Are AI Diagnostic Tools Regulated in Europe? A Deep Dive into the Dual Framework of MDR and the AI Act

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Abstract

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The rapid integration of Artificial Intelligence (AI) into healthcare, particularly in diagnostic tools, promises a revolution in patient care. From analyzing medical images to predicting disease progression, AI-powered diagnostics are becoming indispensable. However, this innovation is met with a critical question: **Are AI diagnostic tools regulated in Europe?** The answer is a definitive and complex **yes**, governed by a powerful dual regulatory framework: the **Medical Device Regulation (MDR)** and the newly enacted **Artificial Intelligence Act (AI Act)**.

The Foundation: AI as a Medical Device

For an AI system to be considered a diagnostic tool, it must first meet the definition of a medical device under Regulation (EU) 2017/745, the Medical Device Regulation (MDR) [1]. The MDR classifies software, including AI, based on its intended purpose and the risk it poses to the patient. Since AI diagnostic tools are intended to provide information for the diagnosis, monitoring, or treatment of a disease, they are generally classified as medical devices.

Under the MDR, the classification of AI diagnostic tools typically falls into Class IIa, Class IIb, or even Class III, depending on the severity of the decision-making impact. For instance, an AI tool that directly guides critical treatment decisions would likely be Class III, the highest risk category. Compliance with the MDR requires manufacturers to establish a robust **Quality Management System (QMS)**, conduct extensive **clinical evaluations**, and compile a comprehensive **Technical Documentation** file to demonstrate safety and performance before affixing the CE mark.

The New Layer: The Artificial Intelligence Act (AI Act)

The EU AI Act (Regulation (EU) 2024/1689) [2], which entered into force in August 2024, introduces a horizontal layer of regulation focused specifically

on the AI technology itself. The Act employs a risk-based approach, and AI systems intended to be used as a safety component of a product already covered by EU harmonization legislation—such as medical devices—are automatically classified as **"high-risk"** AI systems.

This designation means that AI diagnostic tools must comply with **both** the MDR/IVDR and the AI Act. The AI Act's requirements are complementary, addressing AI-specific risks that the MDR/IVDR did not explicitly cover [3]. Key obligations for providers of high-risk AI systems include:

Risk Management System: *Establishing a comprehensive system throughout the AI system's lifecycle.* **Data Governance:** Ensuring the use of high-quality, representative, and bias-free datasets for training, validation, and testing (AI Act, Article 10). ***Technical Documentation:*** *Maintaining detailed documentation to demonstrate compliance.* **Transparency and Human Oversight:** Designing the system to be transparent and allowing for effective human oversight. ***Accuracy, Robustness, and Cybersecurity:*** *Implementing measures to ensure the AI system performs consistently and is resilient to security threats.*

The AI Act’s requirements for data governance and technical robustness are particularly significant for AI diagnostic tools, which rely heavily on sensitive patient data and must maintain high levels of accuracy and reliability in clinical settings. The Act ensures that the AI component itself is trustworthy, while the MDR ensures the overall device is safe and performs as intended.

The Interplay: A Unified Compliance Strategy

The European Commission’s Medical Device Coordination Group (MDCG) has issued guidance (e.g., MDCG 2025-6) to clarify the ***interplay*** *between the MDR/IVDR and the AI Act [3]. The core principle is one of* ***simultaneous and complementary application****. Manufacturers are encouraged to integrate the AI Act's requirements into their existing MDR/IVDR QMS and technical documentation to avoid duplication.*

The AI Act effectively raises the bar for high-risk medical devices by imposing stricter requirements on the underlying AI technology. This dual compliance model is designed to foster innovation while ensuring the highest standards of safety, ethics, and fundamental rights protection for patients and healthcare professionals across the EU.

In conclusion, the regulation of AI diagnostic tools in Europe is not a matter of a single law, but a sophisticated, layered system. It is a testament to the EU's commitment to creating a trustworthy digital health ecosystem. For professionals navigating this complex landscape, understanding the nuances of both the MDR and the AI Act is paramount.

For more in-depth analysis on this topic, the resources at [www.rasitdinc.com] (https://www.rasitdinc.com) provide expert commentary and further professional insight into the convergence of digital health, AI, and regulatory compliance.

Academic References*

1. European Parliament and of the Council. Regulation (EU) 2017/745 on medical devices. Official Journal of the European Union*. 2017; L 117/1. 2. European Parliament and of the Council. Regulation (EU) 2024/1689 laying down harmonised rules on artificial intelligence (Artificial Intelligence Act).* Official Journal of the European Union*. 2024; L 2024/1689. 3. Medical Device Coordination Group (MDCG).* MDCG 2025-6: Interplay between the Medical Devices Regulation (MDR) & In vitro Diagnostic Medical Devices Regulation (IVDR) and the Artificial Intelligence Act (AIA)*. European Commission. 2025. 4. Aboy M. Navigating the EU AI Act: implications for regulated digital medical products.* npj Digit. Med.* 2024; 7(1): 83.
