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Evaluating the Impact of the EU AI Act on Medical Device Regulation

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Abstract. Artificial Intelligence (AI) is increasingly incorporated into medical devices, revolutionizing diagnostics, treatment planning, and patient monitoring. To ensure AI's safe and ethical use, the European Commission published the AI Act in 2024, which places stringent obligations on AI systems, especially those classified as high-risk, such as medical devices. This paper evaluates the impact of the EU AI Act on existing regulations such as the Medical Device Regulation (MDR) and the In Vitro Diagnostic Regulation (IVDR). It explores challenges related to compliance, certification processes, and potential conflicts between the AI Act and existing medical device frameworks while providing recommendations for harmonization.

Keywords. AI Act, MDR, IVDR, medical devices, compliance, risk management

1. Introduction

Artificial intelligence will transform healthcare diagnosis through its integration into regulated digital medical products. The legal regulation of AI will have great prominence in regulated digital medical products involving medical devices [1]. The legal framework that adorns the top level comprises the overarching legal framework concerning AI/ML-enabled medical products. It shapes their development, authorization, market introduction, deployment, and use. In the past, several other regulations were applied to medical devices. This has now changed. The EU has just cleared the world's first omnibus legal framework for AI, the EU AI Act [2]. The Act was approved on 13 March

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2024 and despite being titled as an "Act," in fact, it is an EU Regulation (2024/1689). By implication, the EU AI Act has an identical legal instrument and status to the EU Medical Device Regulation (MDR) [3], the EU In Vitro Diagnostic Medical Devices Regulation (IVDR) [4], the EU Clinical Trials Regulation (CTR) [5], and the EU General Data Protection Regulation (GDPR) [6]- these four European regulations which have seriously impacted regulated digital medical products. This paper aims to evaluate the impact of the EU AI Act on existing medical device regulations, specifically the MDR and IVDR. It focuses on compliance challenges, certification processes, and the potential overlaps or conflicts between these regulatory frameworks affecting AI-powered medical devices.

2. Overview of Current Medical Device Regulations

Generally, two main legislative frameworks decide the oversight of medical devices in the European Union: the Medical Device Regulation and the In Vitro Diagnostic Regulation.

2.1. Medical Device Regulation (MDR)

Regulation EU 2017/745, known as Medical Device Regulation, was implemented in May 2021 and replaced the earlier Medical Devices Directive. This new regulation aimed to reinforce the rules on medical devices for patient safety, increase transparency, and ensure clinical efficacy for products released to the EU market [7]. Medical equipment is classified under the MDR according to its risk, category, and intended use. Devices that pose a greater danger to patients, like implanted devices and AI-driven diagnostic tools, are subject to more stringent regulation. The MDR mandates that manufacturers prove their devices' clinical efficacy and safety through clinical trials, especially for high-risk devices [7]. The creation of the European Database on Medical Devices (Eudamed) improves openness by enabling public access to information about medical devices, clinical trials, and post-market surveillance efforts. The MDR places a lot of emphasis on post-market surveillance, requiring manufacturers to continuously monitor the performance of their products and report adverse events [7].

2.2. In Vitro Diagnostic Regulation (IVDR)

The IVDR (Regulation (EU) 2017/746), which became effective in May 2022, governs in vitro diagnostic medical devices used to examine specimens derived from the human body, such as blood tests and genetic screening. Like the MDR, the IVDR introduces a risk-based classification system into four risk categories (Class A, B, C, and D), with Class D being the highest risk, such as those used in life-critical diagnostics, subject to greater regulatory scrutiny [8]. The IVDR imposes stricter requirements on manufacturers to provide clinical evidence supporting the performance and safety of their devices. Notified bodies must conduct conformity assessments for higher-risk devices to ensure they meet all regulatory requirements before being placed on the market [9]. Like the MDR, the IVDR includes robust post-market surveillance requirements and mandates the use of a unique device identification (UDI) system to improve device traceability [8].

2.3. Regulatory Requirements for AI-Powered Medical Devices

AI-powered medical devices are regulated under the MDR and IVDR, depending on intended use and classification. Safety and performance requirements shall apply to AI systems integrated into medical devices, whether these will take the form of diagnostic algorithms or decision-support aids. Manufacturers must prove that their gadgets' AI components are dependable, especially in high-risk applications [10]. The evolving nature of AI systems necessitates ongoing post-market monitoring to guarantee that these devices stay safe and effective throughout their lives [11].

3. Impact of the EU AI Act on Medical Device Regulations

This section presents the expected outcomes/benefits of implementing the EU AI Act.

3.1. Key Provisions Relevant to Medical Devices

The AI Act establishes a classification system for AI systems based on their potential risk to safety and fundamental rights. AI systems used in medical devices are generally classified as high-risk, given their potential impact on patient health and safety. As high-risk systems, these devices must comply with stringent obligations under the AI Act, including risk management, transparency, data governance, and human oversight [12].
One of the AI Act's key requirements is implementing robust risk management processes. Manufacturers must continuously assess and mitigate the risks associated with their AI systems, ensuring they operate safely and effectively. Transparency is another critical component of the AI Act, with manufacturers required to provide transparent information about the capabilities and limitations of their AI systems to end users [13]. The Act emphasizes data governance and requires manufacturers to ensure the representativeness, authenticity, and impartiality of the data used for training, validating, and testing their AI systems [12].

3.2. Intersection with MDR and IVDR

The AI Act overlaps with the MDR and IVDR in certain areas, including risk management, technical documentation, and post-market monitoring. The AI Act and MDR/IVDR require manufacturers to implement comprehensive risk management methods for identifying, mitigating, and continuously monitoring potential hazards [10]. Manufacturers of AI-powered medical equipment may be compelled to do separate compliance studies for each regulation, resulting in duplicative efforts and increased time and costs [11]. Also, discrepancies in concepts and phrasing between the AI Act and the MDR/IVDR [10] can pose extra challenges to complying with both regulatory frameworks.

4. Compliance Challenges and Future Outlook for AI-Powered Medical Devices

With more and more artificial intelligence being integrated into the design of medical devices, the regulatory environment is becoming increasingly complex. Complementing

the recently proposed EU AI Act, current regulatory frameworks—the MDR and IVDR—are adding a new layer of compliance requiring very thoughtful and skillful navigation. The present section highlights, in detail, some of the challenges concerning device manufacturers with regard to conformity assessments, data governance, and technical documentation preparations. It also considers the broader implications for innovation, including the need for a harmonized regulatory framework that will not impede technological development while protecting patient safety. The policy suggestions seek a balance that promotes innovation while protecting the interests of healthcare providers, manufacturers, and patients.

4.1. Compliance Challenges

Developers of AI-powered medical devices encounter a multifaceted regulatory landscape, necessitating adherence to both the AI Act and the MDR/IVDR. A major problem is the dual conformity assessment procedure, requiring producers to prove adherence to both regulatory frameworks. This may result in heightened complexity, prolonged timeframes, and elevated costs, especially for small and medium-sized firms (SMEs) that may lack the capacity to manage these procedures effectively [14]. A further problem is the restricted number of notified entities authorized to evaluate compliance with both the AI Act and MDR/IVDR. This shortage may result in delays in the certification process, postponing the approval and accessibility of AI-powered medical devices [10]. Manufacturers must generate comprehensive technical documentation that complies with both rules, which may be both resource-intensive and time-consuming [7].

4.2. Post-Market Monitoring and Data Governance

AI-powered medical devices require continuous post-market monitoring to ensure they remain safe and effective as they evolve through machine learning. Manufacturers must implement robust data collection and analysis mechanisms to track the performance of their devices and promptly report any adverse events [11]. Ensuring compliance with data protection laws, such as the GDPR, adds another layer of complexity to the compliance process [12].

4.3. Potential Impacts and Policy Recommendations

Manufacturers may face substantial problems due to the AI Act's concurrent regulatory obligations with the MDR and IVDR, especially with regard to resource allocation and operational capabilities. In order to address these issues, the AI Act must be linked to the MDR and IVDR in order to guarantee consistency in nomenclature, vocabulary, and data governance guidelines across all three regulations [10]. Establishing integrated conformity assessment methodologies would allow manufacturers to conduct a single review that fits both regulatory frameworks, reducing duplication and increasing compliance efficiency [14]. Interaction with stakeholders is critical for guaranteeing the relevance of regulatory frameworks and preventing the stifling of innovation. Involving industry executives, healthcare experts, and patient advocacy groups in the regulatory drafting process may help identify possible conflicts and support the creation of more equitable rules [13]. Detailed guidance materials and real answers to compliance difficulties are critical for manufacturers navigating the overlapping obligations of the AI Act, MDR, and IVDR [10].

5. Conclusion

The European Union's AI Act significantly advances the regulation of AI systems, particularly those used in high-risk applications like medical devices. The Act imposes substantial compliance requirements on manufacturers, especially SMEs and startups. The AI Act and MDR/IVDR are putting regulatory demands on compliance assessments, technical documentation, and data governance. Despite these challenges, integrating the AI Act with the MDR and the IVDR presents an opportunity to enhance patient safety and foster innovation. Regulatory authorities may minimize duplication efforts and provide a more efficient regulatory environment by unifying regulatory standards and streamlining conformity evaluations. To establish a regulatory framework that fosters innovation and safety in AI-driven healthcare technology, it is essential to implement a collaborative approach including stakeholders from the healthcare sector, the industry, and patient advocacy groups.

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