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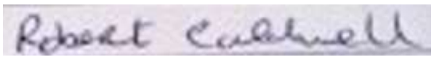

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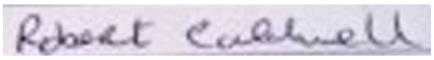
Developing a Strategic Regulatory Framework for Compliance of AI-Enabled Medical Devices under EU MDR 2017/745 and EU AI Act 2024/1689

Candidate Declaration

Candidate name: Robert Caldwell

I certify that the dissertation titled: “Developing a Strategic Regulatory Framework for Compliance of AI-Enabled Medical Devices under EU MDR 2017/745 and EU AI Act 2024/1689” submitted for the Msc in Medical Device Technology & Business (MDT) is the result of my own work and that where reference is made to the work of others, due acknowledgement is given.

Candidate Signature: 

Date: 13/08/2025

Supervisor Name: Dr Áine Behan, PhD

Supervisor Signature:

Date:

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Abstract

Since the enactment of EU MDR and the EU AI Act 1689, Artificial Intelligence enabled medical devices (AIeMD) now must ensure compliance with dual regulatory requirements. This research dissertation examined the current regulatory landscape that exists for developers and deployers of AI enabled medical devices (AIeMD) and sought to identify if the need exists for the development of a Strategic Framework of Compliance for AI enabled medical devices to EU MDR 745, the EU AI Act 1689.

The primary research undertaken consisted of qualitative semi-structured interviews with MedTech industry professionals involved in the research, development, and regulation of AIeMD. A mixed methods approach was undertaken, with the data gathered from an industry survey of similar industry professionals used to compliment or present alternative views to those identified during the thematic analysis.

In addition to this, secondary research was undertaken to assess the current landscape for AI enabled medical device conformity pathways and status of CE marking for a sample of AIeMD in each medical field using the FDA AI Medical Device Database and EUDAMED,A case study of the Medtronic O-Arm Surgical Imaging System which forms part of the “AiBle™” product offering from Medtronic was also used. Finally, a document analysis of EU MDR 745, and the EU AI Act 1689 was conducted to outline areas of harmonisation, and divergence within the two pieces of EU legislation.

This mixed methods approach allowed for the delivery of a comprehensive interpretation of the current regulatory challenges that developers and deployers of AIeMD face, while also presenting the opportunities that AI technology now places on the global healthcare system to achieve the elusive quadruple aims in healthcare. The research revealed a strong lack of, and demand for, harmonised compliance frameworks that aid organisations in navigating a complex regulatory landscape, and the criticality that standards and guidance play in dual regulatory compliance.

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Abbreviations

A.I – Artificial Intelligence

AIeMD - Artificial Intelligence enabled medical devices.

MDAI - Artificial Intelligence as a medical device

SaMD – Software as a medical device

MDR – Medical Device Regulation

AIA – EU AI Act 1689

MDCG – Medical device co-ordination group

Gen AI – Generative AI

LLM – Large Language Model

LLMaMD – Large Language Model as a medical device

GPT – Generative Pre-Trained Transformer

FDA – Food & Drug Administration

ML – Machine Learning

IOT – Internet of Things

1.0 Introduction

The medical device industry now sits on the brink of a transformative shift driven by recent advancements in Artificial Intelligence (AI) technologies, including machine learning, Large Language Models (LLM's), adaptive AI systems and Generative AI. These technologies are poised to revolutionise the healthcare system by enabling faster access, diagnosis, and treatment of patients. The European Commission (2025) states:

"In addressing the complexities of global healthcare challenges, AI is emerging not just as a tool but as a transformative force reshaping how we approach healthcare delivery."

As per the FDA (Food and Drug Administration) AI/ML-Enabled Medical Devices Database there has been in excess of 1,200 AIeMD approved onto the US market since 1995 with the number of devices increasing year on year. The trend shows that over the last 10 years there has been an exponential increase in AI enabled medical devices receiving approval. The medical fields of Radiology, Cardiology, and Neurology make up over 90% of the population of AI enabled medical devices approved by the FDA over the past 30 years (Radiology 77%, Cardiology 9%, Neurology 4%).

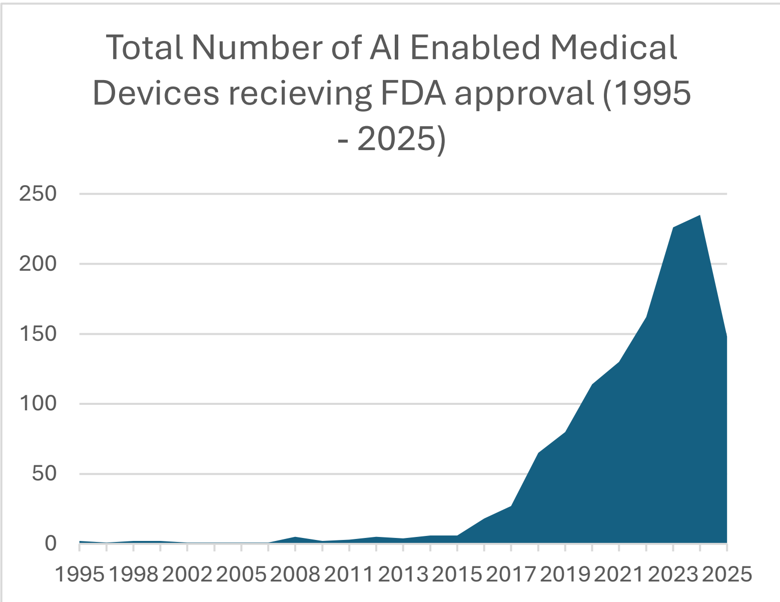


Figure 1 - FDA Approved AI Enabled Medical Devices (1995 – 2025): Image Source FDA AI/ML-Enabled Medical Devices Database

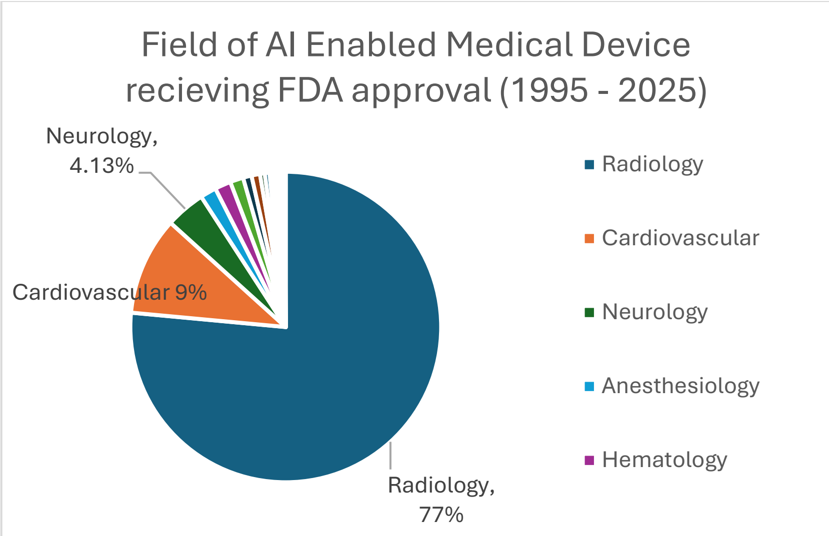


Figure 2 - Medical Field FDA Approved AI Enabled Medical Devices (1995 – 2025): Image Source FDA AI/ML-Enabled Medical Devices Database

The FDA AI/ML database has been introduced to allow for greater transparency over these devices. With the full implementation of the EUDAMED database delayed, coupled with the oversight of including an “AI” or “ML” field, the equivalent search of EUDAMED database could not be completed, however a search for “Software” returns more than 3,000 devices. Considering the global scale of many medical device companies, one can assume that the trend of EU AI enabled medical devices will follow that of its US counterparts. The EU AI Act 1689 now mandates that “High Risk” AI systems be registered on the EU AI Database thus a similar analysis could be completed once this goes database goes live. (St John Lynch *et al.*, 2024)

This rapid technological evolution presents significant regulatory challenges. AI enabled medical devices introduce complexities in relation to data quality, model transparency, human oversight, and post market surveillance activities. At present there are no harmonised regulatory standards guiding the development of such devices (Muehlematter et al., 2021), however many EN Standards are now in development since the introduction of the EU AI Act. These technical standards issued by one of Europe’s approved standard bodies such as CENELEC are used to assist harmonisation between national standards, and European legislation within the member states (Packard, 2024).

The EU Medical Device Regulation (EU MDR) remains the most up to date comprehensive legislative instrument governing medical device safety and performance in the EU, and yet despite this it fails to mention Artificial Intelligence across its 123 articles and 17 annexes. In contrast, the recently enacted EU AI Act 1689 introduces the legal requirements for the research, development and bringing to the market AI technologies across the European Union of which includes AI technology embedded in medical devices. This has created a dual regulatory environment which poses challenges for those medical device manufacturers that must now navigate both MDR and the EU AI act simultaneously. Whilst EU MDR ensures clinical safety, the AI Act addresses algorithmic risk, however the interaction between both remains unclear and untested in practice (Aboy *et al.*, 2024).

While “Safety” remains at the forefront of both these pieces of legislation, patient safety in relation to EU MDR, and public safety with regards to the EU AI Act, they collectively form a complex evolving regulatory landscape, one where innovation must be allowed to flourish, without impacting the public good (Olbrechts, 2024).

This body of research seeks to identify and address whether or not there is a critical industry need for a Strategic Compliance Framework, that will aid medical device manufacturers in the development of AI enabled medical devices in order to adhere to both EU MDR 2017/745 and EU AI Act 2024/1689. With the medical device industry at the forefront of A.I innovation, ensuring regulatory clarity is essential in maintaining patient safety, whilst maximising the beneficial outcomes of adopting the usage of these cutting-edge software technologies. The research has several objectives such as.

- Investigate if the need exists for the development of a Strategic Regulatory Framework for Compliance of AI-Enabled Medical Devices under EU MDR 2017/745 and EU AI Act 2024/1689.
- Present an overview of the current regulatory landscape with regards to AI enabled medical devices in the European and American markets, identifying what complexities exist, if any.
- Identify key compliance challenges in the development of AI enabled medical devices that adhere to EU MDR 2017/745, and EU AI Act 2024/1689.

- Propose areas for harmonisation of EU MDR 2017/745, 21 and EU AI Act 2024/1689.
- Outline examples of what a strategic regulatory framework for compliance with EU MDR 2017/745 and EU AI Act 2024/1689 may contain, such as.
    - Harmonisation Map – A comparison table documenting overlapping and divergent requirements between EU MDR 2017/745 and EU AI Act 2024/1689.
    - A Decision tree or Flowchart – A visual representation that aids organisations in the assessment of which regulatory pathway applies based on elements such as, AI Type, Risk Classification, Adaptability, Post Market Surveillance etc.
    - A Risk Assessment Framework that aids organisations in the identification of AI specific risks
    - A Compliance Checklist – A practical checklist that can be used by organisations to guide them through MDR and AI Act requirements.

The research will consist of a mixed methods approach, using a convergent parallel design, thus enabling concurrent collection of both qualitive and quantitative data from primary sources. The research will be qualitative led with the quantitative research garnered from an industry survey being used to reinforce the themes from interviews with MedTech industry professionals. This approach will support the timeframes in place for this research study and will allow for the triangulation of results from both sources supporting an in-depth understanding of the regulatory complexities in this evolving arena.

2.0 Literature review

2.1 Introduction to the literature review

Over the course of this literature review the researcher will seek to establish the history of AI enabled medical devices, and how recent advancements in AI technology have spurned a new generation of devices. It will involve discussion and critique of current available published literature on the regulatory landscape as it stands around the development of AI enabled medical devices and recognises where areas for harmonisation have already been identified in these two regulations.

The scope of this literature review will be broad to ensure that research carried out on AI enabled medical devices that do not fall under EU MDR or the EU AI act but may fall under the FDA's 21 CFR 820 set of regulations may also be reviewed. Due to the relative newness of the EU AI Act, the amount of research available may be limited, however the concepts, technologies, risks, regulatory complexities and potential benefits of AI enabled medical devices are such that insights gathered from research undertaken on devices outside of the scope of the EU would also be relevant to those devices that do fall under the European legislation.

2.2 The evolution of AI in medical devices and healthcare systems

According to the European Commission (2019) "A.I (Artificial Intelligence) refers to systems that display intelligent behavior by analysing their environment, and taking actions, with some degree of autonomy, to achieve specific goals". These systems can be software based, existing in a virtual domain only, for example Large Language Models (LLM's), speech or facial recognition software's etc. Alternatively, AI can be embedded in physical devices such as robotics, drones, autonomous vehicles, or medical devices. Essentially AI is intelligent software that acts on data to mimic human cognitive function such as learning, and problem solving. The output of which may be virtual, or physical. (Bajwa et al., 2021)

AI enabled medical devices can also be defined as medical devices or medical systems into which some form of Artificial Intelligence has been integrated with the aim of improving diagnostics, treatments, or decision-making processes in a healthcare setting. (Witowski, 2024)

The triple aims in healthcare according to Berwick (2006), are 1. Improve patient experience, 2. Improve population health, 3. Reduce costs These 3 goals were then expanded by Bodenheimer, and Sinsky (2008) by adding an additional goal of improving clinician care and are now referred to globally as the “Quadruple Aim in Healthcare”. Bodenheimer, and Sinsky argued that the “Triple aim” would never be achieved without in tandem addressing the issue of clinician burnout, recognising that the wellbeing of caregivers globally was critical in achieving the other 3 goals of healthcare improvement.

According to Weeks et al (2024) AI is now seen as a viable tool in addressing these 4 aims, and in particular AI enabled medical devices, and AI healthcare systems now offer the healthcare industry methods to improve patient outcomes, improve population health, and reduce healthcare costs through the implementation of these new technologies.

Kaul et al (2020), argues Artificial Intelligence in healthcare has evolved significantly since the first inception of AI by Alan Turing during early 1950’s, when he first coined the phrase “Intelligent Machinery”, not long thereafter John Mc Carthy first spoke about “Artificial Intelligence” during the Dartmouth College summer workshop in 1956 which is now considered the founding event in the field of study in AI. Closely followed by the development of systems during the 1960’s such as “MYCIN” for antibiotic development, and the glaucoma diagnosis software “CASNET”.

Toosi et al (2021), discusses how AI in healthcare has survived two AI winters, the first during the mid 1970’s and subsequently during the late 1980’s. It then finally emerged once again as a viable tool for physicians during the 2000’s, driven by a step change in the capabilities of AI. This was enabled through increased capabilities in computing power and the ability to access larger datasets.

A breakthrough during the mid 2000’s around the area of “Deep Learning” again brought the capabilities of AI assisted healthcare back to the forefront of the industry. Modern applications like IBM’s Watson, and FDA approval of imaging tools such as “Artery’s” presented a vision of a future partnership where AI medical systems work hand in hand with clinicians to achieve the goals of the “Quadruple aims in healthcare”. Today AI enhances the healthcare industry through many methods such as increased accuracy of diagnostics, personalised medicines, workflow efficiency, and Adaptive AI based medical devices with the capability to adapt in real time to patients. (Chakraborty *et al.*, 2023)

The recent rise of software intended for use in the healthcare industry, as a direct medical device without an accompanying physical device also known as Software as a Medical Device (SaMD), offers up new opportunities for diagnosis, treatment, and patient care. SaMD coupled with recent advancements in 5G availability, IOT technology, and an uptake in the concept of “Self Managed Healthcare” where patients no longer relying solely on physicians to manage medical issues and have taken a greater ownership over their own healthcare. These recent changes, coupled with the rise in AI enabled medical devices, and AI assisted healthcare systems, now present us with a transformative force in healthcare (Medloft, 2024)

EU MDR sets clear requirements for SaMD around the areas of Risk classification, Clinical Evaluation, and Post Market Surveillance, along with the requirement to bear its own UDI. However, it fails to offer the same clarity to AI enabled medical devices which has been seen to lead to skepticism on the future of AI enabled medical devices among physicians due to regulatory ambiguity. (Khan *et al.*, 2023)

Hermon et al (2021), maintain that Software as a Medical Device SaMD lacks a consensus view in research and that it remains highly contextual, allowing for ambiguity. In addition, they argue that the industry could benefit from clearer regulations and terminology with regards to SaMD.

According to Laï et al (2020), who studied 40 stakeholders within the AI healthcare realm in France, many physicians remain cautiously optimistic of the capabilities of AI enabled medical devices, and AI assisted healthcare, emphasising patient care, safety, regulatory unclarity, and the overpromise of exaggerated media narratives. The report highlights the need for interdisciplinary collaboration and transparency, that includes the input of clinicians, developers, and patients in addition to being provided with regulatory clarity and oversight to ensure patient safety remains paramount.

2.3 Current application of AI technology in medical devices

The recent advancements in AI technology for diagnostic devices has enabled improved accuracy, faster diagnosis, and has helped improve patient outcomes as discussed by Dorocka, 2024, during a recent World Economic Forum, Digital Health Leaders forum. Traditionally, diagnostics have relied on the interpretation of results by medical professionals which can lead to variation in outcomes, a recent example is the cervical check scandal that cost the lives of 17 Irish women due to incorrect diagnostic results being communicated (Carswell, 2018). Nonetheless, AI can now help to reduce these instances of misdiagnosis or missed diagnosis due to its capability to analyse large datasets in real time providing consistent data driven insights. The evidence of this is shown in the fact that 3 medical fields of radiology, cardiology, and neurology make up over 90% of FDA approved AI enabled medical devices.

As discussed by Najjar (2023), Radiology, since the inception of the field, has experienced several generational leaps that formed part of the basis of modern medicine as we know it. From the discovery of X-Ray images to its recent integration with Artificial Intelligence this discipline shows that a field rich in data and imaging allows for the use of machine learning, vision systems, and artificial intelligence to be utilised to its full potential.

Contaldo et al (2024), argue that although the promise of AI integrated diagnostics is very high, there is a strong need for regulatory clarity, harmonised EU regulations, and defined liability in the use of AI in diagnostic radiology. Furthermore, they highlighted that there currently exists an accountability void, as current frameworks fail to adequately assign responsibility for the potential harm caused by AI diagnostic devices.

Amann et al (2022), research proposes the idea of integrating AI technologies to the “Clinical Decision Support Systems” to aid healthcare workers in the treatment of patients has the capacity to impact on the quadruple aims in healthcare. Through the application of these AI technologies to the CDSS researchers have now identified the potential to personalise treatments based on larger datasets emulating from the patient, improving speed, and reducing the overall healthcare costs. Lab based, proof of concept projects, have shown promising outcomes. However, in real world scenarios where the application of these technologies has been trialed, researchers are seeing little improvements, this, it is argued, could be due to the suggested course of treatment deviating from the established clinical guidelines for treatment. Healthcare professionals can be hesitant to consider the AI CDSS proposed treatment options and revert to standard pathways. Identifying methods to improve healthcare professionals trust in AI enabled Clinical Decision Support Systems therefore is deemed critical for the adoption of this technology.

Raposo (2025), highlights the importance of "Explainability" when it comes to AI in a healthcare setting. Explainability refers to the capability of an AI system to explain "Why" or "How" it has come to the decision that it has and additionally, make that decision making process easily understandable to physicians.

Explainability can be summarised as, what has the AI system concluded based on these results? Why has it made this diagnosis? What factors influenced this result? and finally, can this result be trusted?

The issue of "Explainability" when it comes to AI enabled medical devices is identified as one which must be overcome to enable widespread adoption of this technology in the CDSS arena. Ultimately, decisions have the potential to effect patients lives, and solving the issue of "Explainability" demands that AI made decisions must be transparent as to how they were arrived at, clinically interpretable, and verifiable by experts. Often described as the "Black Box" issue in AI adoption this refers to inability to access the dataset on which the AI model has been trained, which can cause unease with those using the technology in a clinical setting (Amann et al., 2022).

When it comes to Oncology, the EU has adopted a new model. The European "Beating Cancer Plan" is made up of 2 pillars, pillar 1 Prevention and pillar 2 Early Detection. AI enabled medical devices have been identified as crucial in the success of the plan. Simoens and Schittecatte (2024), highlight how AI technology is now being used in the

CRC (Colorectal Cancer Screening) process. An example of this is currently being studied in Belgium, where the use of an early detection tool for "Non-Invasive pre-symptomatic Cancer detection by liquid biopsy Testing (NICT)" is using AI to sequence the genome in real time. If successful, this innovation could provide a cost-effective, minimally invasive method for cancer screening and early diagnosis using AI technology. However, the authors have highlighted the need for regulatory clarity in the use of AI technologies to assist in the delivery of this plan. Guidance is needed around the areas of explainability, interoperability, and GDPR compliance before the use of AI technology becomes widespread in oncology. Derraz et al (2024), also discusses that AI assisted precision personalised medicine is now a real-world application, in particular in the area of oncology, where AI is being used to personalise drug protocols, adapt dosing in real time, and design targeted cell therapies that now mark a notable step change in cancer treatment beyond standard approaches. However, regulatory bottlenecks, fragmentation, and disconnect between European and FDA approaches to approval pathways are hampering the progress of AI assisted personalised treatments much to the disappointment of patients who view regulators as standing in the way of access to potentially life saving therapies. The report identifies a multitude of systematic regulatory issues, such as outdated legislation, overreach, contraindications, and regulatory complexity, all which are identified as hampering the development of these targeted breakthrough therapies.

Another medical field that has seen advancements due to its integration with AI is that of assisted robotic surgeries Surgeons are now capable of performing minimally invasive surgeries through 3D vision systems and a console, with the patient being operated on by a robot. The "Da Vinci" surgical robot manufactured by Intuitive Surgical represents the biggest selling surgical robot globally over the last number of years (Tindera, n.d, 2024) due mainly to the fact of it being 1st to the market to receive FDA clearance. However, its uncontested crown is now under threat by behemoths of the medical device industry such as Medtronic, Siemens and Smith & Nephew, who are all bringing robotic surgery devices to the market. The integration of AI technologies such as interoperative assistance, image processing, and interoperative feedback now represents the next generational leap in this technology (Iftikhar *et al.*, 2024).

Knudsen et al (2024), discuss how AI enabled robotic surgical devices now have the capability to identify tissues during surgery, automate surgical steps, and provide real time feedback to surgeons in the areas of speed, vibration and accuracy. However, they also highlight the concerns around "Transparency" where the Black Box model of AI training raises concerns with surgeons around trust, along with the large volume of biometric data raising concerns around data management and cyber attacks. They also flag that patient safety may be distorted by commercial pressures.

Farhud and Zokaei, (2021), present the impact that Artificial Intelligence will have, and is having, on the medical device and healthcare industries, illustrating the potential that exists in the not-so-distant future. Furthermore, they argue that an alternative narrative runs concurrently with the lofty promises of medical device manufacturers and futurists, one of cautious optimism.

Although there were many instances where generational leaps have been identified in research and development settings, or delivered in real world clinical applications, through the incorporation of AI technology into medical devices, and medical systems, there were common themes identified in a large proportion of literature. The management of, access to, and safety of large datasets were all raised as common concerns. The risk of large monopolies occurring due to big techs access to large datasets could dwarf the smaller players in the industry. Access to these new cutting-edge technologies by all social demographics was identified as a risk by several researchers, and the need to ensure healthcare equality. The risk of commodification of the patient as a data point instead of a patient also exists as the widespread implementation of this technology accelerates over the coming years. Regulatory concerns were also raised by several of the authors and the need for regulatory clarity, simplification, and harmonisation. This uncertainty has the potential to hamper innovation, trust, and investment.

Gerke (2021), highlights that investor confidence will be impacted by inconsistent or unclear regulatory definitions on what constitutes a AI enabled medical device, risking increasing compliance costs, and difficult market entry points. Matulionyte et al (2022), questions the uncertainty that "Explainability" raises in clinical settings and whether AI enabled medical devices deserve a place in clinical settings if their decisions can not be explained to clinicians and patients alike. The murkiness that is brought on by the lack of transparency through "Black Box" model training may raise concerns around liability, and informed consent. Reddy et al (2019), warns against the "Over Hyping" of the potential benefits of AI enabled medical devices that may lead to situations where Return on Investment is overestimated by ignoring training, data integration, and regulatory costs.

2.4 Current regulatory landscape with respect to AI enabled medical devices

EU Medical Device Regulation (MDR) 2017 745 and In Vitro Diagnostic Regulation (IVDR) 2017 746 are comprehensive European Union Regulations that govern medical devices, and In Vitro Diagnostic devices manufactured in, or sold on the European market. The regulations were published in May 2017, and by May 2024 all devices sold on the European market must comply with EU MDR 2017 745 or IVDR 2017 746. The new regulations replace previous EEC Directives 93/42 EEC and 90/385 EEC respectively and represent the largest overhaul of medical devices in Europe in several decades (European Union, 2017).

This newly enacted regulation sets out a number of key differences versus the previous EE Medical Device Directive. Greater clinical evidence requirements, the introduction of a Unique Device Identification (UDI) process, the need for devices to be registered on EUDAMED database, stricter requirements around post market surveillance, increased scrutiny of device risk classes, and an expanded oversight of the notified bodies in each member state are all additional requirements to EU MDR versus MDD (Nüssler, 2023).

The regulation does not directly reference Artificial Intelligence, however Software as a Medical Device (SaMD) now has a unique definition, the regulation also introduces specific classification rules for SaMD based on its intended use, and potential risk (Medical Device Coordination Group, 2019).

The lack of reference to AI, Artificial Intelligence, or Machine Learning can perhaps be seen as an oversight of the regulation, as a result of this, these cutting edge technologies are regulated under the general frameworks for Software as a medical device (SaMD) and Medical device software (MDSW) This lack of explicit AI terminology has been identified in research papers as a cause for concern around the placing of AI enabled medical devices onto the European market (Li et al., 2023).

Despite the significant overhaul of medical device regulation, EU MDR has faced several criticisms since coming into force. Significant implementation costs, which tend to be more burdensome on smaller manufacturers, along with significant capacity constraints at notified bodies to deal with the new regulations have led to several bottlenecks at implementation. This coupled with increased requirements around clinical evidence, delayed implementation of the EUDAMED database, and tight deadlines have overshadowed the achievements of the regulation's implementation. However, with regards to Artificial Intelligence, the lack of specific regulations, or definitions within EU MDR have led to regulatory uncertainty around emerging technologies such as AI enabled medical devices, Adaptive AI systems, and Machine Learning technologies that are increasingly been identified as a future element of medical devices. (Muehlematter et al., 2021)

In response to lagging legislation governing Artificial Intelligence technologies, the European Union has recently enacted the EU AI Act 2024 1689. This act is recognised globally as the first comprehensive piece of legislation set out to regulate AI in the European Union. It was enacted in early 2024, and sets out a transition period for implementation, with prohibited practices outlawed within 6 months, and the obligations of high-risk products to be implemented by mid 2026. The purpose of the regulation is to.

"Improve the functioning of the internal market by laying down a uniform legal framework in particular, for the development, the placing on the market, the putting into service and the use of artificial intelligence systems (AI systems) in the Union, in accordance with Union values, to promote the uptake of human centric and trustworthy artificial intelligence (AI) while ensuring a high level of protection of health, safety, fundamental rights as enshrined in the Charter of Fundamental Rights of the European Union (the 'Charter'), including democracy, the rule of law and environmental protection, to protect against the harmful effects of AI systems in the Union, and to support innovation. This

Regulation ensures the free movement, cross-border, of AI-based goods and services, thus preventing Member States from imposing restrictions on the development, marketing and use of AI systems, unless explicitly authorised by this Regulation" (Official Journal of the European Union, 2024)

The act applies a risk-based approach. Although it does not directly list 4 risk categories, the framework implies a risk centric structure ranging from prohibited practices to high-risk AI technologies for which mandatory requirements are set out, finally to limited and minimal applications of AI technology for which opt out clauses and general principles of safety and fairness apply respectively.

Medical Devices that incorporate AI technology are classified as "High Risk" due to their requirement to undergo 3rd party conformity assessment, and the potential "significant" impact it could have on a patient's life. AI systems intended to be used as a safety component of a device, or as a product itself which is subject to a 3rd party conformity assessment under sectoral EU Harmonisation legislation such as EU MDR 2017 745 shall be designated as "High Risk" under EU AI Act 2024 1689, thus setting out a number of mandatory requirements in such areas as data quality, accuracy, transparency and human oversight.

The existing empirical evidence suggests both EU MDR, and the EU AI Act represent the most significant pieces of European legislature to be enacted governing the area of AI Enabled medical devices. EU MDR 745 serves as a cornerstone for the governance of medical devices sold and marketed in EU with the aim of ensuring the performance and safety of those devices. While the EU AI Act 1689 represents the legislative framework designed to regulate the development and use of Artificial Intelligence across various sectors within the Union. As with EU MDR, the EU AI Act adopts a risk-based approach to the research, development, and deployment of AI technology within the Union, ensuring it does not stifle innovation, while also safeguarding the fundamental rights of EU citizens and upholding the values of the union. On comparison of the two pieces of legislation, one can identify where gaps are evident, where overlaps in requirements occur, where tensions are apparent, and where there are easily identifiable opportunities for harmonisation between the two regulations (MDCG and AIB, 2025).

EU MDR establishes rules for placing on the market medical devices and their accessories for human use within the European Union. The scope of MDR extends beyond traditional medical devices to those that may be used in cosmetic instances such as liposuction equipment, or colored contact lenses. The expansion of the scope of EU MDR beyond that of EEC 93/42 that it replaces, also includes software that is used in conjunction with a medical device, or software that is used solely as a medical device itself. This change is in recognition of the increased role that digital technologies play within the medical device market. The broadened scope of MDR now ensures that those medical devices with AI functionality that may have previously fallen outside of the traditional definitions are now subject to its requirements (Becker *et al.*, 2019).

The EU AI Act alternatively forms recently established rules for the Union around the development and making available to the market AI systems. It is applicable to those who develop AI systems, and those who deploy AI systems for use within the EU market, regardless of location. Certain exemptions apply such as in instances where the AI system is used solely for R&D purposes, or military use cases (Official Journal of the European Union, 2024).

Key definitions within the legislation can highlight areas of intersection, and deviation. EU MDR describes a medical device as *"any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific purposes, such as the diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease"*, including that of Software which is now used for medical purposes (European Union, 2017).

The EU AI Act defines an AI system as a *"machine-based system that is designed to operate with varying levels of autonomy and that may exhibit adaptiveness after deployment, and that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content, recommendations, or decisions that can influence physical or virtual environments" (Official Journal of the European Union, 2024)*. The broad definition given to an AI system within the AI Act means it is likely to encompass many software based medical devices, or alternatively a physical medical device with a associated software functionality that incorporates AI technology to achieve its medical purpose.

Regarding Risk Classifications, both EU MDR and the EU AI Act take a risk-based approach to safety. EU MDR classifies medical devices into 4 distinct categories based on risk, Class I (low risk), Class IIa and IIb (medium risk) and class III (high risk) based on their potential to cause harm to a patient. The classification applied influences the conformity assessment route and the extent to which the notified body will be required. In contrast the EU AI Act 1689 adopts a risk-based approach and implies distinct risk levels, Unacceptable, high Risk, limited or minimal risk (MDCG and AIB, 2025).

Most AI enabled medical devices will automatically fall into the "High Risk" category of the EU AI Act due to the wording of Recital 50 *"As regards AI systems that are safety components of products, or which are themselves products, falling within the scope of certain Union harmonisation legislation listed in an annex to this Regulation, it is appropriate to classify them as high-risk under this Regulation if the product concerned undergoes the conformity assessment procedure with a third-party conformity assessment body pursuant to that relevant Union harmonisation legislation. Such products are machinery, toys, lifts, equipment and protective systems intended for use in potentially explosive atmospheres, radio equipment, pressure equipment, recreational craft equipment, cableway installations, appliances burning gaseous fuels, medical devices, in vitro diagnostic medical devices, automotive and aviation"* (Official Journal of the European Union, 2024)

Both EU MDR and the EU AI Act demand a robust Quality Management System (QMS) is in place throughout the whole product lifecycle. With regards to EU MDR the QMS covers all stages of device design, manufacturing and post market surveillance, to ensure product safety and performance. The EU AI Act however introduces new specific QMS requirements aimed at AI enabled medical devices including such elements as data quality and management, AI model transparency, bias, and specific risk management processes (MDCG and AIB, 2025).

With regards to compliance both EU MDR, and the EU AI Act require comprehensive technical documentation to demonstrate compliance. EU MDR requires detailed technical documentation that covers such areas as design, manufacturing, risk management, and clinical evaluation data that proves the devices safety and performance compared to the devices intended use. The EU AI Act however introduces requirements beyond MDR for devices that include AI functionality, such as technical documentation on the AI systems architecture, the data that was used for training the model, and explanations of the AI systems decision making process. This additional documentation requirement seeks to address the unique characteristics of AI enabled medical devices. (MDCG and AIB, 2025)

MDR sets out distinct requirements around post market surveillance of medical devices once they are released onto the market that ensures close monitoring of performance and safety. The EU AI Act however goes further and takes a broader focus on areas such as continuous model performance validation, model performance degradation, and ongoing security and data safety monitoring.

Primarily MDR ensures transparency through clear labelling, UDI requirements, instructions for use, and the EUDAMED requirement for device registration. The EU AI Act significantly increases the transparency and human oversight requirements to an extent where it requires the capability of human oversight and intervention, along with the capability to override AI decisions were deemed necessary. It also requires clear and easy to understand information to be provided to the user on the AI systems capability, limitations, and risks, with the aim of fostering trust in the system. (Fink, 2025)

While MDR addresses the requirements for data security within the broader QMS, around data and device software integrity. The EU AI Act introduces more stringent specific requirements around data robustness and cyber security for AI enabled medical devices. It also sets out the requirements around adversarial attacks, such as data corruption or model manipulation across the entire AI system lifecycle from development to deployment to ongoing operation (Nolte and Rateike, 2025).

The potential for AI enabled medical devices and healthcare systems to revolutionise healthcare globally is now more than ever an achievable task, however with great promise comes great responsibility. Through the enactment of the EU AI Act 1689, coupled with the now established Medical Device Regulations (MDR) the industry has two fundamental pieces of European legislation that will govern the AI enabled medical device field as it moves forward into the 21st century, however the role that guidance documents, and standards play in the interpretation of, and hands on operational implementation of these two pieces European legislation cannot be underestimated, so where are they?

There are several standards available that aid organisations in the development of AI enabled medical devices, such as.

- ASME V&V 40 – 2018 / Assessing Credibility of Computational Modelling Through Verification and Validation: Application to Medical Devices
- IEEE 2801 – 2022 / IEEE Recommended Practice for The Quality Management of Datasets for Medical Artificial Intelligence
- AAMI TIR 34971:2023 / Guidance on the application of ISO 14971 to AI and ML

However, only 1 guidance document could be identified that aided organisations in the development of AI enabled medical devices in adherence to EU MDR and the EU AI Act 1689. Recently the MDCG in conjunction with the Joint Artificial Intelligence Board released MDCG 2025-6 that outlines the interplay between EU MDR and the EU AI Act. The researcher has identified this as a research gap and industry need. Industry standards and guidance documents play a critical role in a dual regulatory environment as they can aid in clarifying ambiguity between legislation, provide an official interpretation of broad legal texts, and enhance harmonisation and efficiency. This research aims to identify if the need exists for a framework for compliance in this dual regulatory environment and establish what other potential obstacles stand in the way of AIeMD fulfilling their potential (Aniela and Zapata, n.d).

2.5 Secondary Data Analysis

2.5.1 Overview of current AIeMD market

The AI enabled medical device (AIeMD) market has experienced explosive growth over the past decade, and is poised to grow at a compound annual growth rate (CAGR) of 38% from 2025 to 2030 taking it from its 2024 market size of $26.57bn to $187.69bn by 2030, which will position it as one of the fastest growing sectors within the medical device industry globally. This explosive growth is being driven by advances in machine learning, real time data analytics capabilities, and personalised healthcare, all aiding in the goal to deliver the quadruple aim in healthcare of improved patient, and caregiver experience, faster treatment, and lower costs. (Grand View Research, 2023)

AIeMD's now span a wide range of applications across healthcare, from diagnostic imaging, surgical assistance, remote monitoring, and clinical decision support systems increasing adoption of AI technologies in both clinician and at home settings (Giansanti and Pirrera, 2025)

The exponential growth in healthcare data that will now be available due to the push to implement Electronic Health Records (EHR) wearable biosensors, genome sequencing etc represent an opportunity where AIeMD can develop actionable insights, and aid in clinical decision support (Grand View Research, 2023). Radiology has by far outweighed the medical field in which AI adoption has been most prevalent, accounting for 77% of all FDA approved AIeMD (FDA, 2021). The dominance of Artificial Intelligence technologies in this field is due to several factors,

- Rich availability of data: Because radiology by its nature generates vast amounts of data e.g. X-Rays, MRI scans, CT scans, this makes the field ideal for AI learning models.
- Suitability for pattern recognition: Convolutional neural networks (CNN's) excel at the task of pattern recognition, and identification of anomalies, thus making them ideal for integration into the field of radiology (IBM, 2021)

- Compatibility with workflows: AI systems capability to easily integrate with Picture Archiving and Communication Systems (PACS) aid in reducing radiologist workloads and improving turnaround time (Pollen, 2019)
- Regulatory clarity: Due to the number of AIeMD devices approved in the field of radiology momentum has built up, and with this comes regulatory familiarity and clarity. High performance benchmarks are available thus aiding in regulatory approval through the 510K pathway.
- Acceptance in clinical environments: The rapid acceptance by radiologists of AIeMD has accelerated growth in this field, as clinicians have identified the capabilities of this technology as a second reader of scans (Suri, 2024)

The secondary research conducted for the study involved an analysis of the FDA AI/ML database from which the researcher identified, the medical field and number of AI enabled medical devices that have received FDA clearance under each field. In addition, the researcher also identified a sample device in each field, its FDA approval pathway, FDA Classification, comparative MDR classification, and finally what classification would be applicable un the EU AI Act 1689. The research suggests that of the 1,247 AIeMD's that have received FDA approval from 1995 to May 2025, 90% (1,195) have done so through the 510(K) approval pathway, 3% (36) of the AIeMD's have been approved through De Novo pathway, and finally 1% (16) of the devices have been approved through the Pre Market Approval pathway, see *Figure 3 – Pathway of FDA approved AI enabled medical devices 1995 – 2024 (Source FDA.Gov)*

The FDA AI/ML database was used as the equivalent search could not be completed using the EUDAMED database as it is currently not fully functional. In the instances of the sample devices chosen, the researcher identified that several of the devices had not yet received CE marking, and others of which CE marking had been approved which could still not be identified on the EUDAMED database.

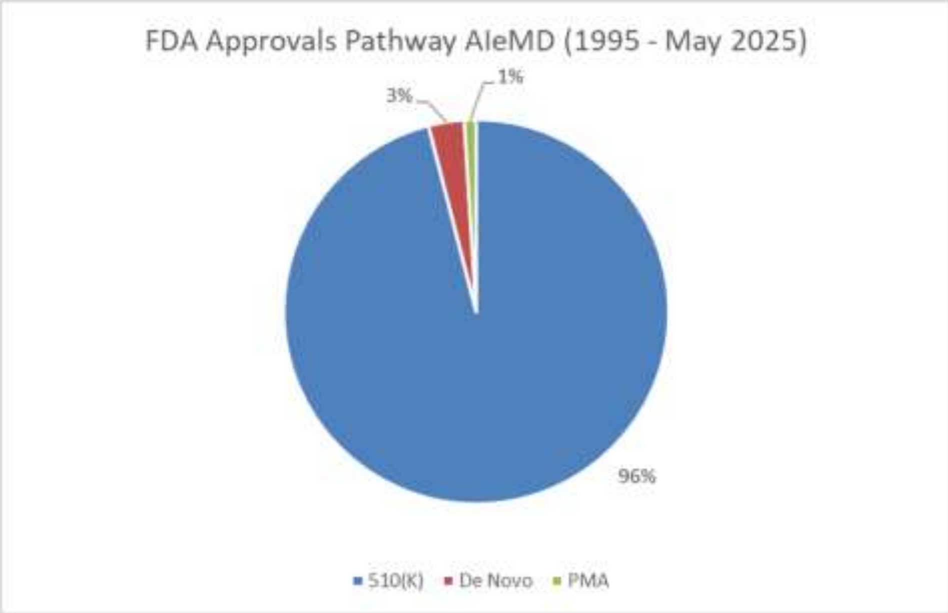


Figure 3 - Approvals pathway for FDA Approved AI Enabled Medical Devices (1995 – 2025)

The aim of this analysis was to research the approvals pathways of a sample device under each field and assess the classification differences that exist under the FDA, MDR / IVDR and AI Act regulations.

A further case study analysis was then undertaken on one of the sample devices identified to outline its history, approval pathway, AI features, and finally identify what additional requirements would not be applicable to the device under the EU AI Act 1689, for the purpose of this secondary research, the device chosen was the O-arm Surgical Imaging System from Medtronic, that falls under the field of "Radiology" with the FDA AI/ML Database.

Medical Field	Number of Devices FDA approved	Sample Device	Organisation	Regulatory Pathway	FDA Class	Year of FDA Approval	Submission Number	CE Marked	MDR Classification	EU AI Act Classification
Gastroenterology/Urology	1	NaviCam ProScan	AnX Robotica	De Novo	Class II	2023	DEN230027	Yes	Class IIa	High Risk
Anesthesiology	22	TipTraQ (TTQ001)	PranaQ	510(K)	Class II	2025	K243268	Not yet CE marked	TBC / Likely Class IIa	TBC / Likely High Risk
Cardiovascular	116	VitalRhythm	VitalConnect	510(K)	Class II	2025	K242129	Not yet CE marked	Could not confirm	TBC / Likely High Risk
Clinical Chemistry	9	DreaMed Advisor Pro	DreaMed Diabetes	De Novo	Class II	2019	DEN170043	Yes	Class IIb	High Risk
Clinical Toxicology	5	BIOPLEX 2200 ANA	Bio-Rad Laboratories	510(K)	Class II	2005	K043341	Yes	Class C (IVDR)	High Risk
Dental	6	X-Guide Surgical Navigation System	Nobel Biocare/X-NAV Technologies	510(K)	Class II	2024	K232148	Yes	Class IIb	High Risk
Gastroenterology-Urology	16	MAGENTIQ-COLO (ME-APDS)	Magentiq Eye LTD	510(K)	Class II	2025	K244023	Yes	Class IIa	High Risk
General & Plastic Surgery	6	NEVISENSE	SciBase	PMA	Class III	2017	P150046	Yes	Class IIa	High Risk
General Hospital	4	SurgiCount+ System	Stryker	510(K)	Class II	2024	K232250	Yes	Class IIa	High Risk

Haematology	19	CellaVision DC-1, CellaVision DC-1 PPA	CellaVision	510(K)	Class II	2020	K200595	Yes	Class B (IVDR)	High Risk
Immunology	1	23andMe Personal Genome Service (PGS) Genetic Health Risk Test for Hereditary Thrombophilia	23andMe	De Novo	Class II	2017	DEN160026	No	N/A	N/A
Microbiology	6	TriVerity	Inflammatix, Inc.	510(K)	Class II	2025	K241676	Not yet CE marked	TBC / Likely Class IIa	TBC / Likely High Risk
Neurology	56	Ahead 300	BRAINSCOPE COMPANY I	510(K)	Class II	2016	K161068	Not yet CE marked	TBC / Likely Class IIa	TBC / Likely High Risk
Obstetrics and Gynaecology	3	PeriCALM Patterns 3.0	PeriGen, Inc.	510(K)	Class II	2025	K241009	Not yet CE marked	TBC / Likely Class IIa	TBC / Likely High Risk
Ophthalmic	10	CLARUS (700)	Carl Zeiss Meditec, Inc.	510(K)	Class II	2025	K243878	Yes	Class IIa	High Risk

Orthopedic	5	Precision AI Surgical Planning System (PAI-SPS)	Precision AI Pty Ltd	510(K)	Class II	2025	K233992	Not yet CE marked	TBC / Likely Class IIb	TBC / Likely High Risk
Pathology	6	Paige Prostate	Paige.AI	De Novo	Class II	2021	DEN200080	Yes	Class C (IVDR)	High Risk
Radiology	956	O-arm O2 Imaging System	Medtronic	510(K)	Class II	2024	K240465	Yes	Class IIb	High Risk

(FDA AI ML Database 1995 – May 2025)

2.5.2 Case Study – O-arm ™ Surgical Imaging System by Medtronic

The O-arm™ O2 Surgical Imaging System by Medtronic is a state-of-the-art 2D/3D imaging system designed for use predominantly during orthopaedic and spinal surgery. The device forms part of the companies Neuroscience product portfolio. The system aids in enabling real time image guided operations through its integration with the StealthStation ™ navigation system. The system also forms part of the AiBLE ™ surgical product ecosystem within the Medtronic product offering (Medtronic, n.d. 2024)

The system is not marketed as a stand alone AIeMD, however several of its software components utilise machine learning, and AI capabilities such as multiple image recognition capabilities, predictive trajectory models through its integration with the StealthStation ™ navigation system, and real time data integration with its surgical instruments (Medtronic, 2025).

The latest device version received FDA clearance in June 2024 under the 510(K) pathways. The device is listed as a Class II Interventional Fluoroscopic X-Ray System in the USA. The device is also available on the European market and is attained CE marking as a Class IIb device in Europe.

Medtronic acquired the device in 2007 from Breakaway Imaging LLC, adding it to their portfolio of image guided surgical solutions (DeGier, 2006). The 2nd generation of the device features faster spin time, improved dose efficiency and higher resolution imaging. The O-arm system is also powered by AI assisted 2D and 3D imaging designed to aid surgeons in highly complex brain, spine, and orthopaedic procedures (Dr. Narayanan, 2025). Some of the standout features of the device include.

- Known-Component Metal Artifact Reduction (KCMAR) is a specialised algorithm, which suppresses this metal artifact on pedicle screws using the “known” geometry of those screws.
- 3D Long Scan is the combination of automatic registration with navigation systems (e.g., Medtronic StealthStation), lateral access to the patient, and a navigated three-dimensional scan of 15-43cm of the patient’s spine.

- Spine Smart Dose feature leverages Machine Learning technology with existing O-arm™ images to achieve reduction in dose on the O-arm™ O2 Imaging System. It is an algorithm designed to reduce the noise of 3D reconstructions acquired from fewer acquisitions so that clinically viable 3D images can be produced using fewer projections.
  (FDA.Gov, 2024)

The device has experienced some regulatory challenges since its launch to market, including:

- Class II Recall (2016)
- Recall Number: Z-1088-2016
- Issue: Loose screws holding the detector panel, causing potential noise, vibration, and poor image quality
- Scope: 1 unit distributed to Austria
- Resolution: Field safety notice issued, service representative inspection and screw torquing

The device is currently marketed on the European market and has an achieved CE marking as a Class IIb device under EU MDR 745. As per Annex VIII Rule 10 *"if they are intended to allow direct diagnosis or monitoring of vital physiological processes, unless they are specifically intended for monitoring of vital physiological parameters and the nature of variations of those parameters is such that it could result in immediate danger to the patient, for instance variations in cardiac performance, respiration, activity of the central nervous system, or they are intended for diagnosis in clinical situations where the patient is in immediate danger, in which cases they are classified as class IIb"* (European Union, Annex VIII Rule 10 2017)

Since the device is a Class IIb under EU MDR it would have had to achieve notified body approval prior to being made available to the European market. Therefore, the device is deemed high risk under the EU AI Act as per the requirements set out in Recital 50 of EU AI Act 1689.

"As regards AI systems that are safety components of products, or which are themselves products, falling within the scope of certain Union harmonisation legislation listed in an annex to this Regulation, ***it is appropriate to classify them as high-risk under this Regulation if the product concerned undergoes the conformity assessment procedure with a third-party conformity assessment*** *body pursuant to that relevant Union harmonisation legislation. Such products are machinery, toys, lifts, equipment and protective systems intended for use in potentially explosive atmospheres, radio equipment, pressure equipment, recreational craft equipment, cableway installations, appliances burning gaseous fuels,* ***medical devices, in vitro diagnostic medical devices****, automotive and aviation" (*Official Journal of the European Union, 2024)

A decision tree for the arrival of manufacturers or deployers of AIeMD may be as follows.

- MDR 745 Class: Class IIb / Rule 10
- CE Marked: Yes
- Use Case: Real time surgical image processing.
- Notified body approval: Yes.
- 3rd Party Conformity Assessment: Yes
- EU AI Act 1689 Classification: High Risk as per Recital 50 and Article 6
    - *"Irrespective of whether an AI system is placed on the market or put into service independently of the products referred to in points (a) and (b), that AI system shall be considered to be high-risk where both of the following conditions are fulfilled:*
      (a) the AI system is intended to be used as a safety component of a product, or the AI system is itself a product, covered by the Union harmonisation legislation listed in Annex I.
      (b) the product whose safety component pursuant to point (a) is the AI system, or the AI system itself as a product, is required to undergo a third-party conformity assessment, with a view to the placing on the market or the putting into service of that product pursuant to the Union harmonisation legislation listed in Annex I"

As per (Official Journal of the European Union, 2024), the additional requirements the EU AI Act would place on the O-arm™ O2 Surgical Imaging System by Medtronic over and above the requirements of EU MDR 745 would be as follows:

1. Risk Management / Risk Mitigation
    a. EU AIA 1689 requires a comprehensive, documented Risk Management system that specifies the AI specific risks. The risk management plan must seek to identify on a continuous basis the risks associated with the AI system, the continuous evaluation of the risk, and the mitigation plans for the AI specific risks identified.

2. Data Management / Data Governance
    a. The AI act imposes strict requirements on the quality, management, and governance of data sets used in the training, validation and testing of AI systems. Data must be relevant, representative, and free of errors. The dataset and data management plan must seek to minimise bias and ensure model safety.

3. Technical Documentation
    a. The AI act mandates detailed documentation that demonstrates compliance with AIA specific requirements, e.g. algorithmic design, model training data, deployer training data, and risk management processes.

4. Transparency / User Information
    a. The AI act requires that AI system deployers provide clear information on instructions for human oversight of the model, explainability of the AI system capabilities, limitations, and appropriate use cases.

5. Human Oversight
    a. The AI Act obligates that deployers of AI systems provide details on the human oversight of the system, include how to override the system to minimise risks, and document clear mechanisms for intervention.

6. Accuracy / Robustness / Cyber Security
    a. The AI Act sets out explicit requirements for accuracy, robustness and cybersecurity of AI systems include the systems resilience to cyber attacks.

7. PMS / Monitoring / Reporting
    a. The AI Act requires ongoing review and maintenance of the AI system performance, drift, and the reporting of serious instances and malfunctions related to the behaviour of the AI.

8. Registration / Database
    a. The EU AI Act requires the registration of high-risk AI systems on a dedicated EU AI database similar to EUDAMED for medical devices.

9. Conformity Assessment
    a. High risk AI systems must undergo conformity assessment from a notified body. Notified bodies will need approval under EU MDR and the EU AI Act to perform combined assessments.

2.5.3 Analysis of legislation: EU MDR 745 and EU AIA 1689

2.5.3.1 Legislation structure

Item	**EU MDR 745**	**EU AI Act 1689**
Entry into Force	May 2017	August 2024
Application Date	May 2021	Phased 2025 – 2027
Chapter's	10	13
Number of Articles	123	113
Number of Recitals	107	180
Number of Annexes	17	13
Function	Medical Device Regulations specific to medical device hardware, accessories and software.	Horizontal Regulation governing Artificial Intelligent technology across all sectors

2.5.3.2 Risk Classifications

EU MDR 745	**EU AI Act 1689**
Class I Non-Invasive minimal risk	Minimal Risk AI Systems All AI systems not covered below
Class Im Measuring	Limited Risk AI Systems AI systems interacting with humans and generating data
Class Is Sterile	High Risk AI Systems AI systems as per Annex III / Used as safety components e.g. medical devices

Class Ir Reusable	Prohibited AI Practices Subliminal AI systems used to cause harm or infringe on fundamental human rights
Class IIa Short term contact / low invasiveness	
Class IIb Medium term contact / moderate invasiveness	
Class III Long term implantable / life supporting	

At what stage does the EU AI Act 1689 apply to a medical device?

"If the medical device as a device itself, or a safety component of that device, uses machine based technology that is designed to operate with varying levels of autonomy, and that may exhibit adaptiveness after it has been deployed, and for explicit or implicit objectives, infers, from the input it receives, how to generate outputs, such as, predictions, content, recommendations, or decisions that can influence a physical or virtual environment, and/or undergoes 3rd party conformity assessment by a notified body" (MDCG and AIB, 2025).

EU MDR 745	**Notified Body Involvement**	**EU AI Act 1689 Risk Classification**
Class I	No	Low Risk
Class Im (Device includes AI Technology)	Yes	High Risk

Class Ir (Device includes AI Technology)	Yes	High Risk
Class Is (Device includes AI Technology)	Yes	High Risk
Class IIa (Device includes AI Technology)	Yes	High Risk
Class IIb (Device includes AI Technology)	Yes	High Risk
Class III (Device includes AI Technology)	Yes	High Risk

2.5.3.3 Requirements for High-Risk Devices / Uses

Requirement	**MDR / IVDR**	**Additional Requirements for the EU AI Act 1689**
Management Systems	Requirement to manage the entire lifecycle of the device for safety and performance	Adds requirements for continuous review, and oversight for system drift, performance decay or bias.
Quality Management System	Emphasises the use of a QMS to ensure safety and performance	Adds requirements for ➢ Data Governance ➢ Human Oversight ➢ Record Keeping ➢ Model Transparency
Risk Management	Requires a continuous, iterative process of risk management in both the premarket and post	Adds the requirement to manage risk throughout the entire lifecycle of the system functioning for

	market phases focussed on health, safety, and fundamental rights	impacts to fundamental human rights, data biases, system robustness.
Data Governance	Requirement for robust clinical data / clinical evidence	Adds the requirement for documentation that the system is built and validated on robust, and trustworthy data.
Data Management	Must comply with GDPR	Adds the requirement for training data transparency, model data management, model data validation, machine learning techniques, and data bias governance.
Technical Documentation	Requirements for comprehensive technical documentation such as descriptions of software, software architecture, data processing methods, risk management strategies, intended use, clinical data,	Adds requirements for documentation on model transparency, human oversight, accountability, data governance, and performance testing and outcomes.
Transparency and Human Oversight	Transparency requirements for intended use, transparency requirements embedded in General Safety and Performance Requirements.	Adds legally binding core comprehensive requirements for transparency, model functionality, human oversight, informed consent for users, model explainability, and model deployment.

		AIeMD must have extensive functionality for human oversight and intervention in the system. The system must not be capable of overriding the human oversight functionality of the system and must ensure responsiveness to a human operator. There must also be clear instructions for the human override of a system.
Accountability	Requires documentation for clinical and performance evaluation, clear and complete on how the device operates	Adds explicit obligations for model transparency which contributes to explainability which in turn facilitates accountability. Deployers of AIeMD must be able to demonstrate and communicate how the system makes decisions and must show accountability for model updating post market.
Informed Consent	Mainly applies to the informed consent of clinical studies and the informed consent of participants.	Adds the requirements of Informed Consent to the deployers of systems to ensure patients awareness to the functioning, capabilities, limitations, and potential risks of the AI system.

Traceability	Requirements for traceability throughout the supply chain and device lifecycle, including UDI registration and PMS. Scope is traceability of device movement	Adds the requirement of system performance traceability through performance logs, and system behaviours. Scope is traceability of system performance.
Accuracy / Robustness and Cyber-Security	Requires risk management practices and procedures protecting against unauthorised access, cyber-attacks, exploits and manipulation that may impact operational resilience or patient safety.	Adds requirements for AI specific cyber-security measures to protect against model poisoning, and unauthorised access to system data at operational, post market and training phase to ensure patient safety and protection of fundamental rights.
Clinical Evaluation	Robust clinical evaluation requirements in place	Adds requirements for accuracy, robustness, cyber-security, and performance of the AI system, including verification and validation of design, manufacturing, data collection, re-processing, model training, and quality management activities include continuous monitoring of model performance.

Conformity Assessment	Requires notified body conformity assessment including audit of the QMS and technical documentation to ensure compliance.	If the device is, consider MDAI or AIeMD then conformity assessment takes place under MDR. If the device is high risk but not determined a MDAI or AIeMD then the conformity assessment takes place under the EU AI Act.
Post Market Surveillance	Requires the establishment of post market surveillance activities that monitor the performance of the device, risk monitoring, adverse even tracking, and taking corrective and preventative action as needed.	Adds the requirement that AI systems incorporated in AIMD or AIeMD to undertake post market surveillance to monitor performance of the system throughout the lifecycle of the system to ensure compliance with obligations related to safety and performance standards, in particular model performance, safety, drift, and bias.

2.5.3.4 Core Requirements

EU MDR 745	**EU AI Act 1689**
Conformity Assessment • CE marking mandatories for all medical devices. • Notified Body involvement for all Classes except Class 1 nonsterile.	**Conformity Assessment** • CE marking mandatories for all high risk uses. • Internal control or 3rd party assessment required. • Registration in EU AI Database

• Clinical evaluation and post market clinical follow up (PMCF) • Unique Identification System • EUDAMED Registration	• Declaration of Conformity for high risk uses
Quality Management System • QMS in place based on requirements of ISO13485. • Technical documentation requirements • Risk management approach as per ISO14971. • Validation requirements • Design Controls and Design History File requirements	**Risk Management Approach** • Risk based approach to classification. • QMS requirements for high risk uses. • Prohibited AI practices identified. • Additional requirements for high-risk use • Transparency obligations in place for deployers of AI systems
Post Market Surveillance • Post Market Surveillance (PMS) requirements. • Vigilance reporting of serious incidents. • Corrective Actions and Field Safety Notice requirements • Dedicated representatives for non-EU manufacturers	**Governance Structure** • AI Office at EU commission level • National member states national supervisory authorities • Market Surveillance Authorities • EU level AI Board

2.5.4 Summary

The EU Medical Device Regulation 745, along with the EU AI Act 1689 represent two landmark pieces of EU legislation that shape and impact how innovative technologies hit the market. The MDR in its sector specific functionality overhauled decades old directives for medical device manufacturers that wish to apply CE marking to their devices and make them available to the European market. In its enactment it has created a high barrier to entry to the market but added stringent requirements significantly strengthening patient safety protections across all member states (Uwe Dettling, 2025)

The EU AI Act 1689 takes a different approach as the worlds first comprehensive horizontal legislation for Artificial Intelligence that cuts across multiple sectors and implies a risk-based approach ranging from outright prohibited practices to minimal oversight of this rapidly evolving AI technology.

What remains consistent though is their approach to the safety, and protection of the fundamental human rights of the citizens of the European Union and sets the standard for safe and ethical development of AI enabled medical devices globally.

3.0 Research Methodology

3.1 Introduction to the research methodology

The objectives of this research are to:

- Investigate if the need existed for the development of a Strategic Regulatory Framework for Compliance of AI-Enabled Medical Devices under EU MDR 2017/745 and EU AI Act 2024/1689.
- Establish an overview of the current regulatory landscape with regards to AI enabled medical devices in the European and American markets, identifying the complexities that exist, if any.
- Identify key compliance challenges in the development of AI enabled medical devices that adhere to EU MDR 2017/745, and EU AI Act 2024/1689.
- Identify areas for harmonisation of EU MDR 2017/745, 21 and EU AI Act 2024/1689.
- Outline examples of what a strategic regulatory framework for compliance with EU MDR 2017/745 and EU AI Act 2024/1689 may contain

The methodology that was undertaken for this body of research was that of a mixed methods approach with the aim of capturing both quantitative and qualitative data using a convergent parallel design. This approach was identified as most suitable as it will allow for the capture of measurable data that was then interpreted using descriptive statistical analysis, and expert insights from industry professionals on which a thematic analysis was conducted to capture themes (Wasti *et al.*, 2022).

The strategic approach to this research methodology was that of concurrent triangulation approach due to the time constraints, quantitative and qualitative primary data collection was undertaken in parallel to ensure timely completion. The simultaneous nature of the concurrent triangulation approach was appropriate as it allowed the author to gain a more comprehensive understanding of the research problem, allowing them to use the strengths of each method to address the weakness in the other in a shorter timeframe (Naidu-Valentine, 2024).

3.2 Research philosophy and approach

The researcher approached the research with a mix of philosophies, as both "Interpretivism" and "Pragmatism" were deemed appropriate due to the mixed methods approach, with convergent parallel design.

Interpretivist research paradigm, which was deemed appropriate as it aligned with the objectives as set out by the researcher to investigate if the need exists for the development of a strategic framework for compliance of AI enabled medical devices to EU MDR, and EU AI 1689. The Interpretivism approach was deemed appropriate as it supported the investigation of complex subjects, where subjective experiences existed, such as the interpretation of complex pieces of EU legislation. Interpretation, judgement, and nuance are all needed to be adopted by professionals in a situation where AI enabled medical devices are now navigating two relatively new pieces of EU legislation, EU MDR, which just celebrated its 4th anniversary of full application, and EU AI 1689 which has only entered into force since August 2024. This paradigm allowed the researcher to investigate the nuanced challenges identified by industry professionals, and stakeholders as they navigate this complex regulatory arena (Ryan, 2018).

The pragmatism philosophy was also deemed appropriate as it focusses on practical outcomes. Pragmatism philosophy was applied as the output of the research is hoped to be a practical, usable, and beneficial framework for organisations engaged in the development of AI enabled medical devices. Adopting this research philosophy allowed the researcher flexibility in their research methods, acknowledging that a mix of qualitative and quantitative data was needed for assessing the need for, and proposing examples of what a Strategic Regulatory Framework for Compliance may consist of. The pragmatic research philosophy is orientated towards providing practical problem solving (Elgeddawy and Abouraia, 2024).

The researcher aimed to produce several tangible outputs from this undertaking, such as harmonisation tables, a flow chart of compliance steps, a risk analysis framework, and a compliance checklist that can all be made available for use by industry professionals as deemed fit. This approach also allowed for the adaptation to the regulation as it develops, since AI technology is advancing so rapidly, a situation may arise where regulations are amended or updated, and by adopting a pragmatic approach it allowed the researcher to adapt the framework as needed (Jansen, 2023).

The research followed an inductive approach, which allowed for the organic emergence of themes and patterns in the data, in opposition to a structured testing of predefined hypothesis (Dudovskiy, 2025). Given the relative newness of the EU AI Act, limited academic literature exists that addresses the intersection of EU MDR, and EU AI 1689 and the implementation complexity that exists for AI enabled medical devices to ensure compliance. The inductive methodology approach allowed the author to uncover nuanced insights. This is important in a rapidly evolving technological landscape where frameworks are yet to be developed, and industry adoption is still maturing.

The mixed methods approach involved collecting primary qualitative data through semi structured interviews with industry professionals such as those involved in the areas of Quality, Regulatory Affairs, R&D, Software Development, and other relevant stakeholders. The aim of these interviews was to capture in depth themes that exist within industry, and in the challenges that exist in developing AI enabled medical devices in adherence to both pieces of EU legislation. Concurrently, a quantitative survey was distributed to capture the inputs of MedTech industry professionals to quantify trends on the current regulatory landscape, risk areas, and preparedness levels.

A solely positivist approach was not deemed appropriate for this body of research as it risked the oversimplification of the complex process involved in the interpretation and application of complex EU legislation such as EU MDR, and EU AI 1689 (Lee, 2025). Quantitative data alone often fails to capture how organisations and individuals alike interpret, prioritise, and respond to often complex and ambiguous or emerging European legislation. Likewise, a solely qualitative approach would fail to capture the hard data that would be required in the development of a strategic regulatory framework for compliance. By combining both approaches, using a convergent parallel design, and conducting them concurrently using the triangulation method, it ensures the research balanced depth and breadth, which should in turn support the development of a practical hands-on compliance framework that will aid organisations in navigating the two acts.

3.3 Research design

3.3.1 Primary Research design:

The researcher conducted interviews using a thematic approach, with industry professionals who are directly involved with either the development, or regulation of, AI enabled medical devices to gain qualitive data that allowed the researcher to identify themes that exist within the research topic. These interviews were run concurrently with the industry survey. The interviews were made up of several semi structured questions aimed at identifying themes that exist in the current development of AI enabled medical devices in adherence to EU MDR, and the EU AI Act.

- The interviews were approximately 30 minutes in duration.
- The interviews were undertaken with 11 industry professionals.
- The interviewees signed an informed Consent Form prior to the interviews taking place.
- The interviews were scheduled over Microsoft Teams.
- The transcripts were recorded, transcribed, and communicated to the interviewees.
- The study was that of an informed consent study.
- The interviewees were provided with a Participant Information Leaflet prior to the interviews taking place.
- The interviews were only scheduled post ethics approval.
- For interview questions/topics see Appendices (*Figure 4: Interview question list)*

Running concurrently with the qualitative interviews was that of a survey of MedTech industry professionals to establish quantitative data, both of which were then analysed independently. The results of these interviews and surveys were then compared and interpreted to identify areas of convergence or divergence in the qualitative and quantitative data.

The survey was made up of several pre-defined questions, a quantity of which were open-ended to allow for commentary to develop and involved some Likert style questioning to establish scales to which participants agree or disagree with a given statement. The survey was developed using Survey Monkey and distributed using LinkedIn, Alumni, and MedTech groups.

- The survey was targeted towards industry professionals engaged in the R&D, QA, Regulatory, and manufacturing functions of organisations involved in the medical device industry to assess to what extent AI forms parts of their organisation's product offering or management system to gain quantitative data.
- The survey was based on a population size of 100 industry professionals, with a margin of error of 5%, and a 95% confidence interval.
- The survey was focused on industry professionals involved in functions directly effected by EU MDR, and the EU AI Act such as QA, Regulatory Affairs, R&D, and Manufacturing.
- The survey consisted of several multiple-choice questions from which statistical data can be gathered, and more open-ended questions from which themes can be identified.
- The survey was undertaken post ethics approval.
- For survey questions/topics see Appendices (*Figure 5: Survey question list)*
- The primary data was then analysed by performing a descriptive statistical analysis of surveys and a thematic analysis of interview data to identify trends, themes, and patterns in responses, and in the Identification of recurring topics using info graphics.

3.3.2 Secondary Research design:

The secondary research undertaken was:

- An analysis of AI enabled medical devices in the leading global medical device organisations to present examples of current AI enabled medical device technologies either currently on the market or currently being brought to market, and their approvals pathway through FDA approval and CE status.
- A case study of the Medtronic O-Arm™ Surgical Imaging system.

- A document analysis of EU MDR and the EU AI Act 1689 to identify areas for harmonisation, and additional requirements of the EU AI Act 1689.

3.4 Data analysis

The data analysis strategy for this body of research followed a multi layered approach that aligned with the mixed methods approach undertaken by the researcher. It included thematic analysis of qualitative interview data, and the descriptive statistical analysis of quantitative survey data, case study analysis of relevant secondary data associated with AI enabled medical devices currently on the market, and finally a document analysis of key legislative texts, in particular EU MDR 745, and EU AI Act 1689 to identify areas for harmonisation.

This combination of analytical approaches to primary and secondary data allowed for the triangulation of findings and offered up a nuanced understanding of stakeholder experiences, along with a comprehensive understanding of the regulatory landscape associated with AI enabled medical devices.

The interviews were transcribed and analysed following Braun and Clarke's six step framework. These steps included familiarization with the data gathered, generating codes for the labelling and grouping of data, identifying themes, reviewing themes, and finally producing the report. Thematic analysis had been selected as being suitable for this body of research as it aligns with the interpretivist strategy and aided in the identification of common experiences, challenges, and approaches to the development of AI enabled medical devices in adherence to both sets of EU legislation (Ahmed *et al.*, 2025).

Survey data collected was analysed using descriptive statistical analysis, this aided in the assessment of compliance readiness, perceived burden, areas of concern, and in the identification as to whether industry professionals would find a strategic framework for compliance to be of benefit to the development of their AI enabled devices. The quantitative data gathered from the survey was used to complement the qualitative findings from the interviews and added context to interview based data.

To further illustrate real world compliance practices and challenges, case studies were selected from publicly available sources to represent current AI enabled medical devices available on the market, and how the new EU AI Act 1689 may impact these devices. For this purpose, the FDA database of AI enabled medical devices was used, and a subsequent search of EUDAMED to establish the status of CE marking of the AIeMD. EUDAMED alone could not be used for this exercise due to its poor functionality and oversight of allowing for "AI" search criteria.

Finally, a comparative analysis was undertaken on EU MDR 745, and EU AI Act 1689 to identify potential gaps, tensions, and areas for harmonisation that exist between these two pieces of EU legislation to which AI enabled medical devices must adhere. This analysis informed the development of a hands-on strategic framework for compliance of AI enabled devices as deemed necessary from the primary research undertaken.

3.5 Ethical considerations

The research project received ethical approval, and as such no ethical issues were identified. The ethical considerations for this body of research were those of the methods of researching primary data. The purpose of the research was clearly communicated, the intention for use of the data, and the voluntary nature of the participation in the primary data gathering. At all times participants' data must was protected and anonymity was maintained. The sensitive nature of information provided by industry professionals was considered, and the nature of data provided. The researcher at all times remained objective in the gathering, analysing and presentation of data.

3.6 Limitations of the methodology

Although the research methodology proposed by the researcher offered up a robust mixed methods design, there were several limitations that should be acknowledged, both the interviews and the survey had a relatively small sample size when compared to the overall size and scope of the medical device market. Although a larger sample size would be more representative of the overall med device market, time constraints existed within the study. The researcher was also cognizant of response bias within the primary data gathered, due to the relative newness of the legislation, and the overtly cautious approach of those involved in R&D, and regulation of AI enabled devices, there may have been bias within the data. The researcher was mindful in identifying and addressing any discrepancies that arose between the qualitative and quantitative data gathered using the concurrent triangulation approach (Lavrakas, 2008).

Themes may have arisen in one method that are not reflected in the other potentially complicating interpretation. The case studies may be limited by the scope of what is publicly available on current AI enabled medical devices available on the market, data was limited in availability of the regulatory decisions, or reports from notified bodies, however the researcher was cognizant that these may not reflect the operational realities of bringing the device to market, or the nuanced internal decision making that took place.

Finally, the complex regulatory landscape that exists limited the success of the research, both EU MDR, and EU AI 1689 are live, evolving pieces of legislation, and as such, regulatory interpretations, guidance documents and corrections became available during the course of the research, additionally the research was approached from a researchers perspective and not that of a legal authority although both are legal documents.

3.7 Research methodology flow

Research Topic: EU MDR 745 and the EU AI Act 1689 Compliance for AI enabled Medical Devices

Research Objectives:

1. Investigate the need for a strategic framework of compliance
2. Identify key compliance challenges
3. Identify areas for harmonisation
4. Propose examples of what a compliance framework would consist of

Research Approach:

- Mixed Methods – Qualitative and Quantitative
- Convergent Parallel Design
- Concurrent Triangulation
- Philosophies: Interpretivism and Pragmatism
- Inductive Approach

Primary Data Collection Methods:

1. Qualitative Interviews with industry stakeholders
2. Quantitative Survey of industry stakeholders

Secondary Data Collection Methods:

1. Case study of AIeMD
2. Document Analysis of EU MDR 745 and the EU AI Act 1689

Data Analysis:

1. Qualitative Analysis – Thematic Analysis of interview data following Braun and Clarke methodology
2. Quantitative Analysis – Statistical Analysis of survey data
3. Concurrent triangulation of results

Outcomes:

1. Comprehensive understanding of the regulatory landscape
2. Identification of themes, trends, and patterns
3. Assessment of state of readiness
4. Tangible outputs: Flowcharts/ Decision Trees/ Checklists/ Matrices

4.0 Findings

4.1 Overview of findings and data integration strategy

A qualitative led, mixed methods design was adopted by the researcher which incorporated both qualitative and quantitative data within a convergent triangulation framework which was used to add to the validity and depth of the findings.

Additionally, the quantitative findings were used to complement and contextualise the qualitative insights, thereby enriching the overall analysis. It must also be documented that the target sample size for quantitative data was not reached, and thus cannot be deemed statistically significant, however when used in conjunction with the qualitative interview data, it assists in the reinforcing of identified themes adding depth to the findings.

Although the researcher has presented the results of the qualitative and quantitative data separately, the findings from the survey were integrated into elements of the thematic analysis of interview data to reinforce and triangulate key themes. This method of approach presented a more comprehensive and nuanced understanding of stakeholder experiences and perspectives within the evolving regulatory landscape of AI enabled medical devices.

4.2 Primary qualitative data analysis

The interviews were made up of the following candidates.

Interviewee Number	**Role**
1	Medical Device Regulatory Affairs, Software, AI and Risk Management expert
2	Managing Director, Hardian Health | SaMD and AIeMD consulting
3	Regulatory Strategist – MedTech & AI

4	Medical Device - Specialist in start-up de-risking and regulatory pathway planning
5	Associate Professor in Medical Device Regulatory Science, Institute for Clinical Trials, University of Galway
6	Product Security Leader for Medtronic's Coronary and Renal Denervation (CRDN) / Medtronic AIeMD Subject Matter Expert EMEA
7	Head of Regulatory and Quality @ Flinn.ai | Notified Body Auditor
8	EU AI Act Trainer, ISO/IEC 42001 Implementer, CEN/CENELEC AI Standards Contributor, AI Governance Consultant
9	Specialist in Privacy and Security of Data in Digital Health and Medical Device Domains
10	Product and Compliance Executive | P&L Leader | 10+ Years Building AI Products | Life Sciences, MedTech, Healthcare, Digital Health
11	AI Specialist | Healthcare data | Interoperability | Products & policy, architecture

4.2.1 Braun and Clarke’s 6 step method for thematic analysis of qualitative data

- Step 1: Familiarisation with the interview data
- Step 2: Generating thematic codes.
- Step 3: Identifying themes within the data.
- Step 4: Reviewing the themes.
- Step 5: Defining the themes.
- Step 6: Drawing conclusions from the data.

Step 1: Familiarisation with the interview data

All interview transcripts and recordings were reviewed in full after each interview. Key discussion points were identified and highlighted. In total 327 discussion points were identified and were then transferred to an excel table to allow for coding.

Step 2: Generating the codes.

The codes developed for tagging and identifying themes in the interview data were as follows:

Number	**Code**
1	Regulatory ambiguity
2	Complexities of dual compliance
3	Proactive vs reactive approaches
4	Challenges around validation and transparency
5	Challenges with post market surveillance and drift
6	Data governance and ethics concerns
7	Classification inconsistencies MDR vs AI Act
8	Innovation impact
9	QMS adaptation
10	Large organisations vs SME's and capacity
11	Notified body ambiguity
12	Demand for frameworks and guidance documents
13	Positive / Potential
14	Managing the risk

Step 3 and 4: Identifying and reviewing themes within the coded data.

The following 7 themes were identified and reviewed against the original transcripts and coded data:

1. Regulatory fragmentation and uncertainty
2. Validation and Transparency challenges
3. Lifecycle management and Post Market Surveillance for AIeMD
4. QMS integration and organisational readiness
5. Innovation pressures
6. Capacity gaps at SME level vs larger organisations
7. The need for compliance frameworks, guidance documents and standards

Step 5: Defining the interview themes.

Theme 1: Regulatory fragmentation and uncertainty

Interviewees expressed concern around the speed at which the AI Act has been developed in relation to MDR, some interviewees expressed concern that organisations are only coming to grips with the requirements of EU MDR and now will need to adhere to the requirements of the EU AI Act for their AIeMD. The classification inconsistencies that exist between EU MDR and the AI Act were also raised as a concern, where an organisation may have a class 1m or 2a device under MDR, but that device will now be classified as high risk under the EU AI Act and must adhere to the requirements for high-risk devices. Regulatory ambiguity was also identified as questions remain around notified body involvement in AIeMD, and without the provision of harmonised standards and guidance documents for implementation manufacturers may struggle with the reconciliation of dual legislation.

Evidence: Devices can be Class 1m/ 1s/ 1r, Class 2a, Class 2b or Class 3 under EU MDR, and all classified as high risk under the EU AI Act thus creating uncertainty in conformity assessments. Interviewees also cited a lack of clarity at the time of interview as to whether dual conformity assessments would be facilitated or are allowed. Also, the discussion point around technical AI capabilities at notified body level must be raised.

Quote: *"There's no notified body yet approved of audit under the EU AI Act area"*, (Interviewee 2: Managing Director, Hardian Health | SaMD and AIeMD consulting)

"In the future NSAI would have competence for medical device software. They could also then have a designation under the AI Act, and you get a single approval at the end. But I think there's some challenges because all of these (AI) notified bodies must be formally designated" (Interviewee 5: Associate Professor in Medical Device Regulatory Science, Institute for Clinical Trials, University of Galway)

"Classification and conformity assessment are two standout areas. A device may be classified as Class IIa under MDR yet simultaneously be labelled a "high-risk AI system" under the AI Act" (Interviewee 3: Regulatory Strategist – MedTech & AI)

Quantitative Data: 83% of survey respondents agreed that "Risk Classifications with EU MDR and the EU AI Act" posed a significant challenge to AI enabled medical devices.

Theme 2: Validation and Transparency challenges

AI specific obligations, e.g. algorithmic explainability and model training data quality, are now more stringent under the requirements of the EU AI Act. Interviewees highlighted that industry readiness is low with concerns raised as to how models will be validated beyond accuracy metrics. Regulator knowledge and understanding was also expressed as a concern. This would have particular implications for those devices that use "SOUP" Software of Unknown Providence, essentially a software component of a medical device that incorporates some AI, or machine learning functionality but which was not specifically developed for the device in which it is used, and for which subsequent documentation, and knowledge around the development process exist. This will present unique challenges around validation, and integrity of training data as per the requirements of the EU AI Act.

Evidence: Recital 67 of the EU AI Act refers to the role "high quality data sets" play in the safe performance and adherence to the intended use of the AI system. Data set integrity, data training, validation and testing practices are all requirements of the EU AI Act.

Quote: *"How are they validated? And they might mention the word accuracy and they might go even further and say sensitivity or even If they go the further step, specificity, they rarely go beyond that. So, I don't think the challenge is going to be for them in terms of the technical ability, then the regulators on the other side they don't know what to look for, so they're going to take whatever they get"* (Interviewee 1: Medical Device Regulatory Affairs, Software, AI and Risk Management expert)

"How are they correcting for bias, what is the data set built on?" (Interviewee 10: Product and Compliance Executive | P&L Leader | 10+ Years Building AI Products | Life Sciences, MedTech, Healthcare, Digital Health)

"I think the number one thing that people are worried about is articles within the AI Act which mandate transparency around training data" (Interviewee 2: Managing Director, Hardian Health | SaMD and AIeMD consulting)

Quantitative Data: 87% of respondents agreed that "Bias and Data Quality" posed a significant challenge to AI enabled medical devices.

86% of respondents agreed that "AI Explainability & Transparency" posed a significant challenge for AI enabled medical devices.

Theme 3: Lifecycle management and Post Market Surveillance for AIeMD

Interviewees highlighted both the challenges that will arise from carrying out PMS on a technology that potentially by its nature, learns and adapts over time, but also with the opportunities that will arise as AIeMD move away from the traditional PMS activities like complaints monitoring to much more bespoke performance feedback activities potentially directly from the patient. Interviewees also noted the tension that exists between the fixed model approach that MDR takes versus the ongoing updating, and adapting that's needed with AI technology. The interviewees also discussed the Prof.Valmed Large Language Model that has recently been certified as the first CE marked Class 2b LLM, a first of its kind, they spoke about how consideration must be given to model learning and updating for compliance purposes. The implications of these additional requirements of the EU AI Act with regards to PMS and lifecycle management will likely include increased operational costs from upskilling of regulatory staff, developing new monitoring systems that move away from that of predominantly complaints based, and the development of new risk assessment frameworks that continuously track AI system performance not just at predetermined intervals.

Evidence: Chapter XI of the EU AI Act documents the requirement that providers of High-Risk AI systems must have a Post Market Monitoring System in place. Article 72 and Recital 155 outline the requirements that must be met for the Post Market Monitoring System.

Quote: *"With great power comes great responsibility. If you're going to be updating a live model that's affecting patient care, then we need to know, are you updating it correctly? Is it getting better? Is it getting worse? Is it drifting? Any new harms?, and that's going to be very, very challenging"* (Interviewee 2: Managing Director, Hardian Health | SaMD and AIeMD consulting)

"Certain things that will come up as an output of your risk management, so there'll be maybe AI specific risks like model drift etc that you will be doing specific PMCF. So, you will be out there on the market looking for Issues with your device" (Interviewee 4: Medical Device - Specialist in start-up de-risking and regulatory pathway planning)

"So, the current PMS system is essentially based upon complaint or incident reporting going to a manufacturer. But you could have much more bespoke ways of gathering patient feedback you know" (Interviewee 5: Associate Professor in Medical Device Regulatory Science, Institute for Clinical Trials, University of Galway)

"The big unanswered question is who does that monitoring?" (Interviewee 11: SaMD and AIeMD Developer with AnaliseAI)

Quantitative Data: 78% of respondents agreed that "Post Market Surveillance activities" posed a significant challenge to AI enabled medical devices.

Theme 4: QMS integration and organisational readiness

A strong theme that emerged during the interviews was that of lack of preparedness with regards to adaptation of QMS's to reflect the additional requirements of the EU AI Act for AIeMD. Only 1 of the 10 interviewees spoke about the current actions they are taking to update their QMS to reflect the requirements of the EU AI Act, such as SOPs for algorithm lifecycle management, data governance and real time performance management. 10 out of 11 interview candidates intimated that the updates required to the QMS of their organisations or the organisations they work in conjunction with was not something that had commenced. This could potentially lead to a situation where a AIeMD is delayed CE marking, subsequently delaying market access and impacting revenue streams for organisations.

Evidence: Article 17 of the EU AI Act and Article 10 of EU MDR both dictate that an organisation must have a QMS in place however the EU AI dictates this requirement for high-risk devices only representing a tension between the two pieces of legislation.

Quote: *"That's not something that's even on their radar yet"* (with reference to whether organisations had begun to update their QMS) (Interviewee 10: Product and Compliance Executive | P&L Leader | 10+ Years Building AI Products | Life Sciences, MedTech, Healthcare, Digital Health)

"We're generally, likely more, as an industry, reactive on implementation QMS, we're proactive in looking at things like awareness in the company, and giving feedback, but we're generally reactive" (Interviewee 6: Product Security Leader for Medtronic's Coronary and Renal Denervation (CRDN) / Medtronic AIeMD Subject Matter Expert EMEA)

Quantitative Data: Only 43% of respondents either had completed or had begun to complete the task of updating their QMS to reflect the additional requirements of AI enabled medical devices under the EU AI Act. 39% had not begun to update their QMS, with the remaining 17% unsure as to whether the update had begun.

Theme 5: Innovation pressures

A common theme that emerged from the interviews was the risk of "Innovation Flight" or "Stifling Innovation" within the European Union by product developers and deployers to a lighter touch regulatory jurisdiction such as that being proposed by the current American administration. However, interviewees were split as to whether the EU AI Act would stifle innovation of AIeMD developers, with some stating that the legislative requirements of EU MDR and the AI Act protected the consumer, and that the EU had set the standard for responsible AIeMD development globally.

Evidence: Article 57, point 5 documents the requirement that the competent authority in member states establish at least 1 regulatory sandbox at national level by the 2nd of August 2026, the goal of which is to allow for the development of a controlled environment that "fosters innovation and facilitates the development, training, testing and validation of innovative AI systems for a limited time before their being placed on the market or put into service pursuant to a specific sandbox plan agreed between the providers or prospective providers and the competent authority" (Official Journal of the European Union, 2024)

Quote: *"Well, I think we need the regulation, but I do think there will be an impact on innovation"* (Interviewee 1: Medical Device Regulatory Affairs, Software, AI and Risk Management expert)

"You can either look at this as like, oh, scary, bad for innovation, or you can look at this as an opportunity and be like, OK well, the next generation of companies are going to be coming out of making compliance to EU AI act as part of their UX and making it seamless" (Interviewee 10: Product and Compliance Executive | P&L Leader | 10+ Years Building AI Products | Life Sciences, MedTech, Healthcare, Digital Health)

"No other jurisdiction has a specific AI act, so we can't really compare it. But I already don't like the term stifling innovation. It's protecting patient safety. And I think these manufacturers, these developers, it's on them to prove what they develop is safe. And if they consider that to be stifling innovation, well, they're wrong. So, I would say it's protecting patient safety. Is it overly protecting patient safety? Probably. But this is

completely untested technology. No one knows how good it is. So that's in fact, increasing evidence is showing that these things aren't that reliable or deterministic. So, I think it's probably sensible to have some breaks on the system" (Interviewee 2: Managing Director, Hardian Health | SaMD and AIeMD consulting)

Quantitative Data: The survey did not include a question on the impact of EU MDR, and the EU AI Act dual compliance would have on innovation. The researcher considers this an oversight of the survey.

Theme 6: Capacity gaps at SME level vs larger organisations

Interviewees raised concerns around the resources available at SME and Start-up level to begin to implement the requirements of the EU AI Act, versus that of the larger conglomerate medical device manufacturers who will have resources available to allocate to the implementation of the act. One raised an interesting point and argued that really, it's the larger organisations that should be developing AIeMD within the guidelines of the legislation and feared that smaller organisations would either try to circumvent the legislation due to the resources required or would exit the market entirely. Typically, MedTech innovation is driven at SME level, developing novel approaches to patient treatment, and breakthrough technologies. The impact that this dual regulatory environment will have on innovation at SME level is yet to be seen however, it must be deemed significant as support for the SME network is strongly called out within the EU AI Act.

Evidence: Throughout the EU AI Act, the provision of support by the member states to fostering innovation at SME level is referenced, Recital 143 speaks directly to the protecting the interests of SME's and the provision of access to regulatory sandboxes at member state level including that of EU health Data. Article 96 of the EU AI Act sets out the guidelines for the implementation of this legislation, it does however give mention to the support that will be needed at SME level to ensure timely implementation of the requirements of the act.

Quote: *"There's an argument that those are the guys who should be making this stuff, not the three-man startup"* Interviewee 2: Managing Director, Hardian Health | SaMD and AIeMD consulting)

"In practice, this creates a documentation sprawl that is hard to scale, particularly for SMEs" (Interviewee 3: Regulatory Strategist – MedTech & AI)

"Product developers for larger companies, they'll have been thinking about this, and they presumably will have a strategy, but it's the new guys who just get completely, you know, shocked by all of these regulations, of both MDR and the AI Act when you're a new product developer." (Interviewee 5: Associate Professor in Medical Device Regulatory Science, Institute for Clinical Trials, University of Galway)

"To a small medium enterprise that do not have that capability. So, you're talking about the Medtronic's and the Boston Scientific's. They have a whole department of RA, and they have people that are even more focused on different areas. And so, you have high expertise in that, but you're talking about a small medium enterprise Or, a startup that doesn't have even the language to be able to understand what the requirements are, so they see a standard and they're looking at it going Oh my God, you know what? What the heck do we do here" (Interviewee 9: Privacy and Security of Data in Digital Health and Medical Device Domains)

"Great question. I do worry a lot for SMEs. I've got that we were now considered a scale up, I think because of our size rather than a start up and there's no doubt that putting all that compliance and even just for the benefit of the vice was a heavy upfront investment.

Quantitative Data: 23% of respondents noted that the "current regulatory frameworks (EU MDR 745, EU AI Act 1689) addressed the challenges in developing and bringing to the market AI enabled medical devices, with the remaining 76% agreeing that the legislation was inadequate (4%), needed substantive improvement (52%), needs clearer guidance (19%),

However, it is important to note that 0% responded that the legislations were "Overly Restrictive"

Theme 7: The need for compliance frameworks, guidance documents and standards

10 out of 11 interviewees agreed that guidance documents, regulatory frameworks, and standards were lacking when it came to the development of AIeMD in adherence to both EU MDR 745 and the EU AI Act. There was a broad consensus that these would be beneficial and are being worked on, but at present are slow to be released. Interviewees that dealt directly with SME's identified a need for standards and guidance documents and agreed that the thesis proposal was needed for the navigation of a challenging dual compliance landscape.

Evidence: Article 66 of the EU AI Act documents the tasks of the board, 1 of which is to *"(l) contribute to, and provide relevant advice on, the development of guidance documents"* (Official Journal of the European Union, 2024) However to date only 1 guidance document has been released. The joint Artificial Intelligence Board and Medical Device Coordination Group released MDCG 2025-6 in June 2025 which documents the interplay between the Medical Device Regulation (MDR) & In Vitro Diagnostic Device Regulation (IVDR) and the EU Artificial Intelligence Act 1689. To date this is the only official guidance document that has been released.

Quote: *"No way, no. Most of them. No, they're they wait for standards"* (Interviewee 1: Medical Device Regulatory Affairs, Software, AI and Risk Management expert)

"There's a role for the Act, for the standard and for the guidance, because industry is so overburdened already" (Interviewee 1: Medical Device Regulatory Affairs, Software, AI and Risk Management expert)

"So, would it be helpful if there were some guidance documents? Yeah, absolutely" (Interviewee 10: Product and Compliance Executive | P&L Leader | 10+ Years Building AI Products | Life Sciences, MedTech, Healthcare, Digital Health)

"Yes — urgently. A dual-compliance framework should offer: a mapping tool that links AI Act articles with corresponding MDR Annexes and GSPRs; a standardised AI-specific risk management and PMS template; guidance on handling adaptive learning systems (e.g.

fixed vs dynamic AI); and clarity on Notified Body expectations for overlapping assessments" (Interviewee 3: Regulatory Strategist – MedTech & AI)

"I do think what you're suggesting be as a checklist or a decision tree would be helpful" (Interviewee 1: Medical Device Regulatory Affairs, Software, AI and Risk Management expert)

Quantitative Data: 71% of respondents agreed that a harmonisation map of the dual regulatory requirements of EU MDR, and the EU AI Act would be beneficial, 81% agreed that a decision tree or flowchart would be beneficial for navigating the dual regulatory landscape, 76% agreed that a risk assessment framework would be beneficial to help identify and manage AI specific risks, 71% agreed that a compliance checklist would be beneficial

Step 6: Findings of the thematic analysis of qualitative interview data

The research study set out to gather qualitative data by conducting semi structured interviews with a sample size of 11 industry professionals involved, the sample size target was achieved across a period of 10 weeks from June 2025 to July 2025.

The thematic analysis of the interview data confirmed broad concern around the speed at which the AI Act has come into force, and its duration since EU MDR implementation. Widespread concern was raised around the dual regulatory burdens facing AI enabled medical device developers. However, interviewees also raised positive points with regards to the strength of the legislation, and the standard that the EU AI Act has set globally. The EU AI Act has placed patient safety and trust at the forefront of the legislation, setting clear guidelines for AI enabled medical device developers while striving to foster innovation. To enable this fostering of innovation that the EU AI Act so clearly documents, interviewees were in consensus that guidance documents, harmonised standards, and practical operational implementation tools and templates are required to help AIeMD developers navigate the dual regulatory requirements of EU MDR and the EU AI Act. The production, and release of these documents should be prioritised to reduce ambiguity and ensure the safe, and ethical deployment of AI to the healthcare system.

4.3 Primary quantitative data analysis

A survey was created using “SurveyMonkey” containing 20 questions with the goal of collecting quantitative data from MedTech industry professionals to asses to what extent AI forms parts of their organisations product offering or management system, and capture views from industry on the interplay between EU MDR, and the EU AI Act and the state of readiness for dual compliance. The survey was made up of pre-defined questions, a quantity of which were open-ended to capture commentary and themes, and Likert style to establish scales to which participants agreed or disagreed with the statements made.

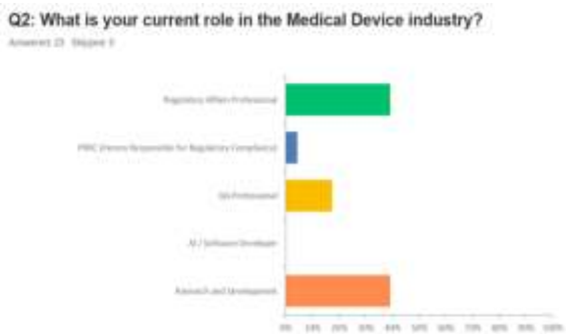
Post ethics approval, the survey was distributed via LinkedIn and also directly sent to 84 people identified as a target audience explaining the background to the survey and asking them to partake. The target sample size was calculated at 100, which would have given the researcher a 95% confidence interval, with a 5% margin of error. The survey was left open for 14 weeks from May 2025 to August 2025.

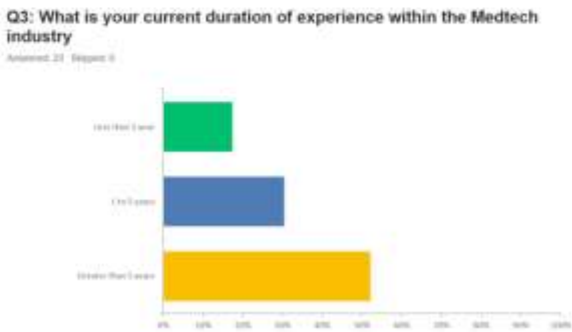
The survey received only 23 responses so cannot be deemed statistically significant, however the results of the 23 responses were reviewed and used to inform the results of the thematic analysis of interview data using a concurrent triangulation method.

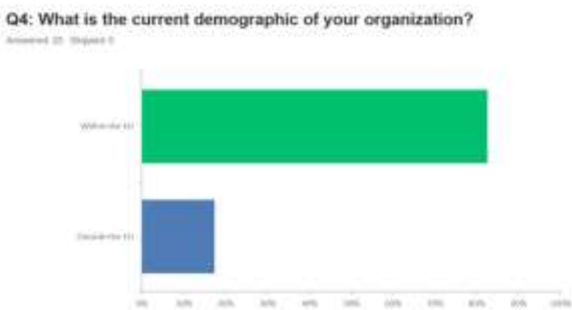
4.3.1 Survey Findings

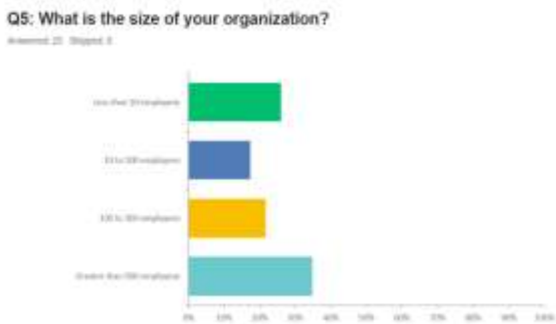
Survey population

- 39% of survey respondents identified themselves as Regulatory Affairs professionals.
- 39% of survey respondents identified themselves as R&D professionals.
- The remainder of survey respondents were split between QA (17%), and PRRC (4%).
- Over half of respondents have worked in the MedTech industry for greater than 5 years.
- 83% of respondents identified themselves as being located within the EU, with the remaining 17% located outside of the EU.
- The organisation size was somewhat evenly split between SME's and larger organisations with employees more than 500.







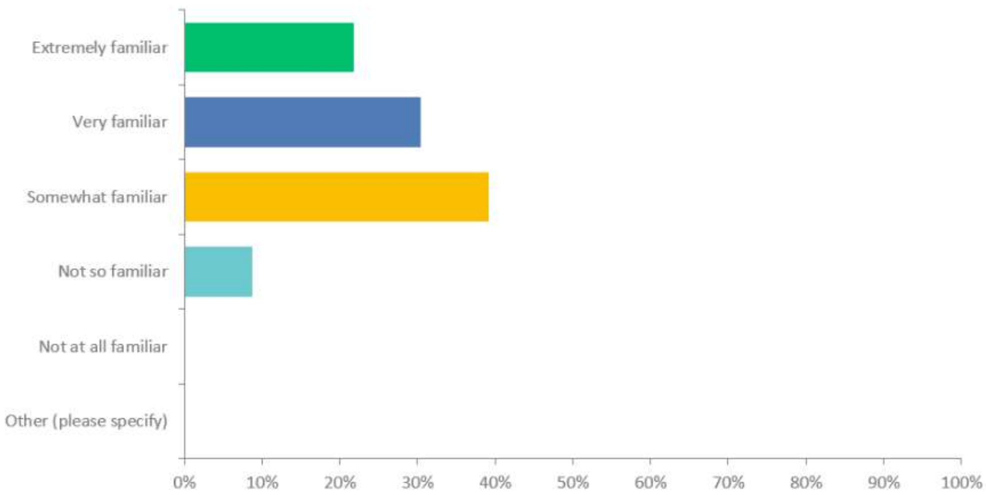


Legislation familiarity

- 90% of respondents were noted as being somewhat, very, or extremely familiar with EU MDR 745.
- However, only 61% of respondents were noted as being somewhat, very or extremely familiar with the EU AI Act 1689. The remaining 39% of respondents deemed themselves either not so, or not at all familiar with the EU AI Act.
- Although Regulatory Affairs professionals leaned more toward "Somewhat" and "Very Familiar" with the EU AI Act, there was no statistical significance between the differing roles and knowledge of the EU AI Act.

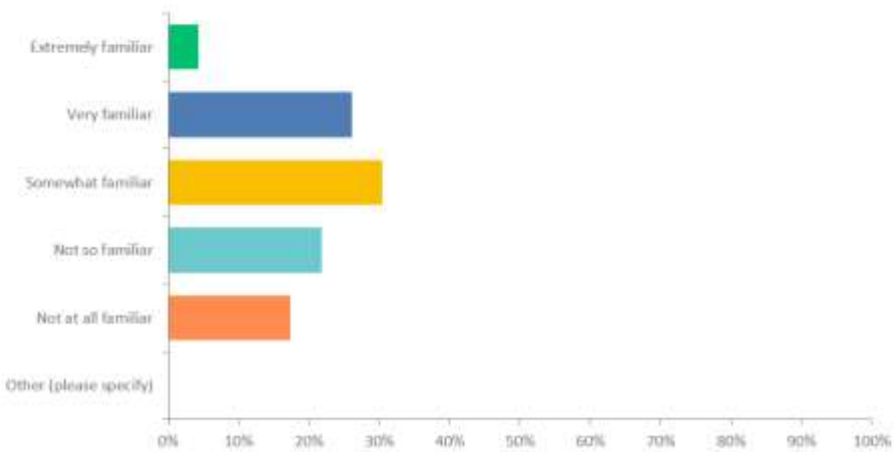
Q6: How familiar are you with EU MDR 2017/745?

Answered: 23 Skipped: 0



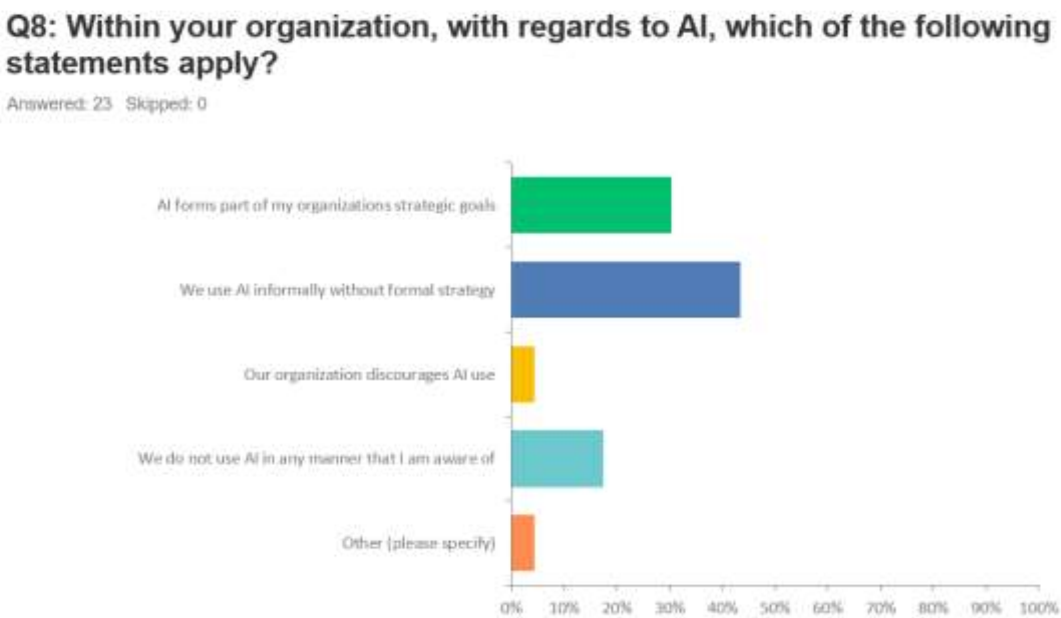
Q7: How familiar are you with EU AI Act 2024/1689

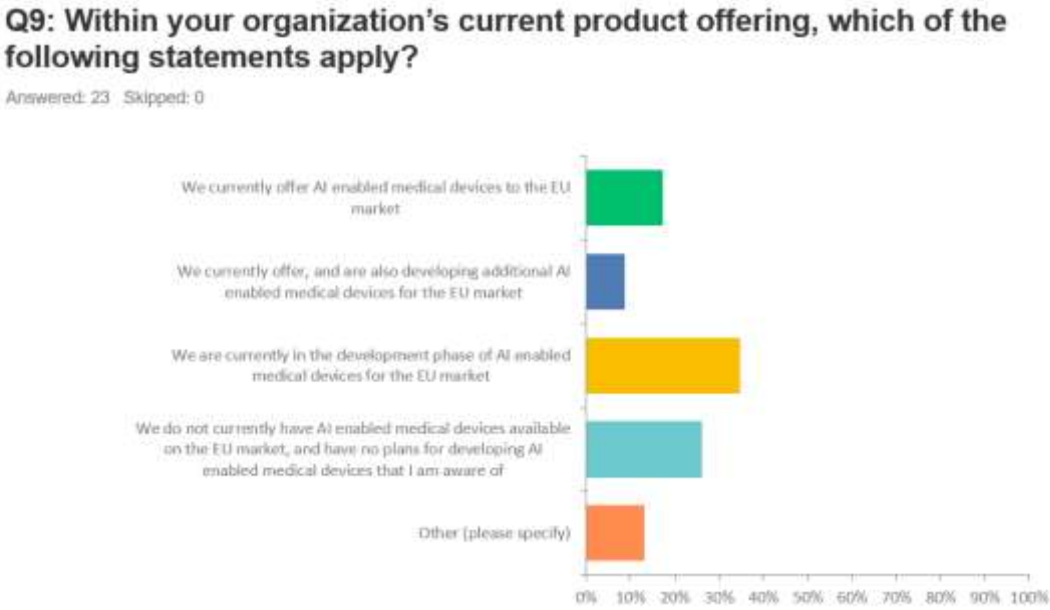
Answered: 23 Skipped: 0



AI systems / AIeMD interaction

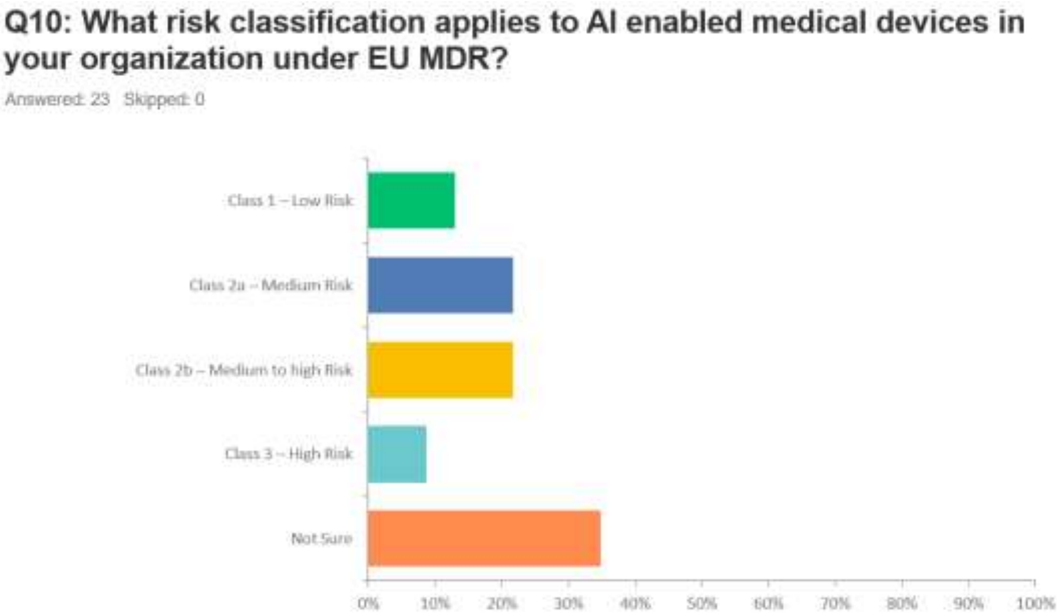
- 30% of respondents noted that AI forms part of their organisation's strategic goals, 43% of respondents noted that they use AI informally without strategy. 17% of respondents noted that they do not use AI in any manner, with the remaining 4% responding that their organisations discouraged the use of AI.
- 26% of respondents noted that their current product offering included AI enabled medical devices, 26% noted that they do not have, and have no plans to offer AI enabled medical devices, finally 35% of respondents noted that they were currently in the development phase of AI enabled medical devices for the European market.

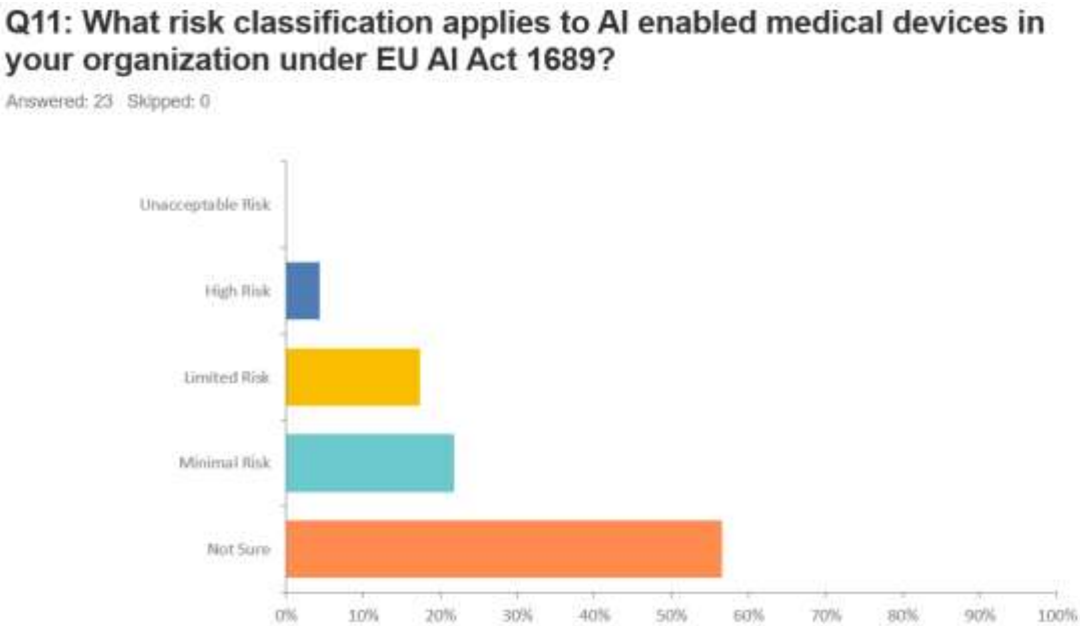




Risk classifications

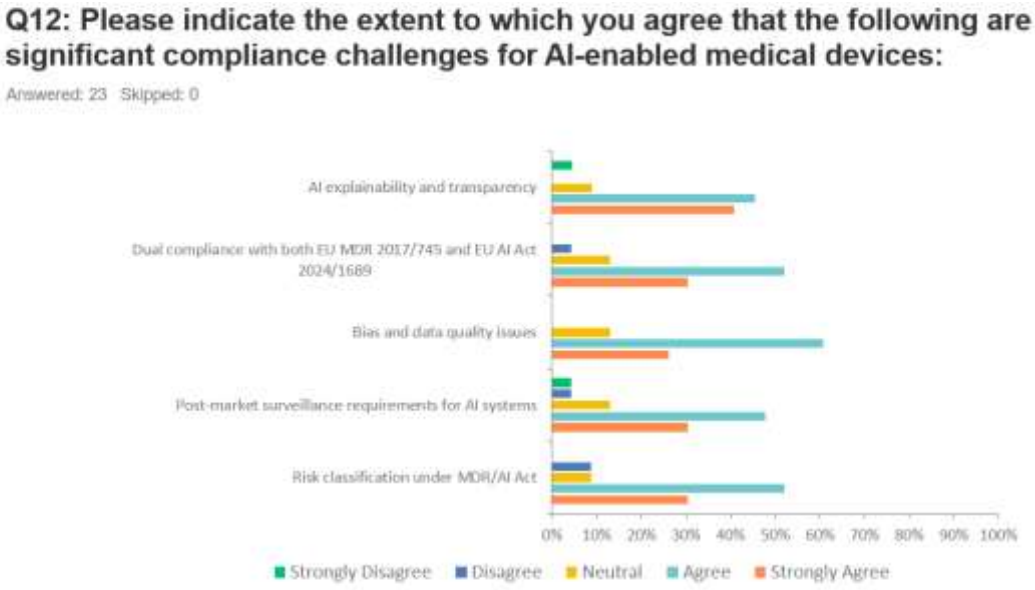
- 35% of respondents were unsure of the classification of their medical device under EU MDR 745, with the remining 65% split between Class 1 low risk, 2a medium risk, 2b medium to high risk and 3 high risks.
- However, 57% of respondents noted they were unclear as to what risk category their device would fall under the EU AI Act. 17% noted limited risk, 22% minimal risk, and 4% as high risk.





EU AI Act perceived challenges

- As can be seen from the below survey respondents, similar to interview findings, concerns exist in industry around the requirements that the EU AI Act place on AIeMD such as AI explainability and Transparency, Dual compliance complexities, Data management and bias, PMS, and Risk Classification ambiguity.
    - 86% of respondents agreed that "AI Explainability & Transparency" posed a significant challenge for AI enabled medical devices.
    - 83% of respondents agreed that "Dual Compliance to EU MDR, and the EU AI Act" posed a significant challenge to AI enabled medical devices.
    - 87% of respondents agreed that "Bias and Data Quality" posed a significant challenge to AI enabled medical devices.
    - 78% of respondents agreed that "Post Market Surveillance activities" posed a significant challenge to AI enabled medical devices.
    - 83% of respondents agreed that "Risk Classifications with EU MDR and the EU AI Act" posed a significant challenge to AI enabled medical devices.

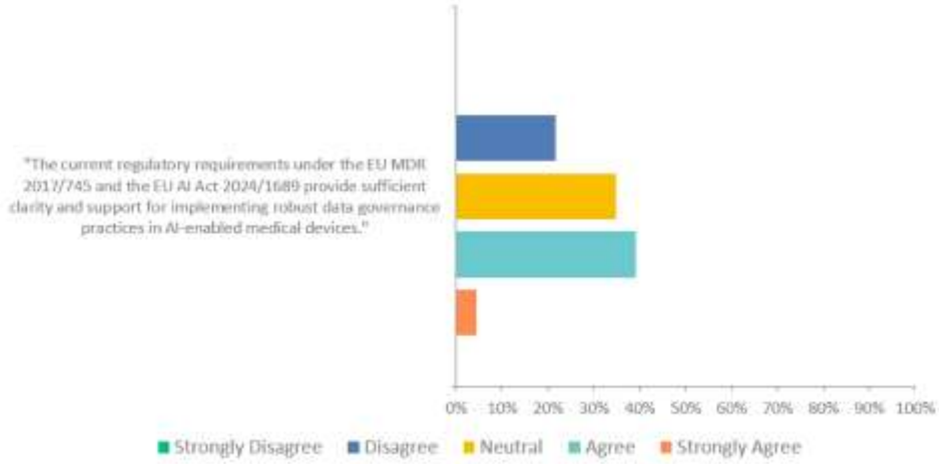


Regulatory clarity with regards to "Data" requirements

- Only 43% of respondents agreed with the statement "The current regulatory requirements under the EU MDR 2017/745 and the EU AI Act 2024/1689 provide sufficient clarity and support for implementing robust data governance practices in AI-enabled medical devices", 22% disagreed, and 35% took a neutral stance to the statement.
- However, when Regulatory Affairs professionals were looked at as a group this figure rose to 50%

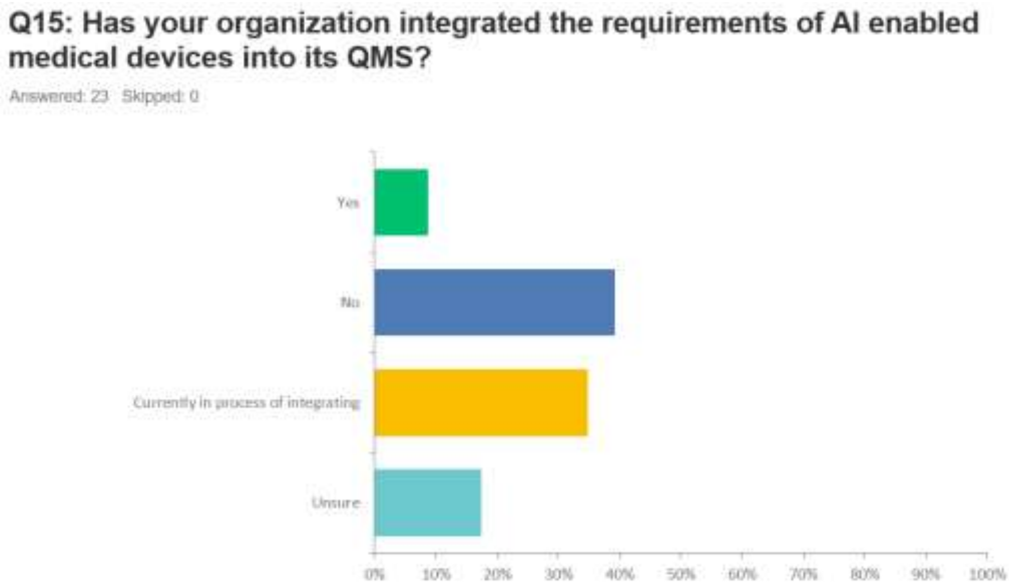
Q13: To what extent do you agree with the following statement:

Answered: 23 Skipped: 0



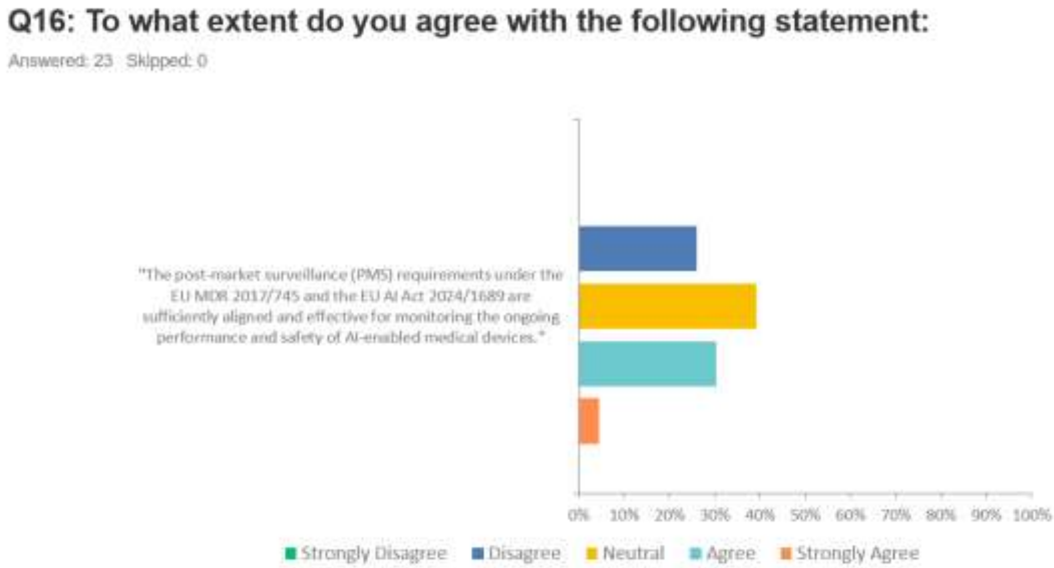
QMS readiness

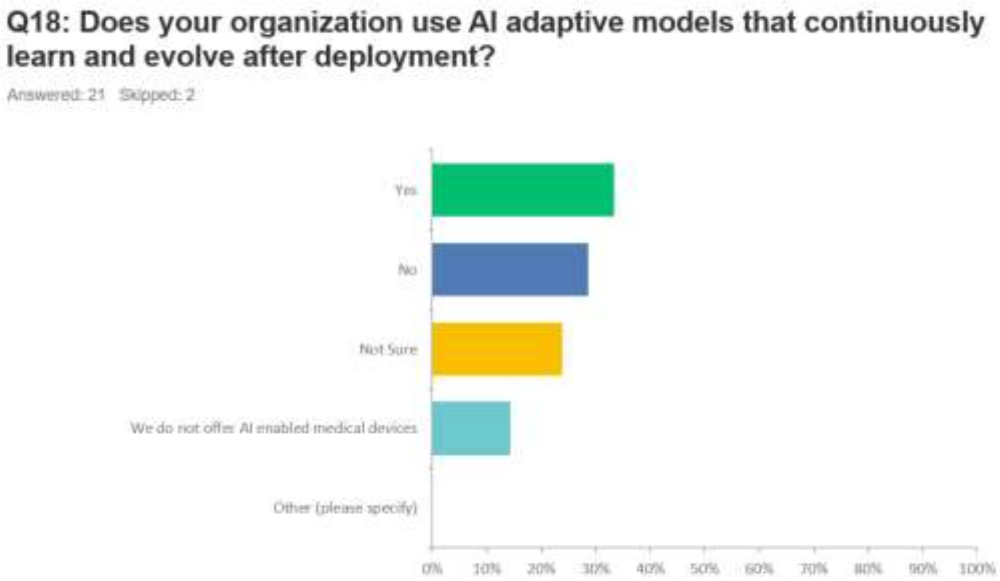
- 43% of respondents either had completed or had begun to complete the task of updating their QMS to reflect the additional requirements of AI enabled medical devices under the EU AI Act. 39% had not begun to update their QMS, with the remaining 17% unsure as to whether the update had begun.
- However larger organisations (> 500 employees) were identified as more likely to be "In the process" of integrating the requirements of the EU AI Act into their QMS versus smaller (<100 employees) reinforcing the theme that emerged during the interviews that the dual regulatory challenges will impact SME's greater. However, with such a small sample size, this could not be deemed statistically significant if viewed in the absence of interview data.



Post market surveillance.

- 35% of respondents agreed with the statement "The post-market surveillance (PMS) requirements under the EU MDR 2017/745 and the EU AI Act 2024/1689 are sufficiently aligned and effective for monitoring the ongoing performance and safety of AI-enabled medical devices", 26% of respondents disagreed with the statement, with 17% remaining neutral.
- 33% of respondents noted Yes, that their organisations offered AI models that learned and evolved after deployment, 29% of respondents replied No, while 24% were unsure.





Assessing the demand for regulatory frameworks and guidance

- 23% of respondents noted that the "current regulatory frameworks (EU MDR 745, EU AI Act 1689) addressed the challenges in developing and bringing to the market AI enabled medical devices, with the remaining 76% agreeing that the legislation was inadequate (4%), needed substantive improvement (52%), needs clearer guidance (19%),

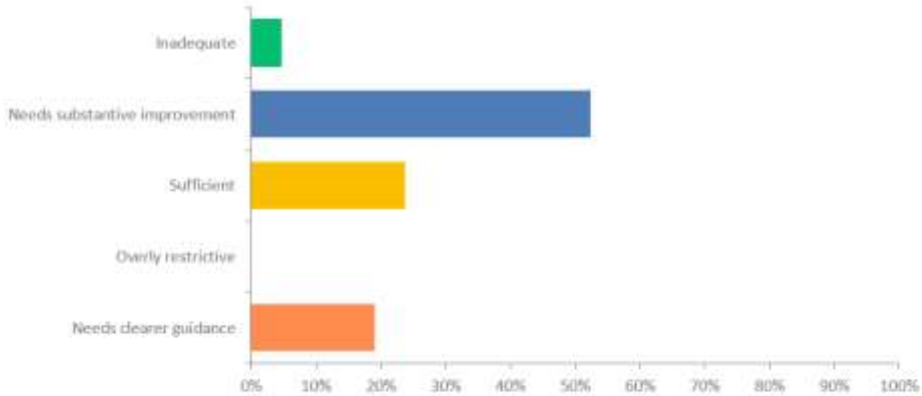
- However, it is important to note that 0% responded that the legislations were "Overly Restrictive", this reinforces the commentary that emerged during the interviews that the EU AI Act sets the standard for Global AIeMD development.
- The data set was uploaded to MiniTab, and a Chi Square test was run exploring the relationship between "Organisation Size" and "How well do you feel current regulatory frameworks (EU MDR 745, EU AI Act 1689) address the challenges in developing and bringing to the market AI enabled medical devices?" the results were not deemed statistically significant.
    - Pearson Chi-square statistic (χ^2): 11.324
    - Degrees of freedom (df): 9
    - p-value: 0.254

  The P value returned >0.05 thus rejecting the null hypothesis, determining there was no statistical significant association between a survey respondents organisation size within the MedTech industry and their current perception of how well the current dual regulatory frameworks address the challenges of developing and bringing to the market AI enabled medical devices.

- Finally 71% of respondents agreed that a harmonisation map of the dual regulatory requirements of EU MDR, and the EU AI Act would be beneficial, 81% agreed that a decision tree or flowchart would be beneficial for navigating the dual regulatory landscape, 76% agreed that a risk assessment framework would be beneficial to help identify and manage AI specific risks, 71% agreed that a compliance checklist would be beneficial.

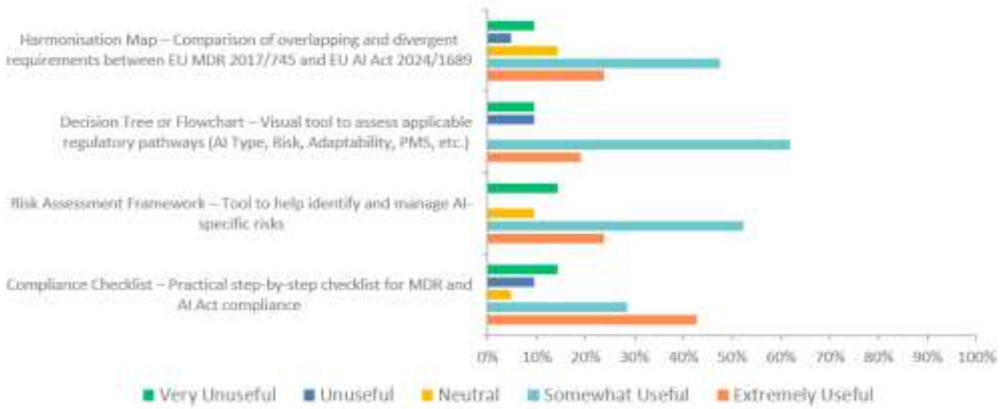
Q19: How well do you feel current regulatory frameworks (EU MDR 745, EU AI Act 1689) address the challenges in developing and bringing to the market AI enabled medical devices?

Answered: 21 Skipped: 2



Q20: Please indicate how useful you believe the following types of regulatory guidance would be for supporting the development and bringing to the market AI enabled medical devices;

Answered: 21 Skipped: 2



Key findings from Quantitative Data:

- Across all roles within the survey respondents, most agreed that improvements were needed in the dual requirements.
- Larger organisations and SMEs were both represented and there was no statistical link noted between role / organisation size and the perceptions of the regulatory frameworks.

- The lack of statistical significance determined between organisation size and the perceived usefulness of regulatory guidance using a chi squared test showed divergence from the theme that ran strongly through the interviews where interviewees expressed concern around the impact the dual regulations place on SMEs. In a larger sample size this theme may have been reinforced, however it must be noted that with the sample size of N=23, both larger and SME size organisations were both leaning towards calling for clearer guidance.
- There is a strong support for guidance and operational tools and templates as most respondents noted some usefulness in structured regulatory guidance tools.

4.3.2 Survey commentary

Survey responses highlighted strong concerns around “data quality” and “risk of bias” as a major hurdle for AIeMD. Many identified “Transparency” and “explainability” as essential for building clinical trust and safety in this new technology, however the unclear insights that remain with regards to “SOUPS” and “Black Boxes” will present challenges with the validation of AIeMD’s.

Compliance in a dual regulatory environment is seen as a balancing act, as overlaps from MDR and the EU AI Act exist. Uncertainty remains with regards to PMS where adaptive algorithms and continuous learning models challenge the traditional model of PMS monitoring systems. Concerns included unclear rules for algorithm updates, version control, real-world validation of performance, and interplay with GDPR restrictions on sensitive data.

The commentary echoed the strong call for clearer guidance and evolving standards to aid organisations in this complex dual regulatory environment. Some warned that companies without established medical device QMS may be unprepared for the demands that the EU AI Act will place on their organisations.

Trust hinges on transparency, data quality, and tightly controlled oversight. Without clearer, evolving frameworks, AI-enabled devices risk running ahead of the regulations designed to keep them safe.

“Regulatory authorities need to continuously review the regulations and guidelines to align with the rate of technological advancement”.

5.0 Discussion

The aim of this research was to examine the complex regulatory landscape that exists in the development and bringing to the market AI enabled medical devices, and establish, through primary research if the need exists for the development of a Strategic Framework for Compliance of AIeMD to EU MDR 745, and the EU AI Act 1689. Through the application of a mixed methods approach which incorporated 11 semi structured interviews with industry stakeholders plus the execution of a structured, targeted survey, the research study identified significant challenges and opportunities in navigating this dual regulatory landscape. The research shone a light on the critical gaps that exist in industry preparedness, resource allocation challenges at SME level, and the urgent need for comprehensive technical guidance frameworks that support the safe and ethical development of AIeMD across all member states. The study also highlighted the importance of a taking a strategic approach to AI technology and its use across organisations to ensure its safe, and responsible deployment.

5.1 Key discussion points

5.1.1 Regulatory fragmentation and industry readiness

The research confirmed the perceived regulatory fragmentation that exists between EU MDR 745, and the EU AI Act 1689, creating complexity for developers and deployers of AIeMD across the member states (Olbrechts, 2024). Through the thematic analysis of 11 interview transcripts, 7 key themes were evident throughout, revealing that regulatory uncertainty extends beyond the simple compliance requirements to fundamental questions around consistency between classifications, notified body competencies, or lack thereof with regards to Artificial Intelligence, and unanswered questions around conformity assessment procedures. Notably 83% of survey respondents identified “Risk classification disparities” as a significant challenge, highlighting the significant regulatory challenges that will arise when a Class 1m device under MDR now become “High Risk” under AIA due to its inclusion of some form of AI technology.

The finding that only 43% of organisations have begun to update their QMS to reflect the additional requirements of the AIA demonstrates a critical preparedness gap across the MedTech industry. This lagging approach to organisational readiness coupled with the reactive rather than proactive approach identified by 90% of interview participants suggests that the MedTech sector may face significant implementation challenges as the AI Act enforcement accelerates.

As discussed in the review of literature Palmieri (2024), highlights that MDR and the EU AI Act while foundational pieces of legislation, leave unanswered questions with regards to “Risk Classifications”. Palmieri (2024) argues that “bias” and “Data quality” requirements have the potential to cause risks to patient safety downstream, and that ambiguity with risk classifications between MDR and the AI Act must be clarified to ensure this does not happen. Palmieri’s identification of complimentary frameworks that intertwine with AIeMD such as GDPR or Cybersecurity legislation links directly with the concerns raised by stakeholders during the interviews of “regulatory fragmentation”. Interviewees raised concerns that developers of AIeMD may try to circumvent the requirements of high-risk devices by ensuring that their devices remain minimal risk and thus subjected to lesser oversight. Palmieri’s analysis provides a more theoretical grounding for these concerns; by linking the findings of the report to those raised during the primary research, the discussion point underscores real industry concerns around the interplay of a number of pieces of EU legislation. Regulatory adequacy must not only be judged on coverage alone but also by the practical operational implications of adhering to the requirements.

5.1.2 Innovation tensions and market dynamics

The research also revealed a nuanced perspective on the impact that the AI Act will have on MedTech innovation, challenging simplistic narratives around regulatory burden. While concerns were raised about “innovation flight risk” to less regulated jurisdictions, interviewees also demonstrated a refined understanding of the balance between patient safety and market competitiveness. The absence of survey responses indicating that the regulations were “overly restrictive” suggests an industry acceptance to robust oversight, even as 76% of respondents called for improved guidance and clearer implementation pathways.

This finding speaks to broader debates that exist in industry around European regulatory positioning in global markets, indicating that the concerns exist more around regulatory clarity and implementation guidance than on the fundamental approach taken by the European Union on safety requirements (Philipp, 2025).

5.1.3 The Diffusion of Innovation

The Diffusion of Innovation Theory, as developed by Everett Rogers in the 1960's serves up a valuable framework for understanding the process that AI enabled medical devices are currently experiencing and how the AIeMD market is developing. The theory identified five adopter categories that can easily be aligned with the current AIeMD market.

1. The Innovators
2. The Early Adopters
3. The Early Majority
4. The Later Majority
5. The Laggards

With regards to AIeMD, The innovators can be identified as those that were at the development phase of this technology, the research hospitals, the innovators, the tech forward looking healthcare professionals that first engaged with IBM's Watson system or Googles DeepMind, This group tend to have a high propensity for risk and strong technical capabilities. The early adopters are those major health systems and speciality clinics that identified a competitive advantage in the use of AI and the application of the technology to their devices and healthcare systems (Monga *et al.*, 2024).

We are currently seeing the emergence of the early majority as regulatory clarity comes and the number of devices receiving FDA approval and CE marking increases exponentially. Forward looking clinicians and hospitals are seeing the benefits and seeking to adopt AI technology and devices into their workflows.

The late adopters and laggards are awaiting guidance in the form of standards and guidance documents and seek to identify cost benefits or validated workflow improvements before jumping to adopt the technology. Until the standards and guidance come, this group will be slow to adopt AI technology.

As discussed by Hassan *et al.*, 2024, in the paper "Barriers to and Facilitators of Artificial Intelligence Adoption in Health Care" The findings demonstrated that the implementation of AI in health care is still, in many ways, dependent on the establishment of regulatory and legal frameworks.

5.1.4 Organisational capacity and resource disparity, a compounded effect

The research identified significant capacity gaps that exist between the larger medical device organisations, and the SMEs, that the EU AI Act directly addresses within the legislation to nurture through access to regulatory sandboxes etc. Interview data revealed resource constrained SME's face particular challenges in navigating dual regulatory environments potentially leading to market consolidation where only the larger players have the resources to effectively develop and bring to market AIeMD. However, one interviewee raised a nuanced point that potentially it's the larger medical device organisations that we want bringing products to market and not the two men start up that potentially miss identifying and addressing risks with the technology. The finding aligns with broader industry concerns around regulatory barriers to entry in highly regulated industries such as the AIeMD market. What impact this has on the medical device market remains to be seen, however where regularity ambiguity remains, and challenges exist around the practical operational implementation of the EU AI Act requirements such as model validation, and Post market surveillance one would expect that this will create compounded burdens for organisations, in particular SME's (Laux *et al.*, 2022)

5.2 Theoretical and Practical Implications

5.2.1 New approach legislation and regulatory architecture

One interviewee highlighted the fundamental challenges of "New approach legislation" when applied to emerging and evolving technologies such as Artificial Intelligence. The EU's new approach, originally designed to harmonise technical standards across the Union faces unprecedented challenges when trying to harmonise such technologies as AI which potentially transcend typical product categories, coupled with the lack of standards that currently exist in publication with regards to AIeMD. The dual regulatory burden discussed in this research study highlights broader tensions within European regulatory architecture when trying to regulate sector specific products through for example MDR, with horizontal technology regulations such as the AI Act where the technology transcends product categories, borders, and society alike (Sybe de Vries *et al.*, 2023).

The inconsistencies that exist between EU MDR, and the EU AI Act risk classifications demonstrate how the "New Approach" framework struggles to accommodate technologies that challenge traditional regulatory boundaries such as AI.

5.2.2 Cost of regulation and market access

The stark disparities that the interviews highlighted with regards to the capabilities that exist at SME vs large organisation levels potentially may have wider implications for the European healthcare innovation ecosystem. The research suggests that dual regulatory compliance requirements may inadvertently favour those larger players with substantial Regulator Affairs departments, resources and budgets to ensure compliance, potentially stifling the entrepreneurial innovation that has historically driven the medical device market. The discussion around "Pay to play" comments with regards to compliance are worthy of discussion on the potential cost-competitiveness challenges especially when compared to the cost to entry of such markets as the USA where lighter touch regulations have been applied to AIeMD.

As discussed by Bayrak et al (2022), there has been significant implementation costs placed on manufacturers already in the move from MDD to MDR and now with the enactment of the EU AI Act, AIeMD manufacturers will now face additional regulatory expenses to make their devices available on the European Market. While this research study did not quantitatively assess regulatory costs, commentary suggested that significant cost implications exist between EU MDR, and FDA approvals which will now be potentially exacerbated with the introduction of the EU AI Act to the AIeMD market. The time and resource investments needed for dual compliance in an environment where the lack of guidelines and harmonised standards likely increase time to market and development costs for European AIeMD developers, and deployers. However, it must also be noted the research additionally suggested some industry stakeholders view rigorous EU standards as a competitive advantage, establishing global benchmarks for the regulation of emerging technology where patient “Trust” and “Safety” are paramount. This perspective echoes the theory of “The Brussels Effect” where stringent European regulations influence global standard development (Bradford, 2020).

5.2.3 EUDAMED infrastructure challenges and the impact on AIeMD

Although the topic was not one discussed in detail during the primary data collection, the use of EUDAMED during the secondary data collection proved difficult in comparison to the FDA AI-Enabled Medical Device Database. EUDAMED implementation has been marred by issues, delays, and ultimately a phased implementation in response to these challenges (Eglovitch, 2025). A search for AI enabled medical devices could not be completed using the EUDAMED database as AI is not a searchable term. Therefore, the secondary data analysis was carried out using the FDA AI enabled Medical Device database which allowed then for cross referencing of EUDAMED to establish the CE status of a sample of AIeMD in each medical field. The data returned from the FDA database was also used in the development of statistics and charts used during the introduction chapter of this research study. As a European, conducting research on EU legislation effecting devices available on the European market, the inability to conduct the search using EUDAMED was deemed by the researcher as an issue that should be highlighted.

These findings echoed the concerns identified by Muehlematter et al. (2021), who observed that while Europe approved more AI/ML devices than the US, the process was more decentralised, less transparent, and often classified devices at lower risk levels. The author also discussed the shortcomings of EUDAMED and the actions that are needed to be taken to improve the understanding of, and risks associated with AIeMD.

5.3 The role of standards and guidance documents in a dual regulatory landscape

5.3.1 Gaps identified in implementation support.

The research confirmed an overwhelming consensus from the interview data where 90% of stakeholders agreed that the current offering of standards and guidance documents were lacking in a dual regulatory environment. This finding represents critical implementation gap that exists, potentially threatening the realisation of EU MDR and the EU AI Act objectives. The delay in releasing harmonised standards and guidance documents creates an environment where regulatory uncertainty blossoms and potentially increases safety risks as developers wrestle with interpreting legislative requirements independently.

The high demand identified by the study for practical implementation tools such as decision trees, harmonisation tables, and risk management templates demonstrates that industry needs extend beyond that of cumbersome regulatory text to practical hands-on operational support documents that aid organisations in identifying the additional requirements of this new legislation.

Morley et al (2021), discuss these shortcomings in the paper “Towards a framework for evaluating the safety, acceptability and efficacy of AI systems for health: an initial synthesis”. The authors highlight an absence of internationally accepted or formalised regulatory standards for evaluating AI safety, impact, and effectiveness in the health space and propose a minimally viable, structured evaluation framework for guiding developers, policymakers, and regulators through the AI lifecycle, aiming to fulfil this standards and guidance gap.

5.3.2 The evolving role of EU Standard publishers

The implications of the research extend to the expanding role of CENELEC and other approved European standard developers in publishing EN standards. The complexity of AIeMD dual compliance suggests that traditional standard development timelines may not be applicable to a technology such as AI where updates, breakthroughs and technological leaps occur at a faster rate than traditional medical device technologies. EN standard developers work on the issuing of guidance documents becomes ever more critical not only for technical guidance but in the production of the hands-on operational supports identified as so badly needed by industry. One interviewee who works directly with CENELEC referred to the fact that multiple guidelines, and standards are in the drafting and approval phase of development with the release of many of these guidelines imminent.

5.4 The whole lifecycle approach and Post Market obligations

5.4.1 Fundamental shift in medical device oversight

The research highlights a fundamental shift in traditional medical device regulation towards a more continuous, life cycle-based oversight approach. The identification of post-market surveillance challenges by 78% of survey respondents reflects a deep question about how current regulatory frameworks needed updating to accommodate AIeMD that continuously learn, update and evolve after deployment.

The contrast highlighted by interviewees around the traditional complaints based post-market surveillance model to one where direct data can be garnered from patients in a more personal and dynamic manner represents a paradigm shift in the approach to PMS, one that presents potential benefits and challenges. The research suggests that this transition requires clear guidance documents and technical approaches to this evolving approach to PMS in AI enabled medical devices.

As discussed in the review of literature, Aquino et al. (2024), highlight in their paper "*Defining change: Exploring expert views about the regulatory challenges in adaptive artificial intelligence for healthcare*" the challenges faced by developers and deployers of

AIeMD with regards to PMS of adaptive systems that evolve beyond that of their initial certification. This aligns strongly with the results of the research where participants emphasised the already challenging demands of PMS under the MDR, and when combined with the requirements of the EU AI Act creates a dual compliance burden. Aquino et al. (2024), argues that effective PMS of AIeMD requires continuous monitoring for model drift, bias and performance, and thus a fundamental change in the approach of a static PMS. The findings of the primary research build on this by presenting that industry stakeholders align with that viewpoint, and that existing PMS approaches are insufficiently flexible to capture real world AIeMD performance. The convergence between my data and that of the conclusions drawn by Aquino et al. (2024), suggests that achieving regulatory adequacy isn't necessarily just a question of meeting the requirements of EU MDR, and the EU AI Act, but that of reimagining PMS processes and agile, dynamic, and active feedback loops.

5.4.2 Regulating adaptive systems.

The finding that 33% of survey respondents work with AI models that continuously learn and evolve after deployment illustrates a challenge of applying static regulatory frameworks to dynamic agile technologies. The research reveals tensions between the EU AI Act's requirements for transparency and explainability and the inherent complexity of adaptive AI systems.

This tension suggests that successful regulation of AIeMD may require new forms of regulatory science that can assess and monitor systems that change over time while maintaining safety and efficacy standards. The whole-life cycle approach demanded by both regulations represents recognition of this challenge (Li *et al.*, 2023).

5.5 AIeMD and Healthcare Transformation

5.5.1 Addressing the quadruple aims in healthcare.

Despite the regulatory challenges that exist, the research findings suggest significant optimism exists around the potential of AI enabled medical devices to revolutionise the global healthcare system. The absence of responses indicating that the regulations were "overly restrictive" combined with the recognition of AI's transformative potential suggests broad industry belief that appropriately regulated AIeMD that have gone through the certification process and place patient safety, trust, and innovation at the core of their offering can potentially aid in the delivery of the quadruple aims of healthcare.

The quadruple aims as discussed during the introduction to the research target the improvement of 4 areas of healthcare, enhanced patient experience, improving population health through increased speed of delivery of healthcare, reducing per capita costs, and the support of caregivers could potentially present a framework for which the success of AIeMD could be measured over the coming years beyond that of purely profitability and regulatory compliance. The research findings suggest that achieving these aims through the deployment of Artificial Intelligence to our healthcare system and devices requires not only technical innovation but clear, robust regulatory frameworks and guidance documents that foster the development of responsible AIeMD while maintaining the highest safety standards and trustworthiness.

As discussed in the review of literature, Weeks *et al.*, 2024 in their paper "*Artificial intelligence: promise and peril in achieving the quadruple aim in healthcare"* discuss how AI technologies applied to healthcare has the potential to deliver the quadruple aims in healthcare while also warning of the risks of haphazard application of the technology. Their emphasis on responsible AI deployment aligns with the findings of the research, the potential exists, but stringent regulatory oversight is needed to ensure patient safety remains at the forefront of innovation. The paper also discussed the shortcomings of current PMS versus that which is needed of adaptive agile PMS models, aligning to earlier discussion points raised by the interviewees. It is clear that the findings of the research converge with the discussion points raised by Weeks et al, the promise of AI in delivering the quadruple aims in healthcare will only be realised if regulatory frameworks enforce responsible practices, otherwise AI risks entrenching biases, inefficiencies, and inequities rather than alleviating them.

5.5.2 Balancing the tension between innovation and safety.

The research revealed a sophisticated industry understanding that the need exists to balance innovation and risk as the development of AIeMD increases over the coming years. The findings that some interviewees view European standards as the benchmark for responsible global AI development suggests an understanding that short term compliance head winds may be needed to ensure longer term competitive advantage through rigorous public safety and unwavering trust in this technology that remains in its infancy to the public. This perspective challenged the perceived notion that innovation comes at the expense of regulation (Sharma *et al.*, 2025) and instead suggested an understanding that well designed regulatory frameworks could enhance innovation by creating stable, predictable development environments that encourage long term investment in safety and efficacy improvements.

5.6 Limitations and future research opportunities

5.6.1 Research limitations

The limitations of this research study centre around the sample size of both interview candidates and survey respondents. The modest survey sample size (n=23) and the limited number of interviews that took place (n=11) limit the findings. In addition, the absence of patient and healthcare provider perspectives also represent an important limitation of the study. The research also focussed primarily on European perspectives, with limited comparisons or exposure to global regulatory viewpoints. It is also important to note the pace at which AI technology itself, AIeMD's, and standards are developing, for example, within the undertaking of the study the Medical Device Co-ordination Group (MDCG) in conjunction with the Artificial Intelligence Board released MDCG-2025-6, a guidance document outlining the interplay between EU MDR and the EU AI Act.

A theme that also emerged through the targeting of survey respondents and interview candidates was the realisation that with a breakthrough technology such as AI, many professionals feel the need to represent themselves as subject matter experts without the technical expertise to back it up. Several candidates that marketed themselves as AI experts or specialists were quick to acknowledge their lack of industry or hands on AI, or AIeMD experience when presented with the interview questions and politely withdrew themselves from the study. This is typical of an emerging technology, as professionals try to position themselves as Subject Matter Experts to drive revenue streams (Mishra, 2024).

5.6.2 Future research priorities

Future research studies could potentially centre around the actual standards that exist in aiding in the development of AIeMD, although many deal directly with AI technology on its own or medical devices on their own, adopting a combination of both would providers developers and deployers with a broad oversight of the responsible development of AI enabled medical devices.

One interviewee commented on an approach they took to the development of a medical device that lacked standards and guidance and presented a situation where although a lack of standards existed, they adapted other available standards for similar risk level devices and applied them to their development device, fulfilling a gap that existed.

"So, what we did is, we ended up looking around like, OK, what are other parts of the body that are super sensitive that have implants? And that there are these sorts of standards for and like, oh, OK, there's a pacemaker standard. All right, well, there's not going to be 100%, you know, match on all the different requirements or what not, but we can look at that as an opportunity to fill a gap" (Interviewee 10: Product and Compliance Executive | P&L Leader | 10+ Years Building AI Products | Life Sciences, MedTech, Healthcare, Digital Health)

Future research could also potentially investigate the actual implementation costs of dual compliance, including quantitative analysis of time-to-market impacts and resource allocation requirements. Comparative studies examining different national approaches to AIeMD regulation could provide insights into optimal regulatory design at European level.

Also, a potential Investigation into the effectiveness of regulatory sandboxes and other innovation support mechanisms outlined in the EU AI Act could provide guidance for optimising these tools to support both innovation and safety objectives, at SME level, a topic raised multiple times during the research.

6.0 Conclusion

This research study demonstrated that the dual regulatory landscape created by EU MDR, and the EU AI Act pose significant challenges and important opportunities for those involved in the development, deployment and regulation on AIeMD throughout the European Union, and globally. While regulatory fragmentation, resource disparities and implementation uncertainty create potential hurdles, the research also revealed industry commitment to responsible innovation in the AIeMD arena recognising the need for robust safety frameworks that ensures patient safety, and trust, remains at the forefront of innovation.

The seven themes identified through the thematic analysis of 11 interviews conducted with industry professionals, regulatory fragmentation, validation challenges, lifecycle management complexity, QMS integration needs, innovation pressures, capacity gaps, and demand for implementation guidance provided a comprehensive overview of the challenges that exist, reinforced by the data garnered from a focussed industry survey. These challenges provide a framework for targeted solutions to be developed at member state and EU level.

The research contributes to the scholarly understanding of how emerging legislation applied using the "New approach legislation" framework intersects with sector specific regulations such as MDR and provides practical insights for industry professionals navigating this complex dual regulatory environment. The findings suggest that successful development and deployment of AIeMD with the EU requires not only technical breakthroughs but also collaborative approaches to legislative implementation to support both patient safety, and innovation objectives.

Ultimately, the research demonstrated that the future of AIeMD within the EU relies as much on hands on guidance documents, and harmonised standards as much as it does European legislation. The role now turns to the standards organisations to produce these guidelines thus enabling the successful application of the legislation. Thus, allowing for the transformative promise of AIeMD to take hold and assist member states in delivering the elusive quadruple aims in healthcare, enhanced patient experience, improving population health through increased speed of delivery of healthcare, reducing per capita costs, and the support of caregivers.

7.0 Recommendations

7.1 Policy recommendations

Based on the research there have been several policy recommendations identified mainly.

Accelerated Guidance Development: Regulatory authorities should prioritise the development and rollout of comprehensive guidance documents that support organisations in meeting the requirements of these dual regulations for AIeMD. The research identified high demand for decision trees, risk assessment frameworks and compliance checklists.

Harmonised Standards Development: The organisations behind standard development such as CENELEC should expedite harmonised standards for AIeMD, with particular emphasis in addressing the classification inconsistencies and conformity assessment challenges identified in this research.

SME Support Enhancement: Throughout the EU AI Act the support for SME's is noted in the legislation, the pressure now turns to member states including Ireland to strengthen the support mechanisms available for SME's involved in the development of AIeMD or digital health so that we remain at the forefront of industry development. These supports should include access to regulatory sandboxes, technical assistance programs, and collaborative environments where the challenges of dual regulatory compliance can be discussed and approached in a collaborative manner.

Infrastructure Improvements: Continued investment and improvement of the EUDAMED architecture is needed to ensure that future research students can conduct data analysis in as easy of a manner as that of the FDA AI Medical Device Database.

7.2 Industry implications

The research also identified several industry considerations that should be addressed, mainly.

Proactive preparation: Organisations, in particular SME's should proactively commence at minimum identifying the resources that will be required to apply the updates to QMS in line with the additional requirements of the EU AI Act 1689. The reactive approach identified from this research may lead to implementation delays and competitive disadvantage.

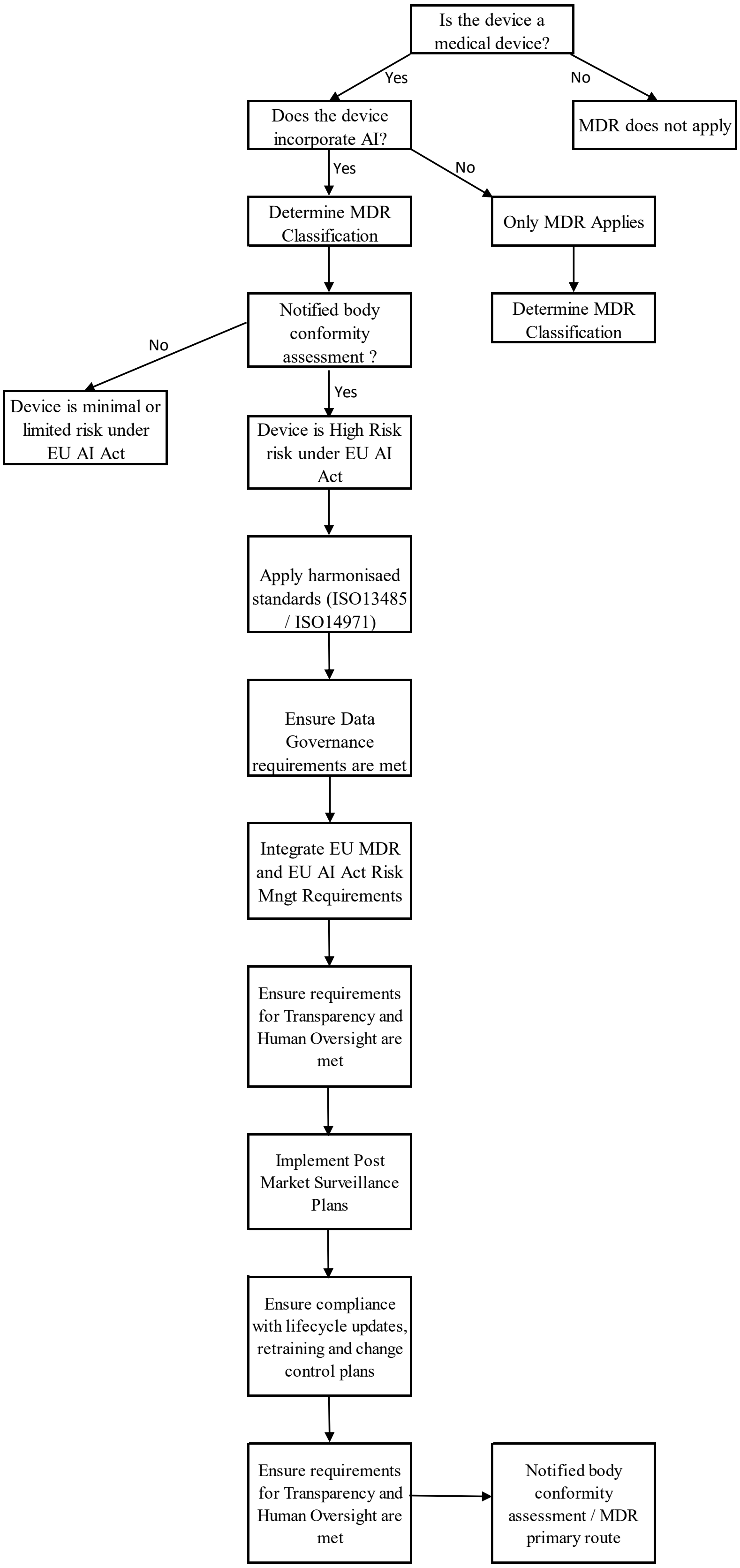
Collaborative approaches: Shared resources should be identified and developed in a collaborative manner by industry associations and networks to accelerate the development of best-in-class standards for AIeMD, this would support SME's who may lack the regulatory expertise or capacity to develop comprehensive compliance programs.

Investment in regulatory expertise: Organisations involved in the development, deployment or regulation of AIeMD should invest in resources at regulatory affairs level to ensure compliance to this dual regulatory environment. Additional training in both legislation and technical expertise will be required as the use of AI technology expands within the MedTech industry.

7.3 Developing practical operational tools and templates.

The research study undertaken clearly identified the need for the development of a strategic framework for compliance of AI enabled Medical Devices (AIeMD) to EU MDR 745 and the EU AI Act1689 as set out in the objectives of the thesis. The researcher sought to establish whether the need exists for such a framework, and through the undertaking of primary research there was broad consensus that current guidance and standards documents are lacking. The research identified a strong call for practical, operational tools and templates that form the guidance and standards that industry is calling for. So, what might these guidance documents and standards contain to fulfil this need?

1. *A decision tree that aids in the navigation of dual compliance to EU MDR 745 and the EU AI Act, for example,*



2. *A matrix overview of EU MDR requirements and additional EU AI Act requirements, for example,*

Requirement	EU MDR	EU AI Act
Management Systems	Requirement to manage the entire lifecycle of the device for safety and performance	Adds requirements for continuous review, and oversight for system drift, performance decay or bias
Quality Management System	Emphasises the use of a QMS to ensure safety and performance	Adds requirements for: > Data Governance > Human Oversight > Record Keeping > Model Transparency
Risk Management	Requires a continuous, iterative process of risk management in both the premarket and post market phases focussed on health, safety, and fundamental rights	Adds the requirement to manage risk throughout the entire lifecycle of the system functioning for impacts to fundamental human rights, data biases, system robustness
Data Governance	Requirement for robust clinical data / clinical evidence	Adds the requirement for documentation that the system is built and validated on robust, and trustworthy data
	Must comply with GDPR	

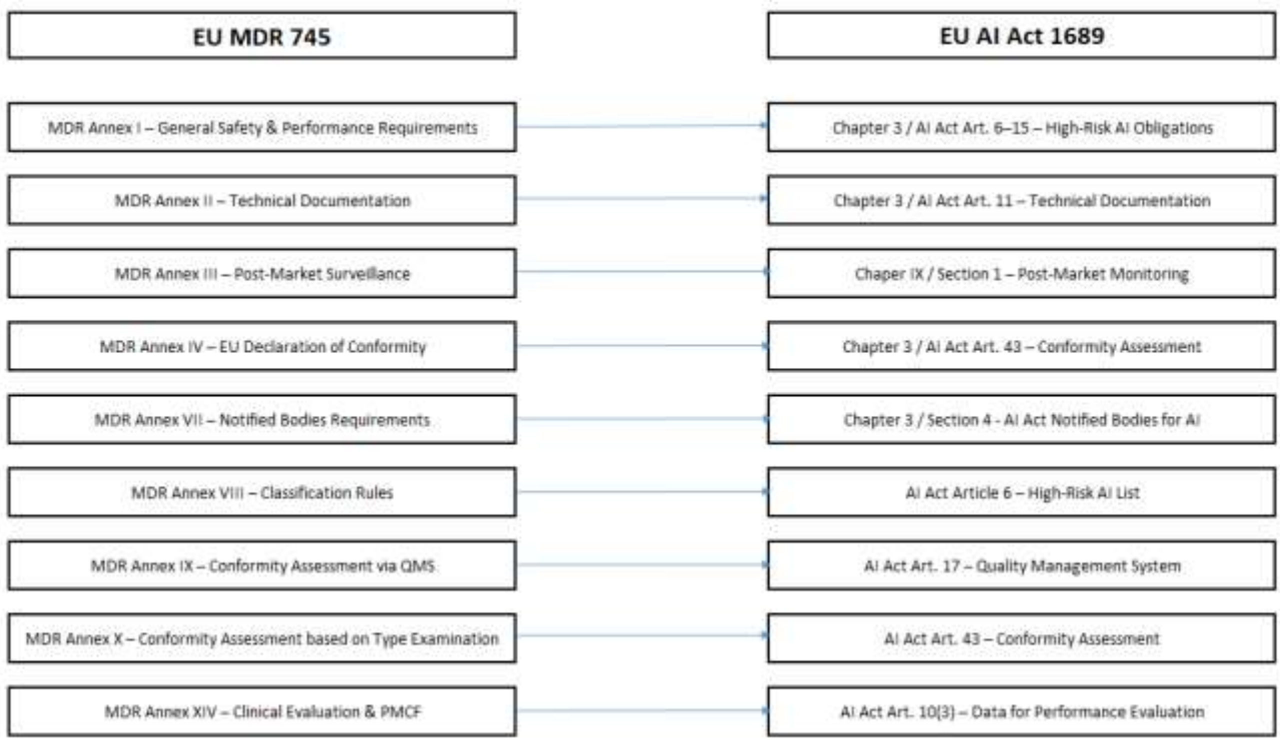
Data Management		Adds the requirement for training data transparency, model data management, model data validation, machine learning techniques, and data bias governance.
Technical Documentation	Requirements for comprehensive technical documentation such as descriptions of software, software architecture, data processing methods, risk management strategies, intended use, clinical data,	Adds requirements for documentation on model transparency, human oversight, accountability, data governance, and performance testing and outcomes.
Transparency and Human Oversight	Transparency requirements for intended use, transparency requirements embedded in General Safety and Performance Requirements.	Adds legally binding core comprehensive requirements for transparency, model functionality, human oversight, informed consent for users, model explainability, and model deployment. AIeMD must have extensive functionality for human oversight and intervention in the system. The system must not be capable of overriding the human oversight functionality of the system and must ensure responsiveness to a human operator. There must also be clear instructions for the human override of a system
Accountability	Requires documentation for clinical and performance evaluation, clear and complete on how the device operates	Adds explicit obligations for model transparency which contributes to explainability which in turn facilitates accountability. Deployers of AIeMD must be able to demonstrate and communicate how the system makes decisions and must show accountability for model updating post market.
Informed Consent	Mainly applies to the informed consent of clinical studies and the informed consent of participants.	Adds the requirements of Informed Consent to the deployers of systems to ensure patients awareness to the functioning, capabilities, limitations, and potential risks of the AI system.
Traceability		

	Requirements for traceability throughout the supply chain and device lifecycle, including UDI registration and PMS. Scope is traceability of device movement	Adds the requirement of system performance traceability through performance logs, and system behaviours. Scope is traceability of system performance.
Accuracy / Robustness and Cyber-Security	Requires risk management practices and procedures protecting against unauthorised access, cyber-attacks, exploits and manipulation that may impact operational resilience or patient safety.	Adds requirements for AI specific cyber-security measures to protect against model poisoning, and unauthorised access to system data at operational, post market and training phase to ensure patient safety and protection of fundamental rights.
Clinical Evaluation	Robust clinical evaluation requirements in place	Adds requirements for accuracy, robustness, cyber-security, and performance of the AI system, including verification and validation of design, manufacturing, data collection, re-processing, model training, and quality management activities include continuous monitoring of model performance.
Conformity Assessment	Requires notified body conformity assessment including audit of the QMS and technical documentation to ensure compliance	If the devices are, consider MDAI or AIeMD then conformity assessment takes place under MDR. If the device is high risk but not determined a MDAI or AIeMD then the conformity assessment takes place under the EU AI Act.
Post Market Surveillance	Requires the establishment of post market surveillance activities that monitor the performance of the device, risk monitoring, adverse even tracking, and taking corrective and preventative action as needed.	Adds the requirement that AI systems incorporated in AIMD or AIeMD to undertake post market surveillance to monitor performance of the system throughout the lifecycle of the system to ensure compliance with obligations related to safety and performance standards, in particular model performance, safety, drift, and bias.

3. A checklist that guides organisations through the additional requirements of the EU AI Act 1689 over and above the requirements of EU MDR, for example

Annex	Requirement	Checklist Item	
Annex VIII	**Information for the registration of High Risk AI systems**	*Identification of AI System and Provider*	☐
		Description of intended purpose	☐
		Description of data inputs and operating logic	☐
		Conformity statement	☐
		Conformity assessment procedure	☐
		Electronic instructions for use	☐
Annex IX	**Information for real world testing**	*A unique signgle identification number*	☐
		Testing authority information	☐
		Scope and purpose of testing	☐
		Testing plan	☐
		Risk assessment plan	☐
		Supervision and monitoring plans	☐
		Data protection and privacy plans	☐
		Notification to authorities	☐
Annex XI	**Technical documantation for GenAI providers**	*Model information*	☐
		Model design specifications	☐
		Training data	☐
		Model architecture details	☐
		Testing and evaluation criteria	☐
		Risk assessment plan	☐
		Governance and compliance plans	☐
Annex XII	**Transparency requirements**	*Public documentation*	☐
		Version number and licence details	☐
		Details on model interaction	☐
		Training data summary	☐
		Copyright compliance	☐
		Model performance information	☐
		Model modality for inputs and outputs	☐
		Safety and security	☐
		Access and updates	☐
Annex XIII	**Criteria for Designation of General-Purpose AI Models with Systemic**	*Computational threshhold assessment*	☐
		Number of parameters of dataset	☐
		Details on the quality and size of the data	☐
		Input and Output modalities	☐
		Benchmark assessments	☐
		Capability assessment	☐
		Market impact evaluation	☐
		Model characteristics	☐
		Risk factor analysis	☐
		Systemic risk assessment	☐
		Documentation and notification	☐

4. EU MDR 745, and EU AI Act 1689 Requirements Mapping Matrix, for example,



These are just some examples of decision trees, matrixes, and checklists that guidance documents should contain to aid organisations in the dual compliance of AIeMD to EU MDR 745, and the EU AI Act 1689.

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8.0 Appendices

Figure 1 – Field of FDA approved AI enabled medical devices 1995 – May 2025 (Source FDA.Gov)

Row Labels	**Count of Panel (lead)**
Radiology	76.48%
Cardiovascular	10.24%
Neurology	4.13%
Anaesthesiology	1.67%
Haematology	1.67%
Gastroenterology-Urology	1.38%
Ophthalmic	0.89%
Clinical Chemistry	0.89%
Clinical Toxicology	0.49%
Microbiology	0.49%
General Hospital	0.39%
Dental	0.39%
Pathology	0.30%
Orthopaedic	0.20%
General and Plastic Surgery	0.20%
Obstetrics and Gynaecology	0.10%
Immunology	0.10%
Grand Total	**100.00%**

Figure 2 – Number of FDA approved AI enabled medical devices per year 1995 – May 2025 (Source FDA.Gov)

Year of Grant	**Count of Year of Grant**
1995	2
1997	1
1998	2
2001	2
2002	1
2004	1
2005	1
2006	1
2008	5
2010	2
2011	3
2012	5
2013	4
2014	6
2015	6
2016	18
2017	27
2018	65
2019	80

2020	114
2021	130
2022	162
2023	226
2024	235
2025	148
Grand Total	**1247**

Figure 3 – Pathway of FDA approved AI enabled medical devices 1995 – 2024 (Source FDA.Gov)

FDA Pathway	Count of Approvals Pathway	% of Total
510(K)	1195	96%
De Novo	36	3%
PMA	16	1%
Grand Total	**1247**	

Figure 4: Interview question list

- What specific requirements within the EU AI Act do you believe go beyond or are not sufficiently addressed by the current EU MDR when it comes to AI in medical devices? Could you provide examples?
- From your perspective, what do you feel are the most significant technical, clinical, or regulatory documentation challenges in developing AI-enabled medical devices to comply with both the EU MDR 745 and the recently enacted EU AI Act 1689?

- Can you provide an example of a compliance challenge you have faced or a strategy your organisation has used to address dual regulatory requirements?
- Have you identified any conflicting requirements between the EU MDR and the EU AI Act that could create difficulties for manufacturers of AI-enabled medical devices? E.g., risk management, conformity assessment, post-market surveillance
- Do you see a need for a more strategic or integrated compliance framework to ensure efficient and effective compliance with both the EU MDR and the EU AI Act for AI-enabled medical devices? If so, what key elements should such a framework include?
- How does your organisation address AI-specific requirements within its quality management system to comply with both MDR and AI Act?
- Are there specific areas of the product lifecycle (e.g., design, development, clinical evaluation, Post Market) that you feel present the greatest need for a compliance framework to align compliance with both the EU MDR and the EU AI Act?
- In your experience, where do you see the most significant overlaps or potential for harmonisation when trying to meet the requirements of both the EU MDR and the EU AI Act for a AI enabled medical device?
- Do you anticipate EU MDR and the EU AI Act will affect the innovation and development timelines for AI-enabled medical devices in the European market?
- Do you think industry standards and regulatory guidance documents should play a role in helping manufacturers navigate the challenges of complying with both the EU MDR and the EU AI Act for AI-enabled medical devices?
- From an industry perspective, what strategic approaches, if any, are you considering to address the dual regulatory requirements of the EU MDR and the EU AI Act for AI-enabled medical devices?
- Given the current regulatory landscape, what do you feel are the focus areas for manufacturers and regulatory bodies to foster innovation in AI-enabled medical devices while ensuring patient safety and compliance with both the EU MDR and the EU AI Act?
- In your experience, do you believe there is currently sufficient regulatory clarity and integration between the EU MDR and the EU AI Act when it comes to bringing AI-enabled medical devices to market? If not, what kind of guidance or structured framework would you find most useful in achieving compliance?

Figure 5: Survey question list;

- I consent to being a participant in this research study.
  - ☐ Yes
  - ☐ No

1. What is your current role in the Medical Device industry?
   - ☐ Regulatory Affairs Professional
   - ☐ PRRC (Person Responsible for Regulatory Compliance)
   - ☐ QA Professional
   - ☐ AI / Software Developer
   - ☐ Research and Development

2. What is your current duration of experience within the Medtech industry
   - ☐ <1 year
   - ☐ 1 year to 5 years
   - ☐ >5 years

3. What is the current demographic of your organisation?
   - ☐ Within the EU
   - ☐ Outside of the EU

4. What is the size of your organisation?
   - ☐ <100 employees
   - ☐ 100 – 500 employees
   - ☐ >500 employees

5. How familiar are you with EU MDR 2017/745?
   - ☐ Not at all familiar
   - ☐ Somewhat familiar
   - ☐ Very familiar
   - ☐ Expert
   - ☐ Other (Please comment) ____________________

6. How familiar are you with EU AI Act 2024/1689
   - ☐ Not at all familiar
   - ☐ Somewhat familiar
   - ☐ Very familiar
   - ☐ Expert
   - ☐ Other (Please specify) ____________________

7. Within your organisation, with regards to AI, which of the following statements apply?
   - ☐ AI forms part of my organisations strategic goals
   - ☐ We use AI informally without formal strategy

- ☐ Our organisation discourages AI use
- ☐ We do not use AI in any manner that I am aware of
- ☐ Other (Please specify) ___________________

8. Within your organisation's current product offering, which of the following statements apply?
   - ☐ We currently offer AI enabled medical devices to the EU market
   - ☐ We currently offer, and are also developing additional AI enabled medical devices for the EU market
   - ☐ We are currently in the development phase of AI enabled medical devices for the EU market
   - ☐ We do not currently have AI enabled medical devices available on the EU market, and have no plans for developing AI enabled medical devices.
   - ☐ Other (Please specify) ___________________

9. What risk classification applies to AI enabled medical devices in your organisation under EU MDR?
   - ☐ Class 1 – Low Risk
   - ☐ Class 2a – Medium Risk
   - ☐ Class 2b – Medium to high Risk
   - ☐ Class 3 – High Risk
   - ☐ Not Sure

10. What risk classification applies to AI enabled medical devices in your organisation under EU AI Act 1689?
    - ☐ Unacceptable Risk
    - ☐ High Risk
    - ☐ Limited Risk
    - ☐ Minimal Risk
    - ☐ Not Sure

11. Please indicate the extent to which you agree that ***the following are significant compliance challenges for AI-enabled medical devices:***

Compliance Challenge	**Strongly Disagree**	**Disagree**	**Neutral**	**Agree**	**Strongly Agree**
a. AI explainability and transparency	☐	☐	☐	☐	☐
b. Dual compliance with both EU MDR	☐	☐	☐	☐	☐

Compliance Challenge	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
2017/745 and EU AI Act 2024/1689					
c. Bias and data quality issues	☐	☐	☐	☐	☐
d. Post-market surveillance requirements for AI systems	☐	☐	☐	☐	☐
e. Risk classification under MDR/AI Act	☐	☐	☐	☐	☐
Other (please					

Can you briefly explain your answer:

____

12. Has your organisation integrated the requirements of AI enabled medical devices into its QMS?
    - ☐ Yes
    - ☐ No
    - ☐ Currently in process of integrating
    - ☐ Not sure
    - ☐ Other (Please specify) ____________________

13. To what extent do you agree with the following statement:

Statement	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
"The current regulatory requirements under the EU MDR 2017/745 and the EU AI Act 2024/1689 provide sufficient clarity and support for implementing robust data governance practices in AI-enabled medical devices."	☐	☐	☐	☐	☐
Other (please specify)					

Please briefly explain what, if any, aspects of data governance you find under-supported (e.g., dataset bias, black box, traceability, data quality requirements, etc.): ____________________

14. To what extent do you agree with the following statement:

Statement	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
"The post-market surveillance (PMS) requirements under the EU MDR 2017/745 and the EU AI Act 2024/1689 are sufficiently aligned and effective for monitoring the ongoing performance and safety of AI-enabled medical devices."	☐	☐	☐	☐	☐
Other (please specify)					

Please briefly explain what gaps or challenges you believe exist in the current PMS requirements (e.g., handling adaptive algorithms, data feedback loops, transparency reporting, real-time monitoring expectations): ____________________

15. Does your organisation use AI adaptive models that continuously learn and evolve after deployment?
    - ☐ Yes
    - ☐ No
    - ☐ Not sure
    - ☐ We do not offer AI enabled medical devices
    - ☐ Other (Please specify) ____________________

16. How well do you feel current regulatory frameworks (EU MDR 745, EU AI Act 1689) address the challenges in developing and bringing to the market AI enabled medical devices?
    - ☐ Inadequate
    - ☐ Needs substantive improvement
    - ☐ Sufficient
    - ☐ Overly restrictive
    - ☐ Needs clearer guidance

17. Please indicate how useful you believe the following types of regulatory guidance would be for supporting the development and bringing to the market AI enabled medical devices;

Type of Guidance	Very Unuseful	Unuseful	Neutral	Somewhat Useful	Extremely Useful
a. Harmonisation Map – Comparison of overlapping and divergent requirements between EU MDR 2017/745 and EU AI Act 2024/1689	☐	☐	☐	☐	☐
b. Decision Tree or Flowchart – Visual tool to assess applicable regulatory pathways (AI Type, Risk, Adaptability, PMS, etc.)	☐	☐	☐	☐	☐
c. Risk Assessment Framework – Tool to help identify and manage AI-specific risks	☐	☐	☐	☐	☐
d. Compliance Checklist – Practical step-by-step checklist for MDR and AI Act compliance	☐	☐	☐	☐	☐

Are there any other forms of regulatory guidance you believe would be helpful? Please specify:

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