

The Dual Regulatory Challenge: What is CE Marking for AI Medical Devices?

Rasit Dinc

Rasit Dinc Digital Health & AI Research

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Abstract

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The rapid integration of Artificial Intelligence (AI) into healthcare is transforming diagnostics, treatment planning, and patient monitoring. As AI-powered medical devices (AI-MDs) move from research labs to clinical practice, the question of regulatory compliance becomes paramount. In the European Union, the **CE marking** is the mandatory certification that signifies a product conforms to the essential health, safety, and environmental protection standards. For AI medical devices, achieving this mark is a complex process governed by a dual regulatory framework: the established Medical Device Regulation (MDR) or In Vitro Diagnostic Regulation (IVDR), and the groundbreaking new EU Artificial Intelligence Act (AI Act).

The Foundation: CE Marking under MDR/IVDR

Before the AI Act, the regulatory journey for AI-MDs was primarily defined by the EU's Medical Device Regulation (Regulation (EU) 2017/745) and, where applicable, the IVDR (Regulation (EU) 2017/746). Under these regulations, AI software that performs a medical purpose—such as diagnosing, preventing, monitoring, predicting, or treating a disease—is classified as a medical device.

The classification of the device (Class I, IIa, IIb, or III) dictates the conformity assessment route to CE marking. Most AI-MDs, particularly those with a significant impact on clinical decision-making, fall into higher risk classes (IIa, IIb, or III) due to the inherent risks associated with software that can change over time (Software as a Medical Device, or SaMD). For these higher-risk devices, a Notified Body must be involved in the conformity assessment process. The core requirements include:

1. **Clinical Evaluation:** Demonstrating the safety and performance of the device based on clinical data.
2. **Risk Management:** Establishing a comprehensive system to identify, analyze, evaluate, and control risks.
3. **Quality Management System (QMS):** Implementing a QMS (often based on ISO 13485) to ensure consistent quality throughout the product lifecycle.

The New Layer: AI-MDs as "High-Risk" under the EU AI Act

The EU AI Act (Regulation (EU) 2024/900) introduces a horizontal layer of regulation for AI systems across all sectors. Crucially, the Act classifies AI systems intended to be used as a safety component of a product, or which are themselves products covered by the MDR or IVDR, as "**high-risk**" AI systems [1]. This designation triggers a cascade of additional, stringent compliance requirements that must be met *in addition* to the MDR/IVDR requirements.

The AI Act's requirements for high-risk AI systems focus on ensuring fundamental rights, safety, and robustness. Key obligations for manufacturers (now also considered "providers" under the AI Act) include:

Risk Management System: *A dedicated AI-specific risk management system (Art. 9) that must be fully integrated with the existing MDR/IVDR risk management.* **Data Governance:** Strict requirements for the quality and governance of training, validation, and testing data sets (Art. 10), including an assessment for potential biases. **Technical Documentation:** *A comprehensive technical documentation file (Art. 11, Annex IV) that details the AI system's design, development process, and performance metrics, which must be kept updated throughout the system's lifecycle.* **Quality Management System:** Implementation of an AI Quality Management System (AI QMS) (Art. 17), which can be integrated into the existing medical device QMS. **Transparency and Human Oversight:** Requirements for traceability, automatic logging (Art. 12), transparency (Art. 13), and ensuring effective human oversight (Art. 14).

Dual Compliance: The Path to CE Marking

For an AI medical device, the CE marking now represents a successful navigation of this dual regulatory landscape. The device must first satisfy the safety and performance requirements of the MDR/IVDR. Subsequently, if classified as high-risk under the AI Act—which is the case for virtually all AI-MDs—it must also undergo a conformity assessment against the AI Act's requirements.

The AI Act provides a mechanism (Art. 11(2)) for manufacturers to create a single, unified technical documentation file, integrating the AI-specific requirements into their existing MDR/IVDR documentation. This integration is key to streamlining the process, but it does not diminish the scope of the work. The AI Act effectively raises the bar for evidence and documentation, demanding a level of rigor in data governance and transparency that is unprecedented.

*The successful attainment of the **CE mark for an AI medical device** is therefore a testament to a manufacturer's commitment to patient safety, data integrity, and ethical AI development. It signals compliance with the world's most comprehensive regulatory framework for digital health.*

The Future of AI-MD Regulation and SEO Value

The regulatory landscape for AI in healthcare is dynamic, and the dual compliance path established by the MDR/IVDR and the AI Act is set to become

the global benchmark for safety and trustworthiness. Manufacturers must view the CE marking process not as a mere hurdle, but as a framework for building robust, ethical, and clinically effective AI solutions. The emphasis on data quality, bias mitigation, and human oversight ensures that these powerful technologies serve the best interests of patients and clinicians.

Understanding the nuances of this dual regulation is critical for anyone operating in the digital health space. The complexity of integrating an AI Quality Management System with an existing medical device QMS, and the detailed requirements for technical documentation, demand specialized knowledge.

For more in-depth analysis on this topic, including expert commentary on the practical implementation of the AI Act's data governance requirements and their impact on clinical trials, the resources at [www.rasitdinc.com] (<https://www.rasitdinc.com>) provide expert commentary.

References

[1] Aboy, M., Minssen, T., & Vayena, E. (2024). *Navigating the EU AI Act: implications for regulated digital medical products.* NPJ Digital Medicine*, 7(1), 237. [https://pmc.ncbi.nlm.nih.gov/articles/PMC11379845/] (<https://pmc.ncbi.nlm.nih.gov/articles/PMC11379845/>)
