two approaches is usually described as pragmatism.

Contrasting the two research approaches undertaken in this study, (Ragab & Arisha, 2017) highlight the corresponding characteristics of each approach in the following table.

Research Approach	Deduction	Induction
Approach to investigation	Highly structured	Flexible
Paradigm	Positivist	Interpretivist
Sequence of Investigation	1. Theory 2. Hypothesis 3. Observation 4. Confirmation	1. Observation 2. Patterns 3. Hypothesis 4. Theory
Purpose	Explanatory; Explanation of causal relationships between variables	Exploratory; Gaining un understanding of the phenomena
Data Collected	Quantitative	Qualitative
Generalisation	Need to generalise conclusions	Less concern with generalisation

Table 2 Research Approach Characteristics (Ragab & Arisha, 2017)

A deductive approach research involves a study where the theoretical and conceptual structure is developed and tested by empirical means. It is sometimes described as moving from the general to the particular. Inductive research on the other hand involves developing a theory based on the empirical data and forming general inferences, the opposite to the method employed in the deductive approach (Collis & Hussey, 2009). Deductive approach is further explained by (Patel & Patel, 2019) as testing the validity of a theory or hypotheses. Inductive approach contributes to the formation of new theories or assumptions

Quantitative research deals with the measurement of amount or quantity, how many times a specific action is undertaken under certain circumstances. Qualitative research deals with a non-numerical approach to descriptive data, reasoning is applied to patterns and uses words. An example of this being, how people feel about their work/life balance. Quantities can be measured, but in order to measure patterns, a relationship or configuration method is employed, the aim of which is to understand the meaning of or describe a situation (Groundar, 2012).

Quantitative research can be viewed as addressing a research question and designing a study to collect quantitative data and analyse that data statistically to prove a hypothesis. Qualitative research involves designing a study to collect qualitative data and have that data analysed by means of quantifying the collected data by the frequency of occurrence of certain words or themes (Collis & Hussey, 2009).

3.4 Data Collection

Secondary research data was conducted utilising searches in Google Scholar, using the words medical device industry, MDR, issues, impacts and challenges. Peer-reviewed articles, journals, textbooks and reputable internet resources were selected to provide a comprehensive review of the research that has been carried out already, in relation to research questions this study aims to answer.

The primary research data was collected in two ways as outlined in Table 1, the Conceptual Framework.

The first method of data collection was in the form of a survey questionnaire, of 15 closed and open questions, and the questionnaire was developed using Microsoft Forms. Closed questions are ones the participant answers from a set of supplied answers. In the case of open questions, the participant answers the question in their own words and opinion (Collis & Hussey, 2009). A link to the questionnaire was distributed via LinkedIn and email to medical device personnel working in Ireland. The survey questionnaire method of primary data collection is the most widely used method and because of the method's ability to harness data across a large sample size and broad statistical analysis options, it is popular in business research (Ragab & Arisha, 2017).

Some of the characteristics of a good questionnaire, according to (Pandey & Pandey, 2015) include; it deals with an important topic and the importance is stated carefully at the beginning of the questionnaire for the participant to understand. The questionnaire should be as short as possible to extract the essential data required. The form should be of good appearance and contain clear and complete instructions, and allow the researcher to interpret, tabulate and summarise with ease.

(Collis & Hussey, 2009) advises to keep the number of open-ended questions to a minimum, so as not to deter the respondents from responding to the survey.

The second method of primary data collection was collected by means of semi-structured interviews carried out by the author, with a number of experts in the field of medical device regulation to ascertain the opinions and possible recommendations of the experts in minimising the consequence of the MDR legislation on the medical device industry.

The interviews were collected in a consistent manner using the same set of questions in an effort to avoid any distortions in the collection of the data. As the interviews were semi-

structured in nature, certain questions may have needed to be withheld or added in in order to gain a more insightful response from the interviewee. Where possible the same questions were asked during the interview

An interview, originated as a psychology and psychiatry research tool and can be described as a discussion with purpose between two or more people. Interviews are widely used in qualitative research. Semi-structured interviews have a set of predetermined questions, but allow a degree of flexibility in the order of the questions asked, and to add or delete some of the predetermined questions in order to allow for new ideas to develop from the discussion (Ragab & Arisha, 2017).

Interview characteristics described by (Pandey & Pandey, 2015) include; it gives the researcher the ability to probe into certain issues, and ascertain attitudes to problems. An interview can deal with delicate and confidential issues. It allows for flexibility as in semi-structured and non-structured interviews and can be applicable to obtaining primary data in the case of historical or experimental studies, but equally as well in case and clinical studies.

The survey questionnaire and the questions asked during the interview are set out in the Appendices section of this study.

3.5 Data analysis

The method of primary data analysis depends on the research paradigm selected; quantitative data is associated with a positivist paradigm. Whilst qualitative data is associated with an interpretive paradigm or in some cases, data collected from both qualitative and quantitative methods, which is termed a mixed methods approach (Collis & Hussey, 2009).

The quantitative data from the completed survey questionnaires was analysed using the frequency of responses to a specific question. The responses were imputed into an Excel spreadsheet and using the software to obtain a graphical representation of the data analysis such as graphs and charts.

The qualitative data from the questionnaires and interviews was analysed using coding, to group together the worded responses on the opinions and recommendation of the participants to the relevant questions.

This method was used because only quantitative data can be analysed be by means of statistical analysis (Collis & Hussey, 2009).

Contrasting the data analysis methods of quantitative and qualitative paradigms (University of Southhampton, 2024), outlines that in order to group and categorise qualitative research data into meaningful themes and patterns, a form of coding is employed. Meanwhile a statistical approach is employed with numerical data in a quantitative paradigm to measure the results against the research question or questions.

3.6 Ethical considerations

The ethical considerations of the primary research participants, was a key concern to the author and as such the following measures were implemented to ensure ethical factors were addressed.
Participation in the primary research data collection was voluntary and this was set out in the participant information letter at the beginning of the survey questionnaire. The letter also indicated that the participant could withdraw their consent at any point during the survey.

No reward or inducements were offered to the participants to take part in the survey or interview and the purpose for the data collection was outlined in the introduction to the questionnaire and a signature was sought from the interview participant on a consent form.

Anonymity and confidentiality of all primary research participants was essential in order to gain honest and reliable responses to the survey, and interviewees were asked if they wished to remain anonymous or wished to reference their regulatory position and experience in light of the information that they provided during the interview on the impact the MDR legislation was having on the medical device industry.

Participants were advised on the storage and publication of the responses in the information letter and interview consent form.

3.7 Limitations

There were a number of limiting constraints encountered in the completion of this study. One of the main limiting factors concerned the collection of primary data. Despite the limited sample size of participants responding to the survey and interviews, the number of responses received, yielded sufficient data in the short timeframe involved in data collection and write-up of the study.

The respondent participants may not be a complete representation of the whole community of medical device industry regulatory personnel in Ireland, and the responses represent a sample of industry personnel at a given point in time.

The author found access to medical device industry personnel limited, hence the small number of respondents agreeing to complete a survey or interview at the time of completing this study.

Chapter Four Findings and Analysis

4.1 Survey Results

1. Do you understand the research and the Participant Information Letter?

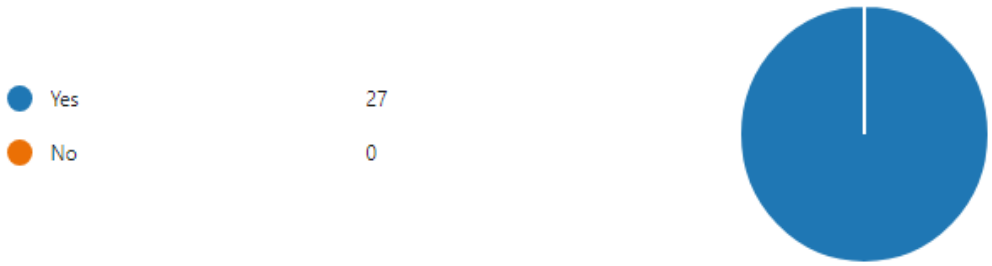

Figure 7 Number of survey respondents understanding the Participant Information Letter and research (taken from Microsoft Forms)

All 27 respondents chose yes, indicating they understood the research and what was involved in participating in the survey. A response to this question was required by the survey participant.

2. Do you consent to participate in this survey?

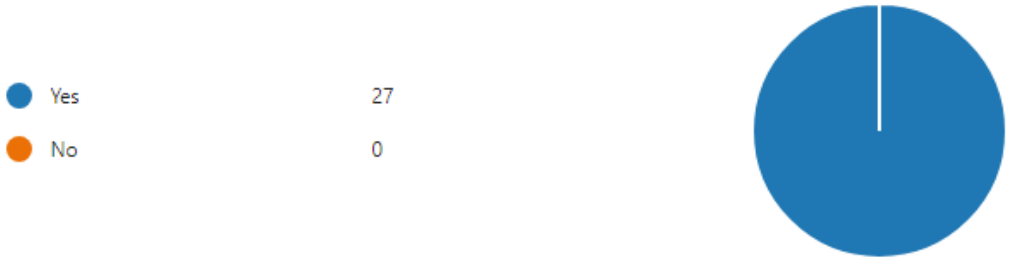

Figure 8 Respondents consent to participate in the survey (taken from Microsoft Forms)

All 27 respondents gave their consent to participate in the survey. A response to this question was required by the survey participant. Questions 1 and 2 were the only questions requiring a response to progress to the rest of the questions.

One person who partook in the survey was an academic, and not working in a medical device company. He answered the questions he could, but as some questions were not relevant to his profession, could not answer all the questions in the survey.

3. Are you employed in the medical device industry in Ireland?

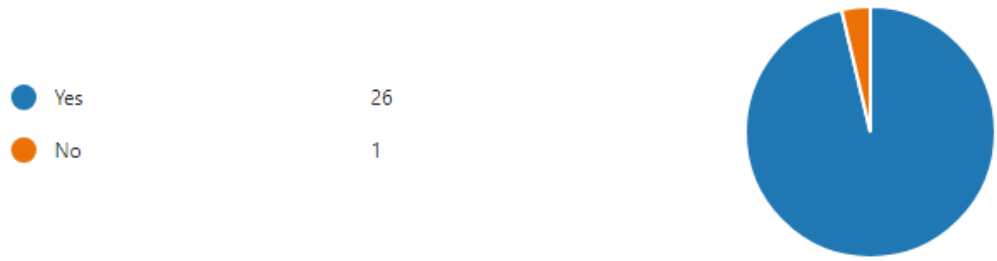

Figure 9 Survey respondents employed in the medical device industry in Ireland (taken from Microsoft Forms)

The results indicate that 26 or 96% of respondents were employed in the Irish medical device industry.

4. Is your company classed as a Small & Medium sized Enterprise (SME) with 250 employees or less?

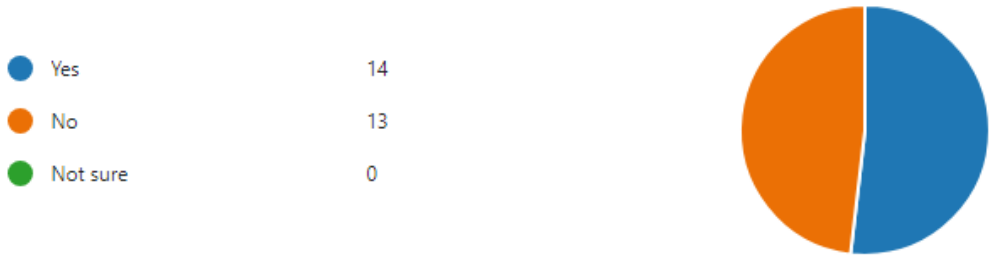

Figure 10 Survey respondents employed in SME or part of a larger company (taken from Microsoft Forms)

52% of respondents to the survey, work in a medical device company classed as an SME, compared with 48% who did not. This question was asked to assess the respondents working in SME companies and their responses to the subsequent survey questions.

5. Has your company begun the process of EU MDR 2017/745 certification, for devices having CE mark certification under the Medical Device Directive?

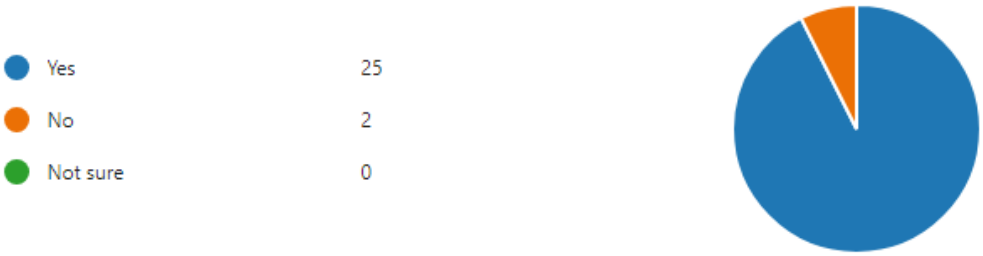

Figure 11 If the survey respondent's company had begun EU MDR certification? (taken from Microsoft Forms)

93% of responses indicated that the survey participants had begun the process of device certification from MDD to MDR.

6. Has your company experienced issues in MDR, CE certification for legacy products previously certified under MDD?

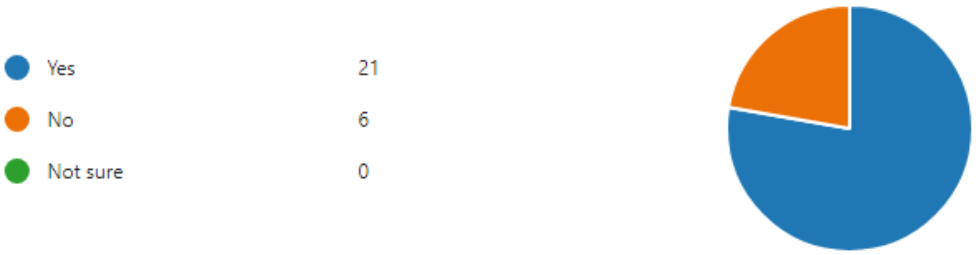

Figure 12 Had the respondent's company experienced issues? (taken from Microsoft Forms)

78% of the 27 survey respondents indicated that their company had experienced issues in regard to MDR CE mark certification of legacy devices.

7. If the answer to question 6 was yes, can you give a brief outline of the issues raised?
    - Staff issues pertaining to extra paperwork for NB
    - Issues surrounding documentation and clinical studies
    - The need for extra documentation and delays in awarding certification. There is also a need to register with NB before end of May causing even more delays
    - clinical studies/documentation
    - Experienced increase length of time for notified body to complete assessment and issue certification
    - Finance
    - Increased costs
    - Increased cost and documentation
    - Extended time dealing with notified body

Figure 13 MDR CE certification issues experienced

The above 9 issues were identified from the 21 survey participants whom answered yes, in the previous question to gain a better understanding of the issues experienced by companies applying for a CE marking for a legacy medical device, under the MDR requirements.

8. Do you think the requirement for sufficient clinical data for legacy devices has an effect on the MDR certification of legacy devices in your company and if yes, is that effect likely to be positive or negative?

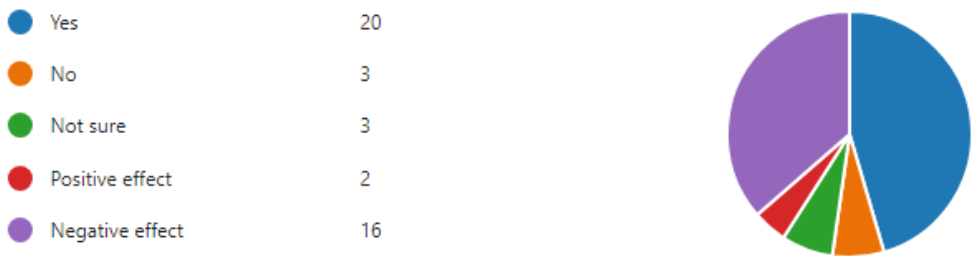

Figure 14 The effect clinical data for legacy devices has on MDR certification (taken from Microsoft Forms)

20 respondents (77%), indicated that they thought the requirement for sufficient clinical data for legacy devices has an effect on the MDR certification of legacy devices in their company, 11.5% indicated no, and 11.5% were not sure. 18 of the 20 respondents that chose the yes answer, indicated a positive or negative effect.16 (89%) respondents indicated that the requirement for clinical data was likely to have a negative effect, with 2 (11%) respondents indicating it was likely to have a positive effect.

9. Does the recently introduced extended transitional provisions from 2025 - 2028, give your company the sufficient time needed to transition devices from MDD to MDR certification?

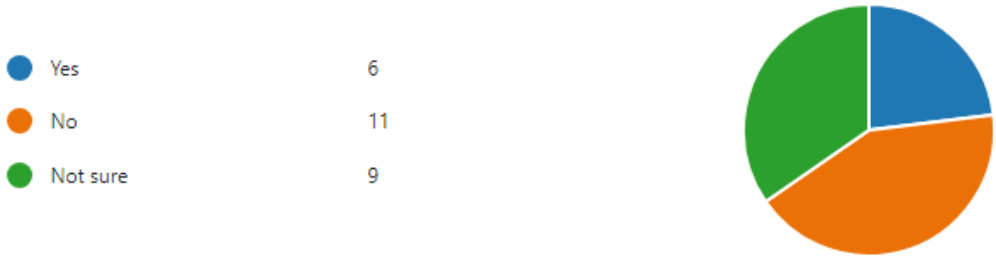

Figure 15 Sufficient time for transition (taken from Microsoft Forms)

23% of respondents indicated that the extended transitional timelines introduced in Regulation EU 2023/607, gave their company sufficient time needed to transition medical devices from MDD to MDR. 42% indicated that the timelines were not sufficient to transition devices, and 35% were unsure.

10. Has your company experienced extra resource issues i.e. costs, staff, in transitioning to MDR CE certification?

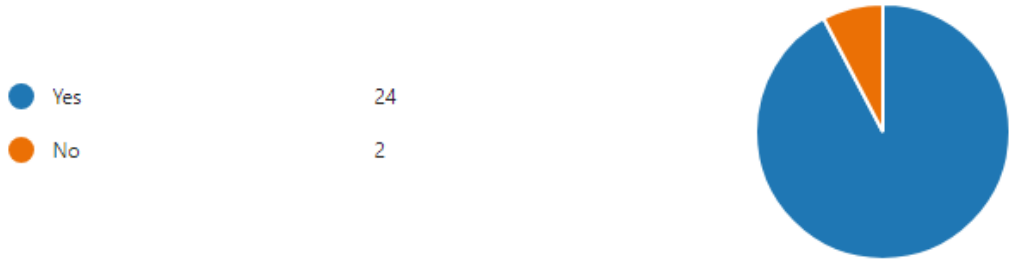

Figure 16 Extra resource issues (taken from Microsoft Forms)

92% of the survey respondents indicated that their company had experienced extra resource issues due to MDR. 8% indicated no extra resource issues.

11. Does Medical Device Regulation EU MDR2017/745 inhibit innovation?

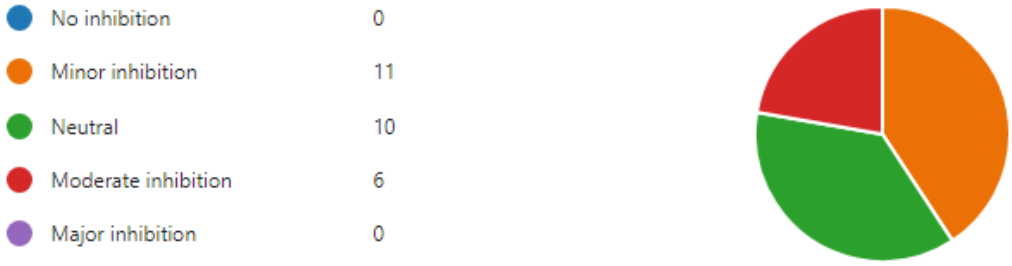

Figure 17 If MDR inhibits innovation? (taken from Microsoft Forms)

Survey respondents indicated their opinion on MDR innovation inhibition, in the following manner. Moderate inhibition 22%, minor inhibition 41%, 37% of respondents were neutral and no respondents opted for major inhibition or no inhibition.

12. How likely are medical device shortages to occur in your company's product pipeline due to the requirements of Medical Device Regulation CE certification?

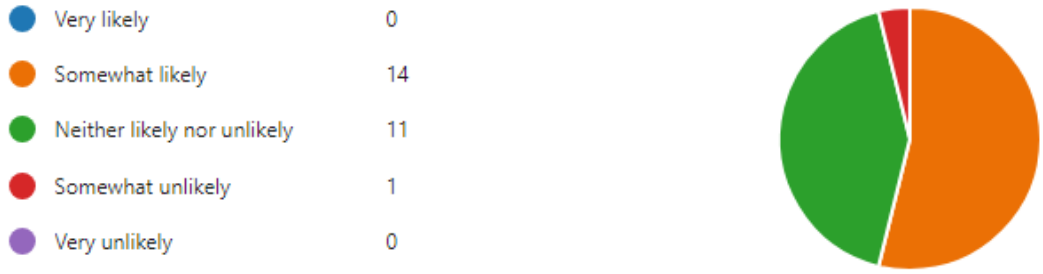

Figure 18 Medical device shortages (taken from Microsoft Forms)

Respondents indicated somewhat likely medical device shortages in their company due to the requirements of MDR CE marking at 54%. Neither likely or unlikely at 42%, and somewhat unlikely at 4%.

This result corresponded with the findings in the secondary data to suggest that medical device shortages is a distinct possibility due to the requirements of the MDR.

13. How likely are medical device discontinuations to occur in your company's product pipeline due to the requirements of Medical Device Regulation CE certification?

Figure 19 Medical device discontinuations (taken from Microsoft Forms)

On the question of medical device discontinuations or withdrawals due to the requirements mandated in the Medical Device Regulation, the perceived occurrence was lower than the perceived occurrence of device shortages. 12% indicated a somewhat likely occurrence, 27% indicated a somewhat unlikely occurrence, and a neither likely or unlikely occurrence indicated by 61% of respondents.

14. What is your opinion on the implementation of the MDR legislation, by the medical device industry?
    - Large organisations are better prepared and have greater economies of scale. Smaller companies have higher relative costs.
    - Treats every device and manufacturer the same, when they are different in many ways

Figure 20 Opinions on MDR implementation

Of the 27 survey respondents, 2 answers were recorded in response to an opinion on the implementation of the MDR legislation.

Larger companies are unlikely to be affected by the MDR legislation requirements. Smaller companies with higher relative costs will be impacted more by the requirements of MDR for device certification. The MDR legislation is generic in nature, in relation to differing devices and manufacturers. (This is the author's interpretation of the actual written response from the survey).

15. Do you have any recommendations regarding the Medical Device Regulation 2017/745 legislation, in relation to the transition of devices from Medical Device Directive to Medical Device Regulation certification?
    - Be aware of forthcoming timelines of May / September 2024
    - Better liaison with stakeholders
    - Liaise with notified body and diligence in documentation submitted

Figure 21 Recommendations on MDR legislation

3 of 27 survey respondents recorded responses to recommendations regarding MDR legislation to device transitioning from MDD to MDR.

One response referred to the extended transition timeline set out in Regulation EU 2023/607, but in order to avail of such extended timelines, manufacturers must register with a Notified Body by 26th May 2024, and have a signed written contract with the Notified Body by 26th September 2024.

There was a need for better stakeholder liaison, to liaise with Notified Body, and diligence surrounding documentation submitted to a Notified Body.

4.1.1 Survey Interpretation – SME Responses v Non-SME Responses

Questions 1 and 2 were provided to record that the survey participant understood the Participant Information Letter, the research, and gave their consent to participate in the survey.

The author found in the secondary research of this study that; SMEs are highly impacted by the requirements of the Medical Device Regulation EU 2017/745. When looking at respondents of the survey employed in SMEs, with 250 employees or less, their responses to questions 5 to 15, are summarised as follows;

SME Responses:

52% of respondents identified as working in a company of 250 employees or less. 93% of the SME companies had begun the process of MDR certification, and 93% of the SME respondents experienced issues in MDR certification of legacy products. When asked to give a brief outline of the issues raised the responses recorded were; staff issues pertaining to extra paperwork for NB, issues surrounding documentation and clinical studies, clinical studies/documentation, finance, increased costs and finally increased cost and documentation.

When asked did the requirement for sufficient clinical data for legacy devices have an effect on certification? 86% recorded a yes response and the effect likely to be negative. 7% indicated with a yes and the final 7% were unsure.

43% of SME respondents indicated that the extended timelines for transitioning devices from MDD to MDR gave sufficient time, 43% said it did not give sufficient time and 14% indicated a not sure response.

93% of SME employees indicated that their company had experienced extra resource issues, such as costs, staff and time in transitioning to MDR CE certification.

In response to the question; does the MDR 2017/745 inhibit innovation? 64% of SME respondents answered minor inhibition, 29% moderate inhibition and 7% neutral.

On the question of medical device shortages and discontinuations in their companies, the SME respondents indicated a 71% somewhat likely device shortage, and a 29% neither likely nor unlikely response for device shortage. For SME device discontinuations, 50% indicated a neither likely nor unlikely response, 29% somewhat unlikely, and 21% indicating a somewhat likely answer to discontinuations.

When asked for an opinion on the MDR legislation, one response was recorded by a respondent employed in an SME, that the legislation treats every device and manufacturer the

same, when they are different in many ways. One response from an SME employee was recorded when asked for recommendations regarding the MDR legislation, the response was; better liaison with stakeholders.

Non-SME Responses:

The responses for the non-SME employees are detailed in the same way as follows:

92% of respondents answered yes when asked had the company begun MDR certification? 8% answered no.

When asked if the company had experienced issues in MDR certification for legacy? 62% indicated they had, compared with 38% who had experienced no issues. When asked to give a brief outline of the issues raised the responses recorded were; extra documentation and delays in certification, increased time taken for Notified Body to complete assessment and issue certification and extended time dealing with notified body.

When asked did the requirement for sufficient clinical data for legacy devices have an effect on certification? 31% answered yes and negative effect, 23% no effect, 15% yes and a positive effect, 15% were not sure, 8% it would have an effect, but declined to say if the effect would be positive or negative.

38% indicated that the extended timelines for transitioning devices gave their company enough time, 31% said it did not, 23% were not sure.

84% of respondents from non-SME companies had experienced extra resource issues in transitioning to MDR, 8% had not. 70% of respondents were neutral on the question of MDR inhibiting innovation, 15% indicated moderate inhibition and 15% minor inhibition.

On the question of medical device shortages and discontinuations in their companies, the non-SME respondents indicated, 54% neither likely nor unlikely, 31% somewhat likely and 8% somewhat unlikely shortages. Device discontinuations; 69% neither likely nor unlikely and 23% somewhat unlikely. These figures indicate little or no device discontinuations from bigger companies and differ from SME figures, where 21% indicated discontinuations.

When asked for opinions and recommendations regarding the MDR, three responses were recorded. Large companies are better prepared with greater economies of scale, smaller companies have higher relative costs. Be aware of forthcoming timelines of May and September 2024 and to liaise with NB and diligence in documentation submitted.

4.2 Interview Profiles and general overview

Interviewee 1:

Interviewee 1 is an academic lecturer and researcher in an Irish University. He has extensive experience and knowledge of the regulation of the medical device industry both in the EU and the US.

Question 1: In your opinion, has the requirement for clinical data in the MDR for legacy devices, impacted the re-certification of such devices, and if so, what is the resultant impact?

Answer 1: SMEs feel overwhelmed by the amount of documentation needed to be read and understood. This includes the Medical Device Regulation legislation, which is 176 pages long and over 100 Medical Device Coordination Group (MDCG) guidance documents.

"Orphan, paediatric and combination products need unique consideration, this is not allowed under MDR as all devices follow the same rules in their risk class grouping." Before Brexit the Medicines and Healthcare products Regulatory Agency (MHRA) gave guidance to manufacturers in the EU when seeking certification for their products under MDR but this has stopped since Brexit.

There are estimated to be 350,000 health and wellbeing apps available from Apple and Google app stores. Many of these apps would be classed as software as a medical device under MDR legislation. These apps are not regulated to the same extent as conventional medical devices, highlighting the disparity of the legislation. Some devices needing unique consideration as outlined in the previous paragraph, and certain digital health technologies operate outside of regulatory assessment.

Question 2: Have medical device SMEs been impacted by the requirements of the Medical Device Regulation and to what extent?

Answer 2: The interviewee agreed that SMEs have been impacted, but to what extent he is unsure. He has heard of medical device companies closing, but unsure if it is because of challenges brought about by MDR or corporate decisions on decreased profits.

The challenges faced by SMEs as a result of the requirements of MDR may lead to market consolidation, as experienced in the pharmaceutical industry.

There are estimated to be 34,000-35,000 medtech companies in Europe. That number will probably decrease, given that SMEs account for a large proportion of those companies. Added

to that are the 350,000 health and wellbeing apps, showing that market strategy and market consolidation has changed the medtech market in the last few decades.

Question 3: In your opinion, has innovation been impacted as a result of the requirements placed upon device manufacturers, in the MDR legislation?

Answer 3: The strategy of SMEs and start-up companies of using the EU market to launch their innovative/new device is dead, because of the requirements placed upon the SMEs by the MDR. Some companies may still choose the EU market to launch their product but most will choose to launch elsewhere as in the US/Canada market. These markets offer a clearer pathway through product assessment and at a fraction of the cost involved for Europe.

The interviewee goes on to explain that there was a lack of hard questioning on the part of the regulators in Europe, when drawing up the MDR legislation, on how to make safe innovation work. The EU legislative body at the beginning of the MDR legislation call out the need to protect safety whilst supporting innovation. The EU do not seem to be applying that principle in a decisive way, and innovation will suffer as a result.

The interviewee makes the point that decisive action needs to be made by the EU on innovation. The question of how do SMEs launch innovative products on the EU market in a safe, economical, and less restrictive way, needs to be looked at in a decisive way by the policy makers in the EU. This will benefit both the SMEs and patients in the EU. He goes on to point out that innovation has indeed been impacted.

The main challenges in obtaining a CE mark certification under the MDR legislation, stems from the fact that the requirement for clinical evidence is unclear. Is there a need for a trial? What kind of trail and is the trial needed before or after device certification? He further highlights that innovation will be curtailed by the legislation, if there is ambiguity surrounding the clinical evidence question.

Question 4: Does the recently introduced extended transitional provisions up to 2028, as set out in EU 2023/607, give manufacturers sufficient time to transition medical devices from MDD to MDR certification?

Answer 4: The interviewee states that the extended timelines give manufacturers sufficient time, but to gain benefit from the extension, the manufacturer must register with a Notified

Body by 26th May 2024 and have a signed written contract with the Notified Body by 26th September 2024.

Several companies have said to the interviewee that they are not going to register with a Notified Body by 26th May 2024, meaning that come the end of September 2024, the company's product can no long be sold in the EU market.

The financial burden for manufacturers of MDR certification must also be looked at. A contributing factor of device shortages and withdrawals is the financial cost of regulation in the EU. "SMEs struggle with the increased financial cost associated with MDR, but start-up companies struggle the most."

The length of time taken for Notified Bodies to carry out conformity assessments and issue certification, took from twelve months to two years during the period 2021-2022. The lack of Notified Bodies designated to carry out MDR conformity assessments during that time was another obstacle encountered by start-up companies. Some companies had to look to other markets for market authorisation or close the company.

Question 5: Are there likely to be medical device shortages in the short to medium term within the EU market?

Answer 5: As outlined in the answer to question 1, the interviewee re-states that there are orphan and paediatric medical device shortages already, and doctors in those areas of medicine face a real challenge to treat patients.

A Medical Device Coordination Group taskforce is to issue guidance on product shortages, but what is really needed according to the interviewee is, much bigger policy interventions. By September 2024, it is his suspicion that more important medical devices will disappear from the EU market. He says "from a public health perspective, when that is the last product type available, we need to have policy that is protecting that product." He proposes a type of amnesty for those devices. The orphan and paediatric devices have little clinical evidence in terms of the MDR requirements to keep them available in the EU market. These devices are only manufactured by a small number of companies, and to comply with the MDR requirements would not be financially viable. Doctors when faced with a patient needing an intervention with one of these devices, would rather have one in a hospital shelf than not have

one available due to legislative policy. He further highlights this point with an example of where paediatric cardiologists from several EU countries had to approach the media to voice their concerns and explain the consequences of the MDR legislation in their profession. He points out that there are several essential products at risk of shortages.

Question 6: Are there likely to be medical device discontinuations in the short to medium term within the EU market?

Answer 6: The interviewee said in terms of device discontinuations, it is hard to know how much medical device discontinuations will happen as a consequence of the MDR requirements and how much of the discontinuations will be attributed to devices with reduced profit margins or other non-regulatory company decisions. Large medtech companies have already gone through MDR regulation with their products, and have made their decisions on products to drop from the market. Next in the queue for MDR certification are the smaller companies and it is harder to predict what devices they will drop from the market, if any.

Question 7: Do you have any recommendations on improvements to the Medical Device Regulation EU 2017/745 legislation, in relation to the transition of medical devices from MDD to MDR CE certification?

Answer 7: After the medical device scandals in the 2010's, the EU legislators decided that every medical device whether existing or new, would have to be certified under the requirements of the Medical Device Regulation. That looked alright on paper, but the practicality of such a bold move was not assessed, as to how it would work in practice. The EU legislators should have put some form of 'grandfathering' in place to exempt existing devices. Not much thought was put into how innovation would be supported through the MDR certification process. The EU Commission carried out an impact assessment of the MDR, but it was not from the manufacturer's perspective. In hindsight, it was a flaw in the drafting process of the MDR.

On the question of recommendations for the medical device Regulation, the interviewee said there is a need to "rethink the basic principles of clinical evidence generation, to start from first principles" and to work out a practical solution that ensures device safety and efficacy, whilst at the same time giving support to innovation, and clarifying when is a clinical trial needed and the type of trial that is needed to generate the desired evidence of safety and efficacy.

Smaller medical device companies, like SMEs and start-ups need guidance and simple solutions when launching a new or innovative device on the market. The regulation of such a device needs to clear and simple, and not place a financial burden on a small company with limited resources. The company also needs clear guidance from the regulators on the route through the regulatory pathway, if need be.

The interviewee reiterates that the EU is not providing clear policy to improve clinical evidence generation, that gives confidence to the doctors and patients that a particular medical device is safe and effective to use.

Under the present MDR legislation, the process of clinical evidence does not provide any new data, but is bound up on extra paperwork, that has grown enormously. The process has made Notified Bodies much bigger than they were under the Medical Device Directive. The interviewee cites an example of BSI a Notified Body designated to carry out conformity assessments against the Medical Device Regulation. He continues, “a few years ago the company would have had 250 employees, now it has 1,000 working on medical device certification, and they are just 1 of 46 Notified Bodies”.

The EU needs to get simple scientific methods into the MDR legislation. It also needs to provide better innovation support. Manufacturers need to be able to get advice on the certification process, be it from a Notified Body or some other entity. The EU is reluctant to allow Notified Bodies give advice, because it is afraid of Notified Bodies creating business for themselves in the form of consultancy to device developers and manufacturers.

Other recommendations the interviewee commented on were; a different policy to ‘grandfathering’, clear principles for clinical evidence and innovation support. These policy changes would go a long way to addressing the issues surrounding the MDR legislation. He does not see these change occurring in the immediate future, and thinks that things will get worse before they get better, in relation to the regulation of medical devices in Europe. He then ponders the question; how long will the EU keep the same Medical Device Regulation policies that do not work, before they must implement policy changes?

Interviewee 2:

Interviewee 2 has worked as a regulatory affairs specialist in the medical device industry, for several years in a Galway based, US multinational company.

Question 1: In your opinion, has the requirement for clinical data in the MDR for legacy devices, impacted the re-certification of such devices, and if so, what is the resultant impact?

Answer 1: The interviewee agreed that the requirement for clinical data for legacy devices in the MDR, impacted the re-certification of such devices. He points out that initially after the MDR came into force manufacturers and Notified Bodies, struggled with what exactly was meant by clinical evidence. Some manufacturers felt that although some of their older products were safe and effective, "the uncertainty was too great and therefore made early decisions to retire some products from their portfolio." Manufacturers found there was a lot of back-and-forth contacts with the Notified Body, when they did submit for legacy devices, about clinical evidence, how it need to be conveyed and if new clinical evidence was needed.

Question 2: Have medical device SMEs been impacted by the requirements of the Medical Device Regulation and to what extent?

Answer 2: "Yes", he points out whilst it was difficult for large medical device multinationals to get their devices certified under MDR, this was multiplied for SMEs. Data from the medical device industry, showed that SMEs struggled to gain access to Notified Bodies initially. Whilst access to Notified Bodies did improve, the wait time did impact on the SMEs initial plans. Feedback from SMEs, indicate that they are mainly concerned with predictability and increased costs.

Question 3: In your opinion, has innovation been impacted as a result of the requirements placed upon device manufacturers, in the MDR legislation?

Answer 3: The interviewee agreed that innovation had been impacted because of the MDR legislation requirements. He points out that existing legacy devices were first in the queue and took up most of the Notified Body capacity, as manufacturers need to get their existing devices re-certified, to keep them on the market in the EU. This situation meant that innovative/new products had to "take a back seat in the queue." Innovation of medical devices suffered as a result.

Question 4: Does the recently introduced extended transitional provisions up to 2028, as set out in EU 2023/607, give manufacturers sufficient time to transition medical devices from MDD to MDR certification?

Answer 4: Interviewee 2 thinks the extended timelines does provide "some short-term relief", but that manufacturers still must go through the full MDR certification process.

Question 5: Are there likely to be medical device shortages in the short to medium term within the EU market?

Answer 5: Device shortages, according to the interviewee is "still an unknown", and various national authorities within the EU, have been tasked with monitoring the situation. Certain product portfolio decisions have been made by companies already, but it is unclear if those decisions will lead to medical device shortages.

Question 6: Are there likely to be medical device discontinuations in the short to medium term within the EU market?

Answer 6: The interviewee agrees that some medical device discontinuations are inevitable. However, as in the medical device shortage question, it is important to make a distinction between discontinuations because of the MDR legislation, and discontinuation of older and less profitable medical devices. Various medical device industry surveys suggest that discontinuations of devices have accelerated, for some product portfolios, due to the MDR legislation.

Question 7: Do you have any recommendations on improvements to the Medical Device Regulation EU 2017/745 legislation, in relation to the transition of medical devices from MDD to MDR CE certification?

Answer 7: The EU has tasked several national authorities to oversee and document medical device shortages and discontinuations, with the Austrian National Public Health Institute, appointed the project lead. Close monitoring of the data is needed to ensure shortages and discontinuations do not pose a risk to public health. The interviewee goes on to point out that "continued dialogue between Notified Bodies and manufacturers and other stakeholders as to 'latest expectations' of where the bar for MDR approval now lies." There needs to be continued

publication from the Notified Bodies of their average review and approval timelines, and continued communications between medical device stakeholders of where MDR issues arise.

4.3 Analysis

The author identified some key themes arising in the survey and interviews. These included the following;

4.3.1 Impact of clinical trials requirements

Both interviewees agreed that certification under MDR has impacted legacy medical devices. The MDR legislation requires that manufacturers of existing devices CE marked certified under MDD, or legacy devices need to show that the device is safe and effective, by means of clinical evidence. The legislation does indicate the exact nature of the clinical evidence needed to confirm to the Notified Body assessing the device, that it is safe and works well to give that device certification, to be placed on the EU market.

This has led to uncertainty amongst manufacturers, as to what evidence is needed to be presented to a Notified Body, to grant certification for that device. Interviewee 1, stated that orphan, paediatric and combination medical devices need unique consideration, under the clinical evidence requirement. This is not possible under the MDR legislation presently, as all devices in their relative risk classes, must follow the same rules.

Interviewee 2, points out that after the MDR came into force, manufacturers, and Notified Bodies struggled with the concept of, what was meant by clinical evidence. This uncertainty led to some manufacturers to drop devices from the company's product portfolio, even though the devices were proven to be safe and effective under the MDD legislation. Manufacturers also came up against increased time taken to certify devices, because of a lot of back-and-forth contacts between manufacturers and the Notified Body, surrounding clinical evidence and what exactly needed to be provided to the Notified Body.

The results for question 8 in the survey also backed up these finding. 20 of 26 respondents felt the requirement for sufficient clinical data for legacy devices, had an effect on MDR certification. If the respondents answered with a yes, indicating an effect, they were then asked if that effect was likely to be positive or negative. 16 of 18 respondents to that positive/negative portion of the question, indicated a negative effect, and 2 of 18 indicated a positive effect on legacy device MDR certification.

4.3.2 Effect on Innovation

Both interviewees agreed that innovation had been impacted negatively by the requirements placed upon medical device manufacturers, in the MDR legislation.

Interviewee 1, stated that the strategy of SMEs and start-up companies, using the EU market to launch their innovative/new devices is no long an option for most of them. Some companies will choose to launch in Europe, but most will decide against it and go elsewhere like the US/Canada market. The interviewee goes on to explain the when the MDR legislation was being drawn up, there was a lack of hard questioning on how to make safe innovation work. At the beginning of the MDR legislation, the EU legislative body call out the need to protect safety whilst supporting innovation. There is a lack of decisive action on the part of the EU, to tackle this issue and other markets for medical devices benefit from European innovative products. He goes on to say that, the question of how do SMEs launch products in a safe, economical, and less restrictive way needs to be looked at in a decisive way by policy makers in the EU. The main challenges in obtaining CE mark certification under MDR legislation, stems from the fact that the requirement for clinical evidence is unclear. He further claims that if there is ambiguity surrounding the clinical evidence requirement, innovation will be curtailed by the legislation.

Interviewee 2 points out that legacy medical devices took up much of the capacity of Notified Bodies when the MDR legislation came into force, as manufacturers scrambled to get their existing device certified under MDR and keep them in the EU market. As a result, innovative and new medical devices “had to take a back seat in the queue,” and because of this innovation of medical devices suffered as a result.

Question 11 in the survey, set out to establish if the Medical Device Regulation legislation inhibits innovation. Of the 27 respondents, 6 indicated moderate inhibition, 11 indicated that there was minor inhibition of innovation due to the legislation and 10 respondents were neutral on the matter.

4.3.3 Impact of MDR legislation on SMEs

Regarding the impact of the MDR legislation on SMEs, both interviewees agreed that the legislation had a negative impact on SMEs and start-up companies.

Interviewee 1 agreed that the MDR legislation has had an impact on SMEs, but to what extent he was unsure. He had heard of medical device companies closing, but did not know if it was due to the legislation or not. He believed that the challenges facing medical device SMEs because of the requirements of MDR, may lead to company closures and market consolidation, as experienced by the pharmaceutical industry. He goes on to say, a that the financial burden for manufacturers of MDR certification, must be examined. A contributing factor of device shortages and withdrawals is the financial cost of regulation in the EU. “SMEs struggle with the increased financial cost associated with MDR, but start-up companies struggle the most.” A lack of access to Notified Bodies by SMEs and start-up companies was another obstacle faced by those companies.

Interviewee 2 points out that whilst it was difficult for large medical device multinationals to get devices certified under the MDR legislation, this was multiplied for SMEs. Highlighting data compiled by the medical device industry, SMEs struggled to gain access to Notified Bodies initially, and that wait time for SMEs to get access to a Notified Body, impacted on the SMEs initial plans. He concludes by saying, feedback from SMEs themselves indicate that their main concerns are predictability and increased costs.

In the survey, 52% of respondents identified as working in an SME, a company of 250 employees or less.

93% of those SME employee respondents experience issues in Medical Device Regulation certification of legacy devices. When asked to give a brief outline of the issues experienced, the recorded responses included; staff issues pertaining to extra paperwork for Notified Body, issues surrounding documentation and clinical studies, clinical studies/documentation, finance, increased cost and increased cost and documentation.

93% of SME employees indicated that their company had experienced extra resource issues, such as finance, staffing and extra time in transitioning device to MDR CE certification.

4.3.4 Medical device shortages and withdrawals

Interviewee 1 indicated that orphan, and paediatric medical device shortages exist already due to the MDR legislation requirements. These devices are manufactured by a very small number of companies, and to comply with the requirement of the MDR. would not be financially viable, and have little in the way of clinical evidence to satisfy the requirements of the MDR to keep them on the market in Europe. In terms of medical device discontinuations, the interviewee, said it is hard to know how much of the device discontinuations in the EU will be attributed to the MDR requirements, and how much will be attributed to devices with reduced profit margins.

Interviewee 2 said that the extent device shortages is still unclear. And that various national authorities within the EU have been tasked with monitoring the situation. It is unclear if certain product portfolio decisions made by companies already, will lead to medical device shortages. In terms of product discontinuations, he agreed that some device discontinuations are inevitable. However, it is important to make a distinction between discontinuations because of the MDR legislation, discontinuations of older less profitable medical devices. Various medical device industry surveys suggest that due to the MDR legislation, discontinuations of devices have accelerated for some product portfolios.

In the survey, questions 12 and 13 asked participants how likely are medical device shortages and medical device discontinuations respectively to occur in their company's product pipeline, due to the requirements of the MDR CE certification?

Medical device shortages: 14 of 26 respondents indicated that device shortages occurrence was somewhat likely. 11 of 26 indicated neither likely nor unlikely and 1 of 26 respondents indicated a somewhat unlikely response.

Medical device discontinuations: 3 of 26 respondents indicated that device discontinuations were somewhat likely, 16 of 26 responded with neither likely nor unlikely, and 7 of 26 indicated a somewhat unlikely occurrence.

The survey responses were somewhat in line with the interviewee's responses, in that device shortages are more likely to occur, but medical device discontinuations are still somewhat unclear at the time of writing this study.

Chapter Five Conclusions and Recommendations

This study set out to investigate the impact of the Medical Device Directive EU 2017/745 clinical data requirement for legacy devices, and the transitional provision timelines set out in Regulation EU 2023/607 on medical device manufacturers in Ireland.

The study had four key objectives; firstly,

- to establish the current status regarding obtaining CE mark certification for medical devices. Secondly,
- to determine the status of products needing re-certification under MDR. Thirdly,
- to determine if the manufacturer in their opinion considers the transitional provisions set out under Regulation (EU) 2023/607 is sufficient. And finally,
- to obtain recommendations from industry as to improvements needed to improve the process of MDR certification.

In respect of the first objective the study found the following:

- The current status of medical device manufacturers wishing to obtain CE mark certification for their products under MDR. The introduction of the Medical Device Regulation legislation has impacted the medical device industry in Ireland, in several areas. Large device manufacturers, initially experienced problems with ambiguity surrounding clinical evidence and Notified Body capacity. As capacity grew with the designation of more Notified Bodies, large device companies assessed the products in their product portfolios dropping old non-profitable products and re-certified new and legacy medical devices under MDR certification. The consensus is that large medical device companies have gone through the process of MDR certification with the devices they wish to market in the EU into the future. Whilst the large companies experienced difficulties at first, those companies, because of their size and wealth have not been impacted as negatively by the MDR transitioning process as smaller companies.

  The status for start-up and SME medical device companies due to the introduction of the MDR legislation, is starker, because of their size and limited financial budget. These companies have been impacted negatively to a greater extent, following the introduction of the MDR legislation, than the larger device manufacturers. Start-up and SME companies, initially were overwhelmed by the amount of documentation and

guidance documents. They had very little access to Notified Bodies, and struggled financially. The need for clinical evidence is a real problem for them as the cost is prohibitive for a company with limited financial means.

In respect of the second objective the study found the following:

- The status of products needing re-certification under MDR. Certain products such orphan and paediatric devices are in immediate danger of disappearing from the EU market, because of the need under the MDR legislation to provide clinical evidence to re-certify them and keep them on the market. These devices are manufactured by a small number of companies, have little clinical evidence in terms of MDR requirements, and to comply with the MDR legislation would not be financially viable. Device shortages and discontinuations is somewhat a possibility. The EU have setup a device shortage and withdrawal monitoring process. There is a strong possibility some shortages and withdrawals will occur, but the full extent of such action is unknown at time of writing this study. Innovation has been negatively impacted in the EU, and some start-up and SME companies have launched their innovative/new devices in other markets, due to the prohibitive cost of obtaining market authorisation for the EU market. Larger companies can absorb the increased costs associated with MDR certification and the devices those companies choose to continue to market will be available to EU patients.

In respect of the third objective the study found the following:

- Manufacturers agree that the transitional provisions set out in Regulation EU 2023/607 gives them sufficient time to transition. The problem for manufacturers is, they have to register with a Notified Body by 26th May 2024, and have a signed contract with that Notified Body by 26th September 2024, in order to avail of the extended timelines for their devices. The deadlines are very short for some manufacturers to avail of the extended timelines, and create a bottleneck with Notified Body capacity. Findings in this study point to medical device shortages and discontinuations, because of the this, but the true extent is not known at present.

In respect of the fourth and final objective the study found the following:

- This study set out to obtain recommendations from individuals associated with, and employed in the medical device industry in Ireland, as to improvements needed with the Medical Device Regulation legislation. More work is needed from the EU on

providing a clearer picture for requirements of clinical evidence, and greater guidance from Notified Bodies with manufacturers, with regard to clinical evidence. There is a need for close monitoring of device shortages and discontinuations. Notified Bodies need to publish data on approval timelines and to highlight issues encountered with MDR conformity assessments. Some form of 'grandfathering' or alternative is needed for existing devices, where it is not financially viable to provide clinical evidence. Innovation support is needed to help start-up and SME companies.

Several themes were identified in both interviews and are highlighted with bullet points, and referenced to similar themes detailed in Chapter 2 Literature Review, as follows;

- "The lack of clear rules surrounding the level of clinical evidence need, if previous clinical evidence will suffice, or if new evidence is needed? Clinical evidence uncertainty difficult for large medical device companies and multiplied for SMEs."

In a survey highlighted by (Sojka, et al., 2023), 30% of the companies have products that will need clinical trials in the next five years to stay in the market, and of those 30% of companies nearly half face additional difficulties due to a lack of clinical trial investigators or negative evaluations by investigating ethics committees. The companies had difficulty with interpreting the requirements of the MDR, not alone with the actual legislation text, but with the amount of guidance documents, currently standing at about 100 documents.

The interviews noted that;

- Impact of MDR felt greatest with orphan, paediatric and combination medical devices. At the time of writing this study there are already device shortages and a real challenge for doctors in those areas of medicine. MDR legislation is the cause of medical device shortages and withdrawals experienced by doctors in Europe.

Confirming that point the literature noted;

(MedTech Europe Document Paper, 2022), urges the EU institutions to take immediate and urgent action to address the imminent threat of medical device shortages, and that without immediate action from the EU, the quality of healthcare to patients in Europe would be severely hampered. In a report in Reuters (Fick, 2023b), the European Academy of Paediatrics have asked Brussels to amend the Medical Device Regulation, to prevent the disappearance of

vital medical devices for children, from being withdrawn from the EU market. 23 medical associations wrote to Stella Kyraikides the EU Health Commissioner in June 2023 outlining their concerns.

- Various medical device industry surveys suggest that discontinuations of devices have accelerated, for some product portfolios, due to the MDR legislation.

A survey conducted by (MedTech Europe, 2022), found that greater than 50% of respondents planned to discontinue their devices by up to one-third, across all product categories.

- Big body of documentation to go through and understand, between the MDR legislation and the large amount of MDCG guidance documents. SMEs feel overwhelmed.

The comprehensive documentation surrounding the MDR legislation document and the numerous guidance documents published by the MDCG was highlighted in Chapter 2 by (Vergani & Francisco Marin Barrios, 2023).

- SMEs and start-up companies have been impacted the most by the requirements of the Medical Device Regulation. The main concerns of these companies surrounding MDR are predictability and increased costs.

(Vergani & Francisco Marin Barrios, 2023) further state that according to MedTech Europe, 95% of medical device companies are SMEs. Those SMEs and start-ups in particular are looking to other markets other than the EU due to the increased costs, documentation and the lack of access to Notified Bodies.

The interviewees noted that there was;

- Difficulty gaining access to Notified Bodies. Manufacturers with existing products sought access first, leaving innovative/new products at the back of the queue.

That same theme was referenced in the literature review as follows;

(Ladd, 2023), made reference to the fact that the MDR did not confer ‘grandfathering’ rights on existing devices, and that all product whether new or existing would be subject to the same requirements under the MDR. (Kaule, et al., 2020), outlined the EU proposal to extend the transitional timelines due to pressure on Notified Bodies to get designated to carry out MDR conformity assessments, and the challenge of lack of Notified Body capacity would lead to product shrinkage in the market.

- Medical device companies are closing, but uncertainty whether it is due to MDR requirements, corporate profit decisions and natural attrition of older products. Market consolidation is a distinct possibility.

In an article on their website (VEEVA MedTech, 2024), a statement from Peter Gaines, a Professor at Sheffield Hallam University, in which he estimates that larger device manufacturers will halve their product portfolios, a large proportion, approximately 30% of smaller manufacturers will shut down and the amount of total medical devices withdrawn from the market will be in the region of 50%.

One of the interviewees noted;

- Medical device companies using the EU market to launch devices is dead under MDR.

The need for clinical data and post-market surveillance may hamper innovation of devices for the EU market. The extra costs and resources involved to bring products to market may lead to a slowing of availability of innovative devices (Ladd, 2023).

- Lack of hard questioning by EU regulators as to how to make safe innovation of devices work. There is also a lack of decisive policy making within European law makers.

(Vergani & Francisco Marin Barrios, 2023) maintains that if the one of the aims of the MDR was to ensure that patients and medical device users had a high level of protection and access to devices, then the MDR is counterproductive in its approach, as the literature has shown that shortages and withdrawal of devices from the market has already occurred.

- Lack of consultation with manufacturers to iron out difficulties with MDR certification. The US has a much clearer pathway to device certification and more manufacturer consultation with the regulatory authority.

(Huusko, et al., 2023) states that successfully passing a Notified Body conformity assessment and obtaining CE marking to place on a medical device, can be a real challenge for manufacturers, as so many of them are SMEs with limited resources.

The interviews further highlighted the following points;

- The extended transition timelines set out in Regulation 2023/607, gives device manufacturers short-term relief, but manufacturers must register with Notified Bodies and have a contract in place by 26th September 2024.

Kaule and colleagues (2020) outlines the EU's proposal to extend the initial transition period due to the significant challenges posed by COVID-19 on all stakeholders involved in transitioning devices from MDD to MDR certification, and the pressure on the Notified Bodies to get certified and deal with the increased workload from manufacturers.

- Prohibitive cost of MDR certification, so devices and companies will leave the EU market after September 2024.

The medical associations feel that the transition extension alone will not solve the problem of shortages of vital lifesaving medical devices, because the company's manufacturing the devices are small in size and the cost of compliance is prohibitive for many of them (Fick, 2023b).

- The increased length of time taken for Notified Bodies to carry out conformity assessments. In 2021 – 2022, it took anywhere from twelve months to two years for an assessment to be caried out.

The results of a survey carried out by (MedTech Europe, 2022), stated that it took somewhere between 13-18 months for MDR Notified Bodies to issue certification, double the time under MDD legislation.

One of the interviewees highlighted the point that;

- Paediatric cardiologists from several EU countries have had to resort to going to the media, to explain the consequences of the MDR legislation on their patients.

(Fick, 2022a), describes that doctors have warned the EU Commission that shortages of lifesaving equipment are being caused by the MDR legislation.

- The need to closely monitor medical device shortages and discontinuations overseen by Austrian Ministry of Health.

It was highlighted in the literature review that;

The EU Commission's Directorate-General for Health and Food Safety (DG SANTE), commissioned a European-wide study of manufacturers and authorised representatives in December 2022 to monitor the availability of medical devices on the EU market. It also sets out to monitor shortages in medical devices and to identify the challenges of such device availability and potential solutions to alleviate shortages (HPRA Health Products Regulatory Authority, 2024).

The interviews also noted;

- The need for the EU to do a lot more regarding innovation support.

The literature in support of what was said in the interviews noted;

The challenges faced by SMEs as a result of the introduction of and the transitioning to the Medical Device Regulation cannot be overstated and SMEs will be affected the most from such changes and may lead to reduced innovation of medical devices and in some cases, companies ceasing to trade (Maresova, et al., 2021).

In this research study, the findings of the primary research broadly confirmed the findings in the secondary research. The primary research was somewhat limited by the small number of participants in both the survey and interviews. The author did not work in the medical device industry, and was limited in accessing industry individuals, except for a small number of contacts.

There is scope for a further study to be conducted, with a larger cohort of participants for the primary research, and a comparison made with this study of limited primary research participants. The further study could also investigate the impact of medical device shortages and withdrawals following the passing of the Regulation EU 2023/607 deadlines, for manufacturers to register and have a contract with a Notified Body, in order to avail of the extended timelines in May and September 2024.

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Appendices

Appendix A Survey Questionnaire

An Investigation into the Impact of the MDR Clinical Data Requirement for Legacy Devices & Transitional Provisions set out in Regulation EU 2023/607 on Medical Device manufacturers.

- Required

I would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Ask questions if anything you read is not clear or if you would like more information. Take time to decide whether or not to take part.

WHO I AM AND WHAT THIS STUDY IS ABOUT

My name is Manus Duggan, and I am a student currently undertaking a Masters in Science in Medical Device Technology & Business at Griffith College Dublin. As part of my studies, I am conducting a research study as part of the dissertation module. This study aims to investigate if Irish CE marked medical device manufacturers are being impacted by the clinical data requirement and the transitional timeframe for medical devices certified under the Medical Device Directive, transitioning to Medical Device Regulation.

WHAT WOULD TAKING PART INVOLVE?

If you choose to participate in the study, you will be required to complete a 15-question survey on Microsoft Forms. The survey will be in two parts, part of the survey will involve answering questions using open-ended and close-ended answers. The survey will involve typing your answers to some questions on your recommendations and opinions, into a text box. The survey should take about 5-6 minutes to complete.

WHY HAVE YOU BEEN INVITED TO TAKE PART?

You have been invited to take in this study as a person involved in the medical device industry in Ireland in a regulatory capacity. This gives you a perspective on the medical device industry view in transitioning from MOD to MDR of legacy device products.

DO YOU HAVE TO TAKE PART?

Please note the following points: Participation is completely voluntary;
A decision not to consent will have no adverse consequences;

Consent can be withdrawn at any time without the need for reason, if you need to withdraw, please contact me at, manus.duggan@student.griffith.ie

WHAT ARE THE POSSIBLE RISKS AND BENEFITS OF TAKING PART?

The benefits of participating in the study are; the researcher will analyse and report the findings in the study and gain a greater understanding of transitioning medical devices from MOD to MDR from a regulatory and industry point of view.

As some of the questions asked may be classed as commercially sensitive in nature, the researcher has outlined this a risk. If a participant feels they cannot answer such questions during the survey or interview, they may need to opt-out. Full anonymity is assured and no individual or company will be identified.

WILL TAKING PART BE CONFIDENTIAL?

Confidentiality and anonymity for all participants will be maintained throughout the data collection, storage, analysis of results and write-up of the study. After five years the data will be destroyed as appropriate to the storage medium.

HOW WILL INFORMATION YOU PROVIDE BE STORED AND PROTECTED?

Information collected as part of this study will be stored securely on the researcher's password protected computer and the Griffith College Dublin server and will be handled with complete confidentiality. Access to the information is confined to the researcher, dissertation supervisor and college ethics committee. All data will be stored and protected in accordance with GDPR and data retained post qualification will be retained in accordance with Data Protection requirements and in line with educational institutions in Ireland with high quality and reputable Data Protection Policies for Ethics. The data will be retained for five years after which it will be destroyed.

WHAT WILL HAPPEN TO THE RESULTS OF THE STUDY?

At the end of the data collection process, the results will be collated and analysed for the purpose of inclusion in the researcher's dissertation, and submitted to Griffith College Dublin for academic assessment. Future dissemination of the data for inclusion in publications may occur. All dissertation research projects and their content will be made accessible in the Griffith College library, and could potentially be made available in online e-journals or college research repository.

WHO SHOULD YOU CONTACT FOR FURTHER INFORMATION?

If you do not understand any aspect of this research, or have questions regarding the collection, use, confidentiality and anonymity of the data for this study, please feel free to contact:

Manus Duggan - Researcher, Griffith College Dublin, manus.duggan@student.griffith.ie

I would be most grateful to you if you would consider participating in this study and thank you for taking the time to read this participant information letter.

1. Do you understand the research and the Participant Information Letter? *

Q Yes

Q No

2. Do you consent to participate in this survey? *

Q Yes

Q No

Survey Questions

3. Are you employed in the medical device industry in Ireland?

Q Yes

Q No

4. Is your company classed as a Small & Medium sized Enterprise (SME) with 250 employees or less?

Q Yes

Q No

Q Not sure

5. Has your company begun the process of EU MDR 2017/745 certification, for devices having CE mark certification under the Medical Device Directive?

Q Yes

Q No

Q Not sure

6. Has your company experienced issues in MDR, CE certification for legacy products previously certified under MDD?

Q Yes

Q No

Q Not sure

7. If the answer to question 6 was yes, can you give a brief outline of the issues raised?

8. Do you think the requirement for sufficient clinical data for legacy devices has an effect on the MDR certification of legacy devices in your company and if yes, is that effect likely to be positive or negative?

□ Yes

□ No

□ Not sure

□ Positive effect

□ Negative effect

9. Does the recently introduced extended transitional provisions from 2025 - 2028, give your company the sufficient time needed to transition devices from MDD to MDR certification?

Q Yes

Q No

Q Not sure

10. Has your company experienced extra resource issues i.e. costs, staff, in transitioning to MDR CE certification?

Q Yes

Q No

11. Does Medical Device Regulation EU MDR2017/745 inhibit innovation?

Q No inhibition

Q Minor inhibition

Q Neutral

Q Moderate inhibition

Q Major inhibition

12. How likely are medical device shortages to occur in your company's product pipeline due to the requirements of Medical Device Regulation CE certification?

Q Very likely

Q Somewhat likely

Q Neither likely nor unlikely

Q Somewhat unlikely

Q Very unlikely

13. How likely are medical device discontinuations to occur in your company's product pipeline due to the requirements of Medical Device Regulation CE certification?

Q Very likely

Q Somewhat likely

Q Neither likely nor unlikely

Q Somewhat unlikely

Q Very unlikely

14. What is your opinion on the implementation of the MDR legislation, by the medical device industry7

15. Do you have any recommendations regarding the Medical Device Regulation 2017/745 legislation, in relation to the transition of devices from Medical Device Directive to Medical Device Regulation certification?

Interviewee 1:

Question 1: In your opinion, has the requirement for clinical data in the MDR for legacy devices, impacted the re-certification of such devices, and if so, what is the resultant impact?

Answer 1: SMEs feel overwhelmed by the 176-page Medical Device Regulation (MDR) document and over 100 Medical Device Coordination Group (MDCG) guidance documents.

Orphan, paediatric and combination products need unique consideration, this is not allowable under MDR as all devices follow the same rules in their risk class grouping. The Medicines and Healthcare products Regulatory Agency (MHRA), in the United Kingdom did a lot of consultations with manufacturers in the EU, but post-Brexit this does not happen with EU companies.

Digital health technologies have a completely different interaction with regulation. Software development comes from the software community usually and because of their technology exceptionalism, they operate on a develop now, and worry about the regulation later attitude. There are estimated to be 350,000 apps available from the Apple & Google apps stores that come under the umbrella of health and wellness. How many of those would be classed as medical devices or not?

Some medical device companies are feeling the heat from MDR legislation, and others operate in a "wild west" environment. Different challenges all round.

Question 2: Have medical device SMEs been impacted by the requirements of the Medical Device Regulation and to what extent?

Answer 2: Yes, for sure. To what extent? I have heard of companies closing, but do not know if it is because of MDR challenges, or corporate decisions based on decreased profits.

SME challenges may lead to a market consolidation, as exampled by drug manufacturing. In the 1970's drug companies were smaller, but since then regulation has become more complex. Now drug companies must be enormous, as to get a drug to market costs in the region of €1 billion. There are something like 34,000 – 35,000 medtech companies in Europe. That number will probably reduce, you would have to imagine, depending on the way you look at it. You also have 350,000 health apps, so market consolidation and market strategy have changed fundamentally in the last few decades.

The EU-first strategy of medical device companies marketing products in the EU first is dead. Some may choose to go that route, but it is not the open runway it used to be.

You will hear form Enterprise Ireland that their New York office has had numerous companies with no market history, are arriving at their door looking to launch medtech devices in the US market.

On the question of Europe losing competitiveness, it is somewhat similar to the medtech campaign of 2012, entitled 'Don't lose the three'. This was where the medtech industry fought against the adoption of the European Medicines Agency. The industry feared it would lose its three-year competitive advantage from innovative technologies.

What the industry have not stressed is that innovation is fine, but it also must be safe, in order for people to use the product with confidence and that doctors do not take any risks on behalf of their patients, when using the product.

There was a lack of hard questioning on behalf of regulators in Europe, as to how to make safe innovation work. When you read the MDR document, the first recital is about protecting safety and supporting innovation. The EU legislative body do not seem to be applying that principle in a decisive way.

Question 3: In your opinion, has innovation been impacted as a result of the requirements placed upon device manufacturers, in the MDR legislation?

Answer 3: This was covered somewhat in the answer to Question 2.

We must ask ourselves, what do we want by innovation? It is okay having the new products, but when you hear the EU Commissioner for Health in 2023 saying that MDR was introduced because of severe scandals or loss of life in some cases. The legislator or EU Commission wanted to improve medical device safety, and it is very hard to strike a balance between innovation and safety, unless you do it in a very decisive way.

Everything with the Medical Device Regulation is basically a creature of compromise. Under the usual procedure in Europe for drafting legislation, the Commission write the first draft, then the co-legislators the EU Council/Parliament churn over the wording until agreement is reached. From the first draft of the MDR to the final draft there was not a single definition left intact. Everything was changed, and that is a strategy of compromise. It is a difficult strategy to apply if you must keep 27 member states happy, and will not be decisive.

Has innovation been impacted? It has, the EU have set up pilot expert panels to give advice to medtech companies. But the problem is the advice is given confidentially, so the other 34,000 companies do not get to understand the advice given to the one company.

When you pare it all back, a lot of the challenges in the system come from the fact that clinical evidence is still unclear. Do I need a trial? What does the trial look like, and is the trial before or after the CE mark certification from the Notified Body?

In the United States system, those questions are answered more clearly, and the Food and Drug Administration will talk to the companies involved. In Europe you do not have any of that and that is why innovation is challenged. Until the clinical evidence question is sorted out, innovation is curtailed by the legislation.

Question 4: Does the recently introduced extended transitional provisions up to 2028, as set out in EU 2023/607, give manufacturers sufficient time to transition medical devices from MDD to MDR certification?

Answer 4: It is plenty of time, but manufacturers must register with a Notified Body before 24th May 2024, and have a signed contract in place with the Notified Body before 26th September 2024, to take advantage of the extended timeframe set out in Regulation EU 2023/607.

Several companies have said to me that they are not going to apply to the Notified Body by 26th May 2024, so their products are gone come 26th September 2024.

There is a suggestion to include MDR Article 10(a), which would require manufacturers to give six months' notification to the EU, in the event of a product withdrawal. That notification period will not kick-in until after all those products have left the market.

The problem of medical device shortages and withdrawals experienced by doctors currently, is caused by regulation. Usually, regulation is used to solve problems caused by other sources. And it did not ring alarm bells as you would have expected it to be raised to date.

The financial cost of regulation in the EU is also contributing to shortages and withdrawals of devices from the market. An example is a catheter for neo-natal babies, for EU versus US/Canada access. €135,000 quote for Notified Body conformity assessments in the EU for five years market access, compared to $3,000 to get 510(k) FDA approval for lifetime market access in the US/Canada.

SMEs struggle with the increased financial cost associated the MDR. But start-up companies struggle the most. They must build a runway as they call it, to launch a product.

The start-up companies look for financial backing for their product. But that financial backing disappears very quickly with product launch activities and especially when the time to launch is extended, as is the case with back-logs associated with Notified Body assessments.

In 2021-2022, it was taking Notified Bodies anywhere from twelve months to two years to carry out an assessment. The start-up company would be bankrupt at the end of that time. Another problem start-up companies would have encountered during that time was the lack of designated Notified Bodies available. Some start-up companies would approach multiple Notified Bodies, only for the companies to be told that the Notified Body could not take them on and to back to the notified Body in two years' time. The start-up companies had no option but to look elsewhere for market authorisation or fold the company.

It has been a real challenge.

Question 5: Are there likely to be medical device shortages in the short to medium term within the EU market?

Answer 5: There are orphan and paediatric product shortages already, and it is a real challenge for doctors in those areas of medicine.

The Medical Device Coordination Group (MDCG) taskforce is to issue guidance on product shortages, but what is needed is much bigger policy interventions. At the moment it is a waiting game with the EU to see if policy interventions happen by September 2024. By September my suspicion is that more important products will disappear from the shelves. From the public health perspective, when that is the last product type available, we need to have policy that is protecting that product, something like an amnesty.

These are products with not much clinical evidence in terms of the requirements for MDR, but they are products with not much options, and doctors would much prefer to be looking at them on hospital shelves than looking for them. If we are to say that MDR is the source of the problem, and it is, and that is politically difficult but it is true. Then you basically need to do whatever needs to be done to keep them on the EU market.

What happens then is we start taking about derogations under Article 59 of MDR. The trouble with Article 59 is there has only been one EU wide derogation issued under MDR. It was not for an orphan or paediatric product, and it had some regulatory reason for getting an EU wide

derogation. Article 59 was adopted at the start of the COVID-19 pandemic in April 2020. MDR implementation was pushed back from May 2020 to May 2021, because of the outbreak of the pandemic. If Article 59 was kept from 2020, someone in the EU Commission must have been thinking, with such a pandemic we will probably need to exceptionally approve a lot of products. Not a single EU wide derogation was given during the COVID-19 pandemic. That tells you, that whole pathway does not work. So, what we are relying on for September 2024, to keep products on the market by derogations is not working. We need a much higher-level policy intervention to keep products, which cannot be too complex or it will fall apart. It has to be something like an amnesty, only time will tell.

It is very sad that paediatric cardiologists in several European countries have had to go to the media and explain the consequences of the MDR legislation It is very hard for doctors to explain to parents that their child cannot have the surgery performed because of MDR legislation and CE marking of medical devices. There are a number of essential products at risk of shortages.

Question 6: Are there likely to be medical device discontinuations in the short to medium term within the EU market?

Answer 6: In December 2023, the EU published MDCG guidance, MDCG 2023-7 on equivalence. When you read through it, it looks like what was thought about hard and fast rules on equivalence, is being watered down but not sure by how much. It is still not that predictable, but it seems to be a bit more feasible. There is that on one side and we need clearer rules surrounding equivalence and not the same need for clinical studies.

On the other side large medtech companies can look across their product portfolio and calculate to the euro or dollar when an increase in compliance causes that product not to make a profit. The company will then discontinue that product.

For a smaller company it is more of a pragmatic decision that they must make. They have a smaller product portfolio and they may need to sell all the product accessories with the product, so they bundle products and it is harder for them to make those type of decisions to discontinue devices or not.

It is hard to know how much of medical device discontinuations will happen because big medtech is gone through MDR with their products, where smaller companies are next in the queue, as a general trend. Big medtech have made their decision on trimming products, where the smaller companies may or may not trim products, it is harder to predict.

Depending on the product area there are legitimate supply chain challenges.

For example, after the COVID-19 pandemic there was problems with supplies of integrated circuit chips for processors etc. Europe to some extent realised during the pandemic that it was too dependent on China and outside EU sources for basic essential manufacturing. As a result, the EU policy makers are looking at how to turn this situation around, and they have a buzzword for it ‘open strategic autonomy’. This means an EU strategy going forward that does not rely solely on China in the future. On one side you have an EU policy to develop greater EU autonomy, and you have the Medical Device Regulation EU 2017/745 causing problems on the other side, and as two policy approaches, they are not interacting with each other. The EU want to be less dependent on China, but they do not know how to trickle that down to medical device or medtech legislation policy.

Question 7: Do you have any recommendations on improvements to the Medical Device Regulation EU 2017/745 legislation, in relation to the transition of medical devices from MDD to MDR CE certification?

Answer 7: The EU made a presumption in 2017 that every device would be re-certified, and that was probably the tidiest thing for lawyers. But that presumption was not assessed by means of an impact assessment of how it would work in practice. That was probably the original sin in thinking about legacy devices and transitional timelines. The EU should have adopted grandfathering. If we were to say the MDR is a new system, and yet it cannot resolve the legacy of the old system (MDD), and make improvements in clinical evidence or innovation supports in a targeted way. I think that would have been a more feasible way of doing it, and because we would not have to worry about everything changing at once.

Medical device companies operate under very tight quality management processes and approaches, and yet the EU changed every single definition from first draft to final draft in the MDR. Did they all need to be changed? I do not know, but I think it probably added an enormous burden to the medical device industry, simply as a result of not thinking through the impact. There was an impact assessment carried out in 2012 by the EU Commission, but it was not from the manufacturer's perspective. That was an essential flaw as it turns out now.

As to what can be done or recommendations for the Medical Device Regulation. The EU need to rethink the basic principles of clinical evidence generation, and start from first principles and have difficult conversations as part of that discussion. When does the MDR system expect a clinical trial and when is it okay not to have a trial? The trouble is that we think technocratically when we talk about MDR. We get into the detailed wording about the articles contained therein. We have to remember that there is a lot of small companies that do not care about lawyers fighting about Article 61(6) (b), whether products fit into the category of well-established technology, and therefore does not need additional clinical investigations. These smaller manufacturers need simple solutions at the earliest stage, so that the venture capital funding, or public funding can have some confidence that they are backing something with a viable market access strategy. We are now fundamentally different to the US in that regard.

If you see people going to pitch for money, in Europe there is a lot of, it depends on variables and that means the money goes, well I am not backing that. You are not getting €10 million for a lot of it depends. If you go to the US and you say we are going to this kind of study and meet with the FDA, if they are happy, they outline the pathway and it costs $3,000 or $100,000. You can time it down to the month, you know which route to go; 510(k) or PMA, and that is fundable, whereas in Europe it is still not predictable to be confidently fundable, so the money disappears. That means EU competitiveness suffers.

On one side the EU is not doing anything to improve clinical evidence in a methodological way, that will actually give anyone confidence. If you talk to big medtech companies, they have spent hundreds of millions of euro and how much of that has gone into any new trials, that would give a doctor any confidence that things are getting safer. They have not spent any money on that, it is all on paperwork and justification here and there. It is just the same evidence, but the amount of paperwork has grown enormously. The process is incredibly wasteful and, in the end, tax euro must pay for this in the ultimate sense, as it trickles down to taxpayers eventually.

It has made Notified Bodies very big. For example, BSI (a Notified Body), a few years ago would have had 250 employees, now it has 1,000 working on medical device certification, and they are just 1 of 46 Notified Bodies.

The EU have built this enormous megastructure that loves eating technocratic justifications, but unless we get simple scientific methods into the system, it is not going to be in anyway efficient, predictable, or proportionate. So, I think there is a huge job of work to do and there is a lot of behaviours that need to change. We have to stop thinking like lawyers, saying if we change shall to should, things will work out better, It will not.

The EU need to do a lot more on innovation support. Companies should be able to get advice, and the people giving the advice should be able to say, do a trial like that, and that is fine, it does not matter if it is with another Notified Body and that is fine. Europe has not figured it out yet. The EU is afraid of feeding consultancy, as they do not want Notified Bodies to issue advice to companies. But some entity has to issue advice to developers and manufacturers.

I think if you had a different policy to grandfathering, if you had clear principles and methods for clinical evidence, and innovation advice, it would go a long way to addressing the MDR issues. I do not see those kinds of things getting on the radar in the immediate future, so I sadly think that things will have to get worse before they get better. Then the question becomes, how long is the current policy strategy going to last before the EU come up with a course correction?

Interviewee 2:

Question 1: In your opinion, has the requirement for clinical data in the MDR for legacy devices, impacted the re-certification of such devices, and if so, what is the resultant impact?

Answer 1: Yes, it has impacted as follows. Initially it was unclear to manufacturers and notified bodies what the new 'bar' for clinical evidence was. For some older products (although safe and performing), the manufacturers felt that the uncertainty was too great and therefore made early decisions to retire some products from their portfolio. Also, when manufacturers did submit for legacy devices, there was a huge amount of back and forth with their Notified Bodies on exactly how the total clinical evidence needed to be conveyed or if they indeed did need to generate 'new' data.

Question 2: Have medical device SMEs been impacted by the requirements of the Medical Device Regulation and to what extent?

Answer 2: Yes, the uncertainty was difficult for large multinationals and this was multiplied for SMEs. Industry data showed that they struggled to get access to their Notified Bodies initially and while this may now be improved it did impact their initial plans. The SME feedback is that their main concerns are predictability and increased costs.

Question 3: In your opinion, has innovation been impacted as a result of the requirements placed upon device manufacturers, in the MDR legislation?

Answer 3: Yes, in two ways. The first impact was the fact that existing legacy products took up most of the 'capacity' of the manufacturers and the Notified Bodies (as manufacturers needed to get their existing products on the market). This meant that the 'innovative/new' products had to take a back seat in the queue (at both the Notified Body capacity and manufacturers capacity).

Question 4: Does the recently introduced extended transitional provisions up to 2028, as set out in EU 2023/607, give manufacturers sufficient time to transition medical devices from MDD to MDR certification?

Answer 4: I think that it does provide some short-term relief to help transition but manufacturers still need to go through the full MDR certification pathway (both internally and with their Notified Body).

Question 5: Are there likely to be medical device shortages in the short to medium term within the EU market?

Answer 5: This is still an unknown and the various national authorities are trying to get a handle on this. What is known is that certain product portfolio decisions have already been made but it’s unclear if this will lead to shortages.

Question 6: Are there likely to be medical device discontinuations in the short to medium term within the EU market?

Answer 6: Yes, I believe that some discontinuances will be inevitable. It will be important to distinguish between natural attrition of older products and the impact of MDR, however the general narrative from various industry surveys is that discontinuation has accelerated as a result of MDR for some products in their portfolio.

Question 7: Do you have any recommendations on improvements to the Medical Device Regulation EU 2017/745 legislation, in relation to the transition of medical devices from MDD to MDR CE certification?

Answer 7: Close monitoring of the data that is coming from the Austrian authority will be key. Also, continued dialogue between the Notified Body and manufacturers and other stakeholders as to 'latest expectations' of where the bar for MDR approval now lies. Continued publication of average review and approval timelines. Continued communication of where the MDR hurdles may be.

APPENDIX C COMBINED ETHICS FORMS

Innopharma education

GRIFFITH COLLEGE

Ethics Application & Declaration Form

DISSERTATION TITLE: *An Investigation into the Impact of the MDR Clinical Data Requirement for Legacy Devices & Transitional Provisions set out in Regulation EU 2023/607 on Medical Device manufacturers.*

RESEARCHER'S NAME: Manus Duggan

PROGRAMME OF STUDY: MSMDT

SUPERVISOR'S NAME: Rex Coghlan

DECLARATION:
The information in this application form is accurate to the best of my knowledge. I undertake to abide by the principles outlined by Innopharma/Griffith College ethics policy in my research dissertation. I confirm that I have completed a full ethics assessment for my research dissertation as per the college guidelines. I will not begin my primary research until such approval from my supervisor and/or ethics Committee has been obtained.
I pledge to carry out my research according to the Innopharma/Griffith College academic integrity standards. Any results presented in my dissertation will be from my own, original research, I will reference and/or acknowledge any material or sources used in its preparation and I will not plagiarise the work of anyone else.

For Student:

STUDENT SIGNATURE: Manus Duggan

DATE: 23/03/2024

The research contained within this research dissertation proposal has been approved.

For Supervisor:

Ethics Committee Approval Required: Yes ☐ No ☒ N

SUPERVISOR SIGNATURE:R Coghlan

DocuSigned by: REX COGHLAN 3305EA5EB798422...

DATE:1st April 2024

For Ethics Committee (if required):

Ethics Committee Approval Given: Yes ☐ No ☐

ETHICS COMMITTEE MEMBER SIGNATURE:

DATE:

NOTE: Supervisors are responsible for ensuring their students fill in this fonn correctly and that all ethical areas have been considered.

SECTION 1: DESCRIPTION OF RESEARCH STUDY

1 1 Purpose and objectives of research:

I wish to investigate from an Irish medical device industry perspective, the resource burden associated with legacy device MDR certification, and if the current extension timeframe is sufficient to transition the medical devices needing MDR certification to do so in the time specified to avoid device shortages or discontinuation.

Key Objectives

1. To establish the current status regarding obtaining certification for medical devices.
2. To determine the status of products needing re-certification under MDR
3. To determine if the manufacturer in their opinion considers the transitional provisions set out under Regulation (EU) 2023/607 is sufficient.
4. To gain recommendations from industry as to improvements needed to improve the process of MOR certification

1 2 Research methodology:

The research methodology will be both quantitative and qualitative in nature.

A survey of appropriate questions will be distributed online, and semi-structured interviews conducted, as set out in Section 4 and a draft list of the questions are outlined in Section 10 Appendix.

SECTION 2: POSSIBLE ETHICAL ISSUES

Answer* yes' *or 'no' to the following questions.

SUBJECT MATTER

Does the research proposal involve:

Research into specific company activities that would be deemed sensitive or confidential	Yes
Research into politically and/or racially/ethnically and/or commercially sensitive areas	No
Sensitive, personal, professional or corporate issues	No

RESEARCH PROCEDURES

Does the research proposal involve:

Research that might damage the reputation of companies or participants	No
Research that may negatively affect the reputation of Griffith College/Innopharma	No
Use of personal records without consent	No
Use of company data without consent	No
The offer of any inducements to participate	No
Audio or visual recording without consent	No
Using a language other than English	No

PARTICIPANTS

Does the research proposal involve:

People who are not competent and/or fluent in English	No
Does your research group include any of the following vulnerable groups	No

(Adults with psychological impairments; Adults with learning difficulties; Adults under the protection/control /influence of others (e.g. in care/prison); Relatives of ill people (e.g. parents of sick children); Hospital or GP participants recruited in a medical facility; persons under the age of 18)

If you have answered NO to ALL questions, please go straight to Section 4.

If you have answered YES to ANY question in SECTION 2, you must fill in SECTION 3.

SECTION 3: STEPS TAKEN TO AVOID ETHICAL ISSUES

[Only fill in this section if you answered YES to ANY of the questions in Section 3. For example, if you answered yes to including participants who are not fluent in English, you might put forward a plan that offers your survey in two languages to take this into account. Another example could be a study where the researcher wants to include information about the care received by children with a long-term condition but it would not be ethical to approach the children directly but it might be acceptable to instead ask parents questions about their child's care. If these plans are acceptable to your supervisor, you may not need to apply for ethical approval from the Ethics Committee}.

3 1 If your ethics relates to ***Subject Matter,*** outline your action plan to work around any sensitive issues.

Questions will be asked of the participants regarding impact of the **MDR** on their company's product pipeline and possible discontinuation of medical device products. Consent will be sought and anonymity assured of participants, and these will be outlined in the information letter before commencement of survey or interview. A box to be ticked indicating the participants understanding of these issues will be provided before the commencement of the survey or interview.

3 2 If your ethics relates to ***Research Procedures,*** outline your action plan to deal with possible ethical issues in your research procedures.

3 3 If your ethics relates to ***Participants,*** outline how you will protect vulnerable persons or those that do not have English as their first language.

SECTION 4: ABOUT YOUR PARTICIPANTS

4 1 Outline your participant profile and why you have chosen them for this study

Participants will consist of medical device regulatory personnel in Ireland. This participant profile was chosen as personnel in regulatory affairs have the expertise and knowledge of regulatory impacts on existing products and innovation.

4 2 How do you plan to gain access to/contact/approach your participant(s).

I plan to access participants through my LinkedIn profile and through email of industry contacts who work in the medical device regulatory sector. Industry contacts will be asked for consent to conduct an interview, if they are willing to do so.

SECTION 5: INFORMATION, CONSENT AND CONFIDENTIALITY

5 1 **Participant Information Letter (PIL) for participants**

[You must submit an information letter for participants with this application, as part of your appendices document. For online surveys, it is sufficient to include a paragraph summarising and explaining the purpose of the research at the beginning of the survey. In all other research e.g. interviews, phone calls, a PIL should be provided to each participant before they are asked for their consent to take part. A template PIL is available in Moodie].

Please confirm below that your information letter covers:

Description of the research topic and method Details of what participation will involve Rights to anonymity

Confidentiality

Rights to withdraw from the research

The contact details of the researcher and supervisor (if necessary)

5.2 Informed Consent Form (ICF) for participants

Yes Yes Yes Yes Yes Yes

[Informed consent is required for most research. For online surveys, it is sufficient to get the participant to tick two boxes at the beginning of the survey- one to state they understand the research and one to give consent. In all other research

e.g. interviews, phone calls, a signed consent form is required. If the data is gathered online e.g. zoom, a signed consent form can be scanned and sent to the researcher. A template /CF is available in Moodie. The signed /CFs, along with the surveys, audio files or interview notes etc. must be stored in the primary data folder on moodle and can be accessed by lnnopharma staff for the purposes of verifying the authenticity of the research carried out and the data collected].

Please indicate below if your research requires a signed consent form by selecting the relevant option only:

Yes: my research study involves an online survey and interviews, and does require a signed consent form.

SECTION 6: STORAGE OF DATA

[Please ensure that you are abiding by GDPR and the national Data protection Jaws https:l/www.hrb.ie/fundinglqdpr- quidance-for-researcherslqdpr-and-hea/th-research/).

The student is responsible for storage of data and this will be handed over to the college in an electronic format as part of the thesis submission i.e. primary data and completed /CFs where applicable will be added to the primary data folder on mood/e. The rationale is to keep data as long as it is still useful and there is an intention to use it further for research so if this is not the case then this can be stipulated here and a shorter retention period given.]

How will you store the research data and for how long? How will you manage data protection issues?

The data will be stored safely and securely on the researcher's computer and the college's secure server for data authentication purposes. It will only be accessed by the researcher and the college in line with GDPR and ethical considerations. The data will be kept for five years post-qualification. All primary data held by the researcher on the study will be destroyed after the retention period of 5 years.

SECTION 7: NON-DISCLOSURE AGREEMENT & STUDENT CONSENT

7 Non-Disclosure Agreement (NOA)

Will the final dissertation contain any information pertaining to any source what would warrant the use of a Non- Disclosure Agreement (NOA) e.g. industry-based research?

No

2 Student consent

If a Non-Disclosure Agreement (NOA) is not required, does the student consent to allow their completed dissertation to be held/published by lnnopharma/Griffith College?

Yes

SECTION 8: RECORDING AND RETENTION OF DISSERTATION VIVA

8 Viva Recording

The Dissertation viva will be recorded. This recording may be used to facilitate assessment by lnnopharma staff, a third reader if necessary and/or if requested by the external examiner for the Programme. The recording will be held in line with current GDPR guidelines and will not be made publicly available.

SECTION 10: APPENDIX

GRIFFITH COLLEGE

Participant Information Letter

An Investigation into the Impact of the MDR Clinical Data Requirement for Legacy Devices & Transitional Provisions set out in Regulation EU 2023/607 on Medical Device manufacturers.

I would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Ask questions if anything you read is not clear or if you would like more information. Take time to decide whether or not to take part.

WHO I AM AND WHAT IS THE STUDY IS ABOUT

My name is Manus Duggan, and I am a student currently undertaking a Masters in Science in Medical Device Technology & Business at Griffith College Dublin. As part of my studies, I am conducting a research study as part of the dissertation module. This study aims to investigate if Irish CE marked medical device manufacturers are being impacted by the clinical data requirement and the transitional timeframe for medical devices certified under the Medical Device Directive, transitioning to Medical Device Regulation.

WHAT WOULD TAKING PART INVOLVE?

If you choose to participate in the study, you will be required to complete a 15-question survey on Microsoft Forms. The survey will be in two parts, part of the survey will involve answering questions using open-ended and close-ended answers. The survey will involve typing your answers to some questions on your recommendations and opinions, into a text box. The survey should take about 5-6 minutes to complete.

A number of interviews will also be conducted, using a number of semi-structured questions and audio recordings of the interviews will be used to transcribe the interview later.

WHY HAVE YOU BEEN INVITED TO TAKE PART?

You have been invited to take in this study as a person involved in the medical device industry in Ireland in a regulatory capacity. This gives you a perspective on the medical device industry view in transitioning from MDD to MDR of legacy device products.

DO YOU HAVE TO TAKE PART?

Please note the following points: Participation is completely voluntary;

- A decision not to consent will have no adverse consequences;
- Consent can be withdrawn at any time without the need for reason, if you need to withdraw, please contact me at, manus.duggan@student.griffith.ie

WHAT ARE THE POSSIBLE RISKS AND BENEFITS OF TAKING PART?

The benefits of participating in the study are; the researcher will analyse and report the findings in the study and gain a greater understanding of transitioning medical devices from MDD to MDR from a regulatory and industry point of view.

As some of the questions asked may be classed as commercially sensitive in nature, the researcher has outlined this a risk. If a participant feels they cannot answer such questions during the survey or interview, they may need to opt-out. Full anonymity is assured and no individual or company will be identified.

WILL TAKING PART BE CONFIDENTIAL?

Confidentiality and anonymity for all participants will be maintained throughout the data collection, storage, analysis of results and write-up of the study. Non-anonymised data in the form of signed consent forms and audio recordings for interviews will be collected and retained as part of the research process for a maximum of five years. After the five years the data will be destroyed as appropriate to the storage medium.

HOW WILL INFORMATION YOU PROVIDE BE STORED AND PROTECTED?

Information collected as part of this study will be stored securely on the researcher's password protected computer and the Griffith College Dublin server and will be handled with complete confidentiality. Access to the information is confined to the researcher, dissertation supervisor and college ethics committee. All data will be stored and protected in accordance with GDPR and data retained post qualification will be retained in accordance with Data Protection requirements and in line with educational institutions in Ireland with high quality and reputable Data Protection Policies for Ethics. The data will be retained for five years after which it will be destroyed.

WHAT WILL HAPPEN TO THE RESULTS OF THE STUDY?

At the end of the data collection process, the results will be collated and analysed for the purpose of inclusion in the researcher's dissertation, and submitted to Griffith College Dublin for academic assessment. Future dissemination of the data for inclusion in publications may occur. All dissertation research projects and their content will be made accessible in the Griffith College library, and could potentially be made available in online e-joumals or college research repository.

WHO SHOULD YOU CONTACT FOR FURTHER INFORMATION?

If you do not understand any aspect of this research, or have questions regarding the collection, use, confidentiality and anonymity of the data for this study, please feel free to contact:

Manus Duggan - Researcher, Griffith College Dublin, manus.duggan@student.griffith.ie

I would be most grateful to you if you would consider participating in this study and thank you for taking the time to read this participant information letter.

GRIFFITH COLLEGE

Consent to take part in research

An Investigation into the Impact of the MDR Clinical Data Requirement for Legacy Devices & Transitional Provisions set out in Regulation EU 2023/607 on Medical Device manufacturers.

The researcher retains one copy signed by both themselves and the participant. The participant should also receive a copy of consent form as a record of what they have signed up to.

- I voluntarily agree to participate in this research study

- I understand that even if l agree to participate now, I can withdraw at any time or refuse to answer any question without any consequences of any kind

I understand that I can withdraw permission to use data from my interview within two weeks after the interview, in which case the material will be deleted.

I have had the purpose and nature of the study explained to me in writing and I have had the opportunity to ask questions about the study

I understand that participation involves being asked a series of questions and the interview audio recorded, in order to transcribe the answers

- I understand that I will not benefit directly from participating in this research

I understand that all information I provide for this study will be treated confidentially I understand that in any report on the results of this research my identity will remain anonymous. This will be done by changing my name and disguising any details of my interview which may reveal my identity or the identity of people I speak about.

- I agree to my interview being audio-recorded.

I understand that disguised extracts from my interview may be quoted in the researcher's dissertation, Griffith College Library, Innopharma Education Repository. At a later date, the extracts may be used in conference presentation, published papers, and ejournals.

If data is coming from within one company or specifically pertaining to the one company. I understand that I will adhere to all of the codes of conduct and employee confidentiality for the company, and there is no expectation to breach these by partaking in this research. Include a signed confidentiality statement between researcher and company if deemed necessary.

I understand that signed consent forms and original audio recordings will be retained in the researcher's computer, for 5 years and on the Griffith College Dublin server, until the Griffith college exam board confirms the result of the dissertation. In both cases the information will be securely stored using password protection.

I understand that a transcript of my interview in which all identifying information has been removed will be retained for 5 years by the researcher, from the date the College exam board confirms the result of the researcher's dissertation.

I understand that under freedom of information legalisation I am entitled to access the information I have provided at any time while it is in storage as specified above.

I understand that I am free to contact any of the people involved in the research to seek further clarification and information.

Researcher Details

Name:

Degree Programme: College Details: Contact number: Contact mail:

Manus Duggan

M.Sc. in Medical Device Technology & Business Griffith College Dublin, South Circular Road, Dublin 8 087-9074123

manus.duggan@student.griffith.ie

Signature of participant

/Full Name -Printed}

Signature of research participant

Date

Signature of researcher

I believe the participant is giving informed consent to participate in this study

Date

Signature of researcher

Questionnaire Section

1. Question

Do you understand the research and the Participant Information Letter?

Answer

2. Question

Do you understand the research and the Participant Information Letter?

Yes No

Do you consent to participate in this survey?

Answer Yes No

3. Are you employed in the medical device industry in Ireland? Yes No

4. Is your company classed as a Small & Medium sized Enterprise (SME) with less than 250 employees?

Yes No Not sure

5. Has your company begun the process of MDR certification for devices, having CE mark certification under the MDD legislation?

Yes No Not sure

6. Has your company experienced issues in MDR CE certification for legacy products previously certified under MOD?

Yes No

7. If the answer to question 6 was yes, can you brief outline of the issues raised

8. Do you think the requirement for sufficient clinical data for legacy devices has an effect on MDR certification of legacy devices in your company?

Yes No Not sure

If Yes, please enter general type of issue raised

9. Do the recently introduced extended transitional provisions from 2025 - 2028, give your company sufficient time needed to transition devices from MOD to MOR certification? Yes No Not sure

10. Has your company experienced extra resource issues in transitioning to MOR CE certification?

Yes No

11. Has innovation of new devices in your company been affected by the requirements of the Medical Device Regulation EU 2017/745

No affect, Minor affect, Neutral, Moderate affect, Major affect

12. How likely are medical device shortages to occur in your company's product pipeline due to the requirements for CE certification in the Medical Device Regulation?

l.Unlikely 2. Neutral 3. Likely

13. How likely are medical device discontinuations to occur in your company's product pipeline due to the requirements for CE certification in the Medical Device Regulation?

1.Unlikely 2. Neutral 3. Likely

14. What is your opinion on the operation of MOR legislation?

15. Do you have any recommendations regarding the Medical Device Regulation, in relation to a ensuring a manufacturer friendly transition of devices from MOD to MOR certification?

APPENDIX D SURVEY QUESTIONNAIRE RESULTS

Id	Start time	Completion t	Email	Nam	Do you un	Do you con	Are you em	Is your com	Has your c
1	#########	##########	anonymous		Yes	Yes	Yes	Yes	Yes
2	4/15/24 15:	4/15/24 15:2	anonymous		Yes	Yes	No	No	No
3	4/17/24 18:	4/17/24 18:4	anonymous		Yes	Yes	Yes	Yes	Yes
4	4/17/24 18:	4/17/24 18:4	anonymous		Yes	Yes	Yes	No	Yes
5	4/17/24 19:	4/17/24 19:0	anonymous		Yes	Yes	Yes	Yes	Yes
6	4/17/24 19:	4/17/24 19:1	anonymous		Yes	Yes	Yes	No	Yes
7	4/18/24 14:	4/18/24 14:1	anonymous		Yes	Yes	Yes	Yes	Yes
8	4/18/24 20:	4/18/24 20:2	anonymous		Yes	Yes	Yes	No	Yes
9	4/18/24 21:	4/18/24 21:5	anonymous		Yes	Yes	Yes	No	Yes
10	4/19/24 8:2	4/19/24 8:29	anonymous		Yes	Yes	Yes	Yes	Yes
11	4/19/24 13:	4/19/24 13:4	anonymous		Yes	Yes	Yes	Yes	Yes
12	4/19/24 15:	4/19/24 15:2	anonymous		Yes	Yes	Yes	No	Yes
13	4/19/24 15:	4/19/24 15:4	anonymous		Yes	Yes	Yes	Yes	Yes
14	4/19/24 15:	4/19/24 15:5	anonymous		Yes	Yes	Yes	Yes	No
15	4/19/24 18:	4/19/24 18:3	anonymous		Yes	Yes	Yes	Yes	Yes
16	4/20/24 12:	4/20/24 13:0	anonymous		Yes	Yes	Yes	No	Yes
17	4/20/24 13:	4/20/24 13:3	anonymous		Yes	Yes	Yes	Yes	Yes
18	4/21/24 19:	4/21/24 19:5	anonymous		Yes	Yes	Yes	No	Yes
19	4/22/24 16:	4/22/24 16:5	anonymous		Yes	Yes	Yes	No	Yes
20	4/22/24 16:	4/22/24 17:0	anonymous		Yes	Yes	Yes	Yes	Yes
21	4/22/24 17:	4/22/24 17:0	anonymous		Yes	Yes	Yes	No	Yes
22	4/27/24 0:4	4/27/24 0:49	anonymous		Yes	Yes	Yes	No	Yes
23	4/27/24 15:	4/27/24 15:3	anonymous		Yes	Yes	Yes	No	Yes
24	4/27/24 17:	4/27/24 17:5	anonymous		Yes	Yes	Yes	Yes	Yes
25	4/29/24 17:	4/29/24 18:0	anonymous		Yes	Yes	Yes	Yes	Yes
26	4/29/24 19:	4/29/24 19:2	anonymous		Yes	Yes	Yes	Yes	Yes
27	4/29/24 20:	4/29/24 20:2	anonymous		Yes	Yes	Yes	No	Yes

Has your c
Yes
No
Yes
No
Yes
Yes
Yes
No
No
Yes
Yes
Yes
Yes
No
Yes
Yes
Yes
Yes
Yes
Yes
Yes
Yes
Yes
No
Yes
Yes
Yes
Yes

If the answer to question 7 was yes can you give a brief outline of the issues raised?
Staff issues pertaining to extra paperwork for NB
Issues surrounding documentation and clinical studies
The need for extra documentation and delays in awarding certification. There is also a need to register with N
clinical studies/documentation
Experienced increase length of time for notified body to complete assessment and issue certification
Finance
Increased costs
Increased cost and documentation
Extended time dealing with notified body

Do you think the requireme	Does the r	Has your c	Does Medical Device Re	How likely are medical device
Yes;	No	Yes	Neutral	Neither likely nor unlikely
			Moderate inhibition	
Yes;Negative effect;	Not sure	Yes	Minor inhibition	Somewhat likely
No;	Not sure	Yes	Neutral	Neither likely nor unlikely
Yes;Negative effect;	Not sure	Yes	Minor inhibition	Neither likely nor unlikely
Yes;Negative effect;	No	Yes	Minor inhibition	Somewhat likely
Yes;Negative effect;	Not sure	Yes	Minor inhibition	Somewhat likely
Not sure;	Not sure	Yes	Moderate inhibition	Somewhat likely
Yes;Positive effect;	Yes	Yes	Neutral	Somewhat likely
Yes;Negative effect;	Not sure	Yes	Minor inhibition	Somewhat likely
Yes;Negative effect;	No	Yes	Minor inhibition	Neither likely nor unlikely
Yes;Positive effect;	Not sure	Yes	Neutral	Neither likely nor unlikely
Yes;Negative effect;	No	Yes	Moderate inhibition	Somewhat likely
Not sure;	Not sure	No	Minor inhibition	Neither likely nor unlikely
Yes;Negative effect;	No	Yes	Minor inhibition	Somewhat likely
Yes;Negative effect;	No	Yes	Neutral	Neither likely nor unlikely
Yes;Negative effect;	No	Yes	Moderate inhibition	Somewhat likely
No;	Yes	Yes	Neutral	Neither likely nor unlikely
Yes;Negative effect;	No	Yes	Minor inhibition	Somewhat likely
Yes;Negative effect;	No	Yes	Minor inhibition	Somewhat likely
Not sure;	No	Yes	Neutral	Somewhat unlikely
Yes;	Yes	Yes	Neutral	Neither likely nor unlikely
No;	Yes	Yes	Neutral	Neither likely nor unlikely
Yes;Negative effect;	Yes	Yes	Moderate inhibition	Somewhat likely
Yes;Negative effect	Not sure	Yes	Moderate inhibition	Somewhat likely
Yes;Negative effect	No	Yes	Minor inhibition	Somewhat likely
Yes;Negative effect	Yes	No	Neutral	Neither likely nor unlikely

How likely are medical device d
Neither likely nor unlikely
Somewhat unlikely
Neither likely nor unlikely
Neither likely nor unlikely
Neither likely nor unlikely
Neither likely nor unlikely
Neither likely nor unlikely
Somewhat unlikely
Neither likely nor unlikely
Neither likely nor unlikely
Neither likely nor unlikely
Neither likely nor unlikely
Neither likely nor unlikely
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Neither likely nor unlikely
Somewhat unlikely
Neither likely nor unlikely
Somewhat unlikely
Somewhat likely
Somewhat unlikely
Neither likely nor unlikely
Neither likely nor unlikely
Somewhat likely
Somewhat likely
Somewhat unlikely
Neither likely nor unlikely

What is your opinion on the implementation of the MDR legislation, by the medical device industry?

Large organisations are better prepared and have greater economies of scale. Smaller companies have higher

Treats every device and manufacturer the same, when they are different in many ways

Do you have any recommendations regarding the Medical Device Regulation 2017/745 legislation

Be aware of forthcoming timelines of May / September 2024

Better liaison with stakeholders

Liaise with notified body and diligence in documentation submitted