The EU AI Act: A New Layer of Regulation for AI-enabled Medical Devices

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The regulatory environment for AI-enabled medical devices in the European Union has become increasingly complex with the introduction of the EU Artificial Intelligence Act (AI Act), which now sits alongside the Medical Devices Regulation (MDR), In Vitro Diagnostic Medical Devices Regulation (IVDR), and the General Data Protection Regulation (GDPR). This "regulatory lasagne" requires manufacturers to navigate numerous requirements to ensure that their AI-driven healthcare solutions are compliant.

1. Implications for Swiss-based Companies

The integration of Artificial Intelligence (AI) into medical devices is driving technological innovation, transforming how data is analysed, interpreted, and applied in medical decision-making processes. Key areas of AI implementation include diagnostic imaging to identify anomalies that the human eye might miss, predictive analytics to assess the risk of acute conditions such as cardiac arrest, robotic surgery, chatbots to support mental health and triage, as well as personalized medicine and treatment planning. With the AI Act, the EU introduces new regulations for these solutions.

Switzerland currently has no dedicated AI legislation or sector-specific AI regulation. Rather than introducing a comprehensive, cross-sector AI framework, the Swiss Federal Council proposed in its February 2025 report to align with the Council of Europe's AI Convention. Should ongoing sectoral assessments identify the need for additional regulation, legislative changes are expected to be sector-specific—potentially affecting industries such as life sciences and healthcare. For further insights into Switzerland's evolving AI regulatory landscape, refer to the newsletter by David Vasella and Celine Weber on "AI Regulation: Switzerland to Take a Different Approach than the EU" published in February 2025.

Nonetheless, Swiss-based companies are directly impacted by EU regulations. The AI Act has extraterritorial reach, requiring Swiss manufacturers to comply if their AI-enabled systems or devices are placed on the EU market or generate output used in the EU (Article 2(1)(a) and (c)). According to the AI Act, whereas most AI systems must comply by August 2026, the prohibitions under Article 5 apply from 2 February 2025, and AI systems integrated into medical devices benefit from an extended deadline of August 2027. However, on 19 November 2025, the EU released a proposal to simplify the implementation of harmonised rules on AI ("Digital Omnibus on AI"), according to which application of the AI Act for medical devices would *de facto* be postponed.

In any case, early planning is strongly advised. This newsletter provides a brief overview of the upcoming EU regulatory requirements for AI systems and how they interact with existing sectoral regulations.

2. Scope of AI Act and interplay with MDR/IVDR

Manufacturers of AI-enabled medical devices must soon navigate overlapping frameworks. While the MDR/IVDR focuses on traditional device concerns such as clinical performance and safety, the AI Act introduces a complementary layer of obligations specific to artificial intelligence.

Proper classification under both regulations is critical to determining applicable obligations and certification processes. The MDR classifies medical devices from Class I to III (and Class A to D under IVDR for IVDs), based on the level of risk posed to patients. Most AI-enabled medical devices fall under Class IIa or higher (or Class B, C, or D for IVDs), since they typically influence diagnosis, clinical decision-making, or patient management—functions that exceed the lowest risk category, and as such require the involvement of a Notified Body.

In contrast, the AI Act introduces its own "high-risk" category for AI systems. Nearly all AI-enabled medical devices fall within this high-risk classification since the AI Act defines high-risk AI to include AI systems that are safety components of medical devices or that themselves qualify as medical devices requiring Notified Body involvement under MDR/IVDR. As a result, AI-enabled medical devices will most likely be subject to the full scope of obligations under the AI Act, including:

- AI-specific risk management (e.g. risks to health, safety and fundamental rights arising from bias, inaccuracy, misuse).
- Human oversight to ensure safe, ethical and responsible use.
- Automatic logging of events for traceability.
- Data governance (quality, representation, origin, collection, training, validation, testing etc.).
- Record keeping, technical documentation and quality management system.
- Transparency: clinicians must be able to understand a system's output and level of accuracy.
- Accuracy, robustness and cybersecurity.
- Certain deployers must carry out a Fundamental Rights Impact Assessment in defined scenarios.
- Conformity assessment, CE marking, registration and post-market surveillance.

The AI Act imposes obligations of responsible use, maintenance of performance records and monitoring for adverse effects on not only developers and providers of AI systems, but also on deployers, such as medical professionals and healthcare institutions. However, for medical professionals in Switzerland, these obligations only apply when the generated output – a notion lacking a definition in the AI Act – is used in the EU.

In addition, the Cyber Resilience Act (Regulation (EU) 2024/2847, CRA), adopted in March 2024, introduces a cybersecurity framework for connected products and will apply in full from 2027. The CRA requires manufacturers to embed security-by-design principles, manage vulnerabilities, and provide updates throughout a product's lifecycle. For AI-enabled medical devices, these obligations overlap with the MDR/IVDR and the AI Act but can be integrated through a unified risk-management and documentation approach.

3. Navigating Conformity Assessment and Certification: Double the work?

Both MDR/IVDR and AI Act require the implementation of a robust quality management system (QMS), comprehensive technical documentation and structured risk management, which are evaluated by a Notified Body during a conformity assessment. However, each regulation addresses these requirements through its own lens, raising the question of whether efforts must be duplicated or whether processes can be streamlined.

Fortunately, the EU permits a combined assessment by a single Notified Body. The device will ultimately carry one CE mark, indicating conformity with all applicable legislation. At present, no Notified Body has yet been designated under the EU AI Act. However, the Digital Omnibus on AI provides for incentives and a deadline to apply for AI Act designation. As with the MDR, this is a lengthy process that will take time. Once designated, Notified Bodies under the EU AI Act will be listed in the NANDO register so manufacturers and regulators can verify who is authorised for AI Act conformity assessments[1]. Ideally, companies should select a Notified Body that is, or intends to become, designated under both MDR/IVDR and the AI Act.

With regard to QMS, technical documentation, and post-market surveillance, a practical approach is to conduct a gap analysis to identify the additional obligations introduced by the AI Act. In most cases, it will not be necessary to implement a separate AI-specific QMS. Manufacturers already compliant with ISO 13485 (Medical Device QMS) can extend their existing systems to incorporate AI Act requirements. Likewise, maintaining a single, integrated technical file—with dedicated sections or annexes addressing AI-specific requirements—is advisable.

High-risk AI systems listed in Annex III must be registered before being placed on the market or put into service (AI Act Articles 49 and 71). Whether this registration will be integrated with EUDAMED for AI-enabled medical devices is being explored by the Commission and remains to be seen. For now, manufacturers should plan for dual registration: one entry in EUDAMED as a medical device, and a separate entry in another EU database as an AI system, unless future regulatory developments allow for database interoperability.

1 Cf. <webgate.ec.europa.eu/single-market-compliance-space/notified-bodies> (last visited on 12 December 2025).

4. Data Governance and GDPR

AI systems used in medical technology rely on processing personal and often sensitive health data. The AI Act and the EU General Data Protection Regulation (GDPR) apply in parallel, potentially in addition to other regulation and local laws, with neither of these frameworks replacing the other. Article 10 AI Act introduces data quality and governance obligations, while the GDPR continues to govern the lawfulness, fairness, and transparency of processing and data subject rights.

As such, providers and deployers of AI systems must establish a valid legal basis and comply with GDPR's principles of lawfulness, fairness, transparency, purpose limitation and data minimization. In addition, high-risk AI systems used by private entities providing public services, potentially including hospitals, may require both a Data Protection Impact Assessment (DPIA) under the GDPR and a Fundamental Rights Impact Assessment (FRIA) under the AI Act. The European Data Protection Board (EDPB) and the European Data Protection Supervisor (EDPS) are preparing guidance to align these assessments.

5. Outlook

Switzerland has outlined its regulatory approach to AI, opting for a sector-specific framework that integrates AI considerations into existing laws, not a comprehensive AI Act like the EU.

This presents opportunities and challenges for the life sciences and healthcare industry. While a favourable environment for innovation may facilitate agile development, testing and deployment of AI-driven medical solutions in Switzerland ahead of a Europe-wide launch, companies must remain vigilant regarding evolving requirements across multiple jurisdictions.

Given the extraterritorial scope of the AI Act, companies are strongly encouraged to familiarize themselves with its provisions. New standards and best practices specific to AI in healthcare are expected to emerge and provide guidance. Key sources to monitor in the near future include the Digital Omnibus on AI, guidelines issued by the EU Commission, the AI Office and the MDCG (Medical Device Coordination Group), as well as revisions to relevant ISO standards which may incorporate AI Act requirements and industry consensus. Furthermore, the EU Commission has published a proposal for a regulation to simplify rules on medical and in vitro diagnostic devices on 16 December 2025, which aims at reducing the burden of the rules on medical devices and in vitro diagnostic medical devices. It remains to be seen to what extent this will lead to relief for the companies concerned.

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