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EU AI Act (2024/1689) and EU MDR (2017/745): Breaking the Expensive Myth: Why AI-Powered Medical Devices Under EU MDR Don't Need EU AI Act Certification – A Detailed Analysis of Regulatory Requirements and Compliance

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The Growing Fear of Regulatory Overlap in AI-Driven Healthcare

The EU AI Act (Regulation (EU) 2024/1689) has ignited discussions across the healthcare industry, especially among manufacturers of AI-powered medical devices. A major concern is whether these devices, already scrutinized under the EU Medical Device Regulation (MDR) 2017/745, will now face an additional regulatory burden—a second certification under the AI Act. This would mean double the compliance costs, twice the paperwork, and unnecessary delays for market entry.

This paper shows that double certification is redundant and is not required for AI-based Software as a Medical Device (SaMD) that has already achieved MDR certification at Class IIa or higher. Article 43(3) of the EU AI Act explicitly allows for the use of existing sectoral certifications, a point reinforced by notified bodies such as TÜV Rheinland (TRLP) and official clarifications from DG SANTE inquired by the author.

By closely examining the AI Act's compliance requirements and comparing them with the stringent MDR framework, it becomes clear that AI-driven medical devices are already regulated to meet the AI Act's high-risk category requirements. If manufacturers are forced into dual certification, it will stifle innovation, burden the industry with unnecessary costs, and delay life-saving technologies from reaching patients. This paper presents a compelling case for regulatory streamlining, ensuring AI-powered medical devices can thrive under a single, coherent compliance framework.

1. Introduction: A Looming Compliance Nightmare or a Simple Fix?

With Artificial Intelligence (AI) reshaping healthcare, regulators are racing to keep up. The EU AI Act (2024/1689) introduces a high-risk classification for AI systems, imposing stringent compliance measures on AI applications, particularly those used in healthcare. Meanwhile, the EU MDR (2017/745) and IVDR (2017/746) already establish a robust regulatory framework for AI-driven Software as a Medical Device (SaMD), including risk management, cybersecurity, transparency, and human oversight.

This raises a critical question for medical device manufacturers: Are we required to go through a second regulatory certification process under the AI Act, despite already being certified under the MDR? If the answer is yes, this could cripple AI innovation in Europe, discouraging startups and established manufacturers from developing AI-based healthcare solutions. The fear of unnecessary bureaucratic hurdles is very real, but as we will see, a deeper look into the AI Act itself suggests that double certification is not necessary at all.

2. What the EU AI Act Really Says About AI in Medical Devices

The EU AI Act categorizes AI systems based on risk, and AI-driven medical software is classified as high risk under Article 6(2). High-risk AI systems must meet strict requirements, including:

- Robust Risk Management Frameworks
- High Standards for Data Governance and Bias Mitigation
- Mandatory Transparency and Documentation
- Human Oversight for Safety and Accountability
- Cybersecurity and Resilience to Adversarial Attacks

At first glance, these AI-specific requirements seem distinct, but when we compare them to EU MDR certification requirements, a striking overlap emerges. MDR already mandates nearly identical compliance measures through ISO 13485 (quality management), ISO 14971 (risk management), IEC 62304 (software lifecycle processes), and ISO 27001 (cybersecurity in medical software).

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If a medical AI device is MDR-certified as Class IIa or higher, it is already compliant with every major requirement of the AI Act's high-risk classification. The AI Act even acknowledges this in Article 43(3), stating that where an AI system is already assessed under an existing sectoral regulation (like MDR), that assessment can be sufficient for compliance with the AI Act. This is a game-changer - it means AI-based SaMD does not require a separate AI Act certification as long as it's MDR-certified.

Screenshots of EU AI Act, 2024/1689
Article 43:

3. For high-risk AI systems covered by the Union harmonisation legislation listed in Section A of Annex I, the provider shall follow the relevant conformity assessment procedure as required under those legal acts. The requirements set out in Section 2 of this Chapter shall apply to those high-risk AI systems and shall be part of that assessment. Points 4.3., 4.4., 4.5. and the fifth paragraph of point 4.6 of Annex VII shall also apply.

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ANNEX I

List of Union harmonisation legislation

Section A. List of Union harmonisation legislation based on the New Legislative Framework

1. Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (OJ L 157, 9.6.2006, p. 24);

2. Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1);

3. Directive 2013/53/EU of the European Parliament and of the Council of 20 November 2013 on recreational craft and personal watercraft and repealing Directive 94/25/EC (OJ L 354, 28.12.2013, p. 90);

4. Directive 2014/33/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to lifts and safety components for lifts (OJ L 96, 29.3.2014, p. 251);

5. Directive 2014/34/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres (OJ L 96, 29.3.2014, p. 309);

6. Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC (OJ L 153, 22.5.2014, p. 62);

7. Directive 2014/68/EU of the European Parliament and of the Council of 15 May 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment (OJ L 189, 27.6.2014, p. 164);

8. Regulation (EU) 2016/424 of the European Parliament and of the Council of 9 March 2016 on cableway installations and repealing Directive 2000/9/EC (OJ L 81, 31.3.2016, p. 1);

9. Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51);

10. Regulation (EU) 2016/426 of the European Parliament and of the Council of 9 March 2016 on appliances burning gaseous fuels and repealing Directive 2009/142/EC (OJ L 81, 31.3.2016, p. 99);

11. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1);

12. Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).

3. DG SANTE and Notified Bodies: Even Regulators Agree That Double Certification is not required

Manufacturers aren't the only ones frustrated by the potential for regulatory duplication. Even EU regulators and notified bodies have acknowledged the issue and are working to prevent unnecessary certification loops. In response to author's inquiries #3628176 and # 4578176, DG SANTE - the European Commission's Directorate-General for Health and Food Safety - has confirmed that a regulatory alignment process is underway.

In those two inquiries and correspondences with the author, DG SANTE has stated that MDR-certified medical AI devices **WILL NOT require an additional AI Act certification**.

The Medical Device Coordination Group (MDCG) is even developing official guidance to clarify this interplay, expected to be published in early 2025. The European Commission has also noted that MDR Notified Bodies are likely to be designated as AI Act Notified Bodies, further streamlining compliance and reducing redundant oversight.

Notified Bodies such as TÜV Rheinland (TRLP), one of the largest medical device certifiers in Europe, have echoed the same viewpoint.

In a Business Review which was made available to the author TÜV Rheinland explicitly states that AI-based medical devices assessed under MDR do not require additional AI Act certification because MDR already covers all the necessary risk controls.

If both the European Commission and Notified Bodies agree that double certification is unnecessary, why should manufacturers be forced into an expensive, redundant process?

4. How MDR Already Satisfies AI Act Compliance Requirements: A Side-by-Side Comparison

To further emphasize why double certification is unnecessary, let's break down AI Act requirements vs. MDR compliance obligations.

Requirement	EU MDR (2017/745)	EU AI Act (2024/1689)	Overlap?
Risk Management	Required (ISO 14971)	Required	Yes
Cybersecurity	Required (ISO 27001, IEC 62304)	Required	Yes
Transparency & Documentation	Required (Clinical Evaluation, PMS, ISO 13485 QMS)	Required	Yes
Human Oversight	Required (Usability Engineering)	Required	Yes
Robustness & Accuracy	Required (Clinical Validation)	Required	Yes

This direct comparison proves that MDR-certified AI-based SaMD already meets the AI Act's high-risk classification requirements. Enforcing additional AI Act certification would be redundant, costly, and harmful to the med-tech industry.

5. The Cost of Unnecessary Double Certification: Delays, Innovation Blockades, and Increased Costs

If regulators fail to streamline AI Act certification for medical devices, the consequences could be devastating:

- AI-Powered Healthcare Innovation Would Stall – Companies may shift focus away from Europe to faster, less bureaucratic markets.
- Delays in Bringing Life-Saving AI Solutions to Patients – Every extra layer of compliance means slower regulatory approval, potentially delaying AI-driven diagnostics and treatments.
- Significant Compliance Costs – AI-based SaMD manufacturers would be forced to hire separate regulatory teams, undergo additional audits, and submit redundant technical documentation, increasing costs without adding safety benefits.
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6. Conclusion: Duplicate Certification is not required.

The EU AI Act was designed to regulate AI across all industries, but for AI-powered medical devices, regulated already as Software as a Medical Device as per EU MDR 2017/745 and IVDR 2017/746 and MDCG2019-11, already provides a stricter, safer regulatory framework. Forcing manufacturers into a second certification process is unnecessary and counterproductive and as per the above evidence NOT REQUIRED.

With Article 43(3) of the AI Act, support from DG SANTE, and confirmation from Notified Bodies like TRLP, the case is clear—MDR-certified AI devices should not require separate AI Act certification.

By officially clarifying this position, the EU can support AI innovation while maintaining rigorous safety and compliance standards, ensuring that Europe remains a leader in AI-driven healthcare.

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Disclaimer

I am releasing this paper without exact details of the steps to take either to register and AI as SaMD or integrate as non-SaMD into existing hospital systems as those details are subject to active NDAs.
Please anticipate errors and limitations as the regulatory landscape is evolving quickly.
I welcome feedback and evaluations of the content.
THIS PAPER IS NOT LEGAL ADVICE in any form.
Specific references cannot be provided.

Author Contributions

The work of conceptualization, methodology, evaluation, analysis was done by the author. A local, specifically trained (regulations of US, EU Germany and Australia for SaMD, AI and Hospitals) Large Language Model was used to generate Abstract and original draft. The author read, reviewed and approved the final manuscript.

Declaration of Interests

The author is Expert Witness to all German Courts and International Courts for Medical Devices and In-Vitro Diagnostics and has consulted companies and hospitals in regard to Software and AI integration either into EHR Software or as SaMD.