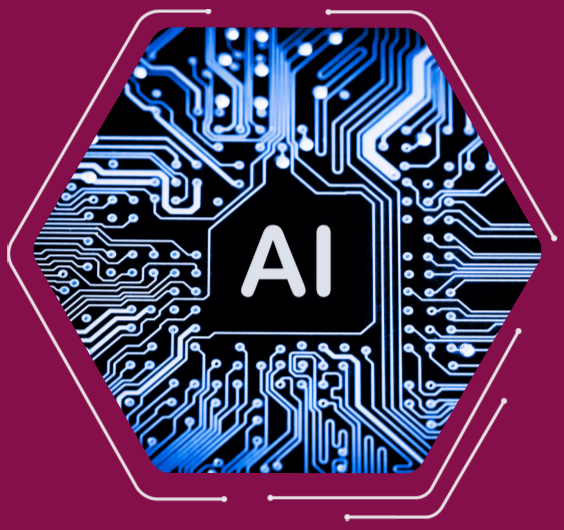

The European Union's AI Act & Its Impact on Medical Devices

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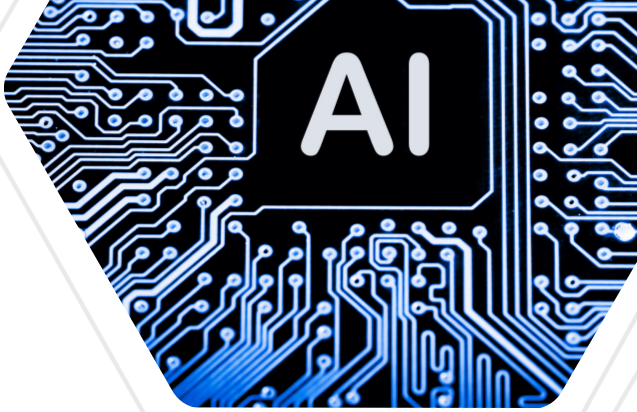

The European Union's AI Act & Its Impact on Medical Devices

The EU AI Act Overview

The EU's AI Act is a regulatory framework designed to align AI systems with the core values of the European Union **approved by the European Parliament on March 13th, 2024**. It introduces **requirements for AI across the EU**, creating a **unified market for AI applications**.

The AI legislation **classifies AI systems by their risk levels**, emphasizing stringent controls on 'High-Risk' and 'General Purpose AI' systems. While low-risk AI and AI used for research have fewer obligations, harmful AI, or AI that contravenes EU principles, is banned.

The Act imposes **duties on AI stakeholders globally** if their **AI is used or developed within the EU**, thus **influencing global AI practices to reflect EU standards.**

High-Risk AI in Healthcare: Summarized

High-risk AI in healthcare includes AI used for diagnosing, physiological monitoring, and guiding treatment choices. Such AI is often embedded in software categorized as a Medical Device or in vitro Diagnostic (IVD) Medical Device, which must pass regulatory conformity assessments. The AI Act deems all AI in Medical Device software as high-risk, with additional specific cases outlined in Annex III.

High-Risk AI in Healthcare: Definitions

In the Act, AI is described as a machine-based system capable of operating independently to different extents and capable of learning and adapting post-launch. The system processes input to produce outcomes such as forecasts, content, recommendations, or decisions that can affect real or digital surroundings.

In addition, AI that satisfies two specific criteria is recognized as high-risk:

1. The AI serves as a critical safety feature within a product, or it is a standalone product that falls under the EU's harmonization laws as outlined in Annex II.
2. The product, which incorporates the AI as a safety element, or the AI product itself, must pass an evaluation by an independent entity to ensure it meets the necessary standards before it can be marketed or used, in line with the EU's harmonization legislation detailed in Annex II.

Moreover, certain applications specified in Annex III are also deemed high-risk. Within the healthcare sector, these include applications related to biometric classification, determining healthcare eligibility, and systems for triaging patients in emergencies.

The relevant legislation in Annex II that pertains to healthcare includes regulations for Medical Devices and In-vitro Diagnostic Medical Devices (IVD), which also pertain to software classified as a Medical Device.

Thus, for AI to be subject to the Medical Device regulations and labeled as high-risk, it must conform to the definition of a Medical Device as per the Medical Device Regulation (MDR) and also be required to undergo a conformity assessment (Above or equal to Class IIa/B).

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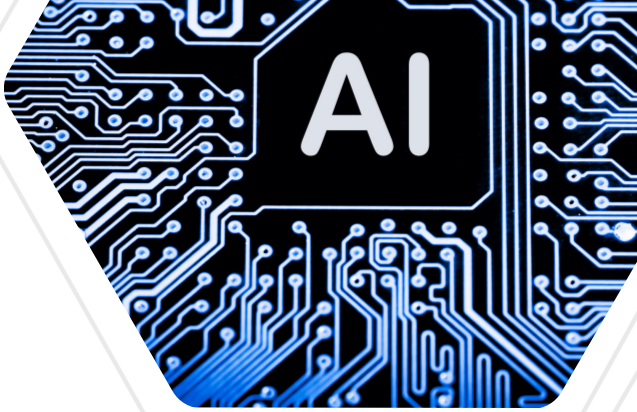

The European Union's AI Act and Its Impact on Medical Devices

Regulatory Demands for High-Risk AI

High-risk AI providers must adhere to regulations concerning:

- Data and data governance
- Technical documentation and record keeping
- Standards, including accuracy, robustness and cybersecurity
- Continual compliance:
  - Risk management system (RMS), including a fundamental rights impact assessment
  - Post-marketing requirements
  - Quality management system (QMS)
  - Authorized representatives
- Oversight:
  - Human oversight
  - Transparency and provision of information to deployers
  - Regulatory Sandboxes
- Accessibility
- Privacy
- Specific obligations for providers, importers, distributers and users

They must ensure downstream users can integrate their AI compliantly. Open-source AI and smaller enterprises have some regulatory leniency.

Certification (AI CE Mark) and Enforcement Timeline

Medical device regulators (Notified Bodies) will evaluate high-risk AI compliance in addition to MDR CE Marking. However, there is uncertainty about the readiness and authorization of these regulators. The Act acknowledges AI's evolving nature and allows for pre-agreed changes without re-assessment. The Act will be enforced in stages, with different timelines for prohibited AI, general purpose AI, and existing high-risk AI.

It is still unclear whether MDR certification could be done simultaneously with AI CE Marking and whether these 2 certifications would be grouped by the regulators, more guidance will be released in the coming months.

For prohibited AI, obligations will apply 6 months after the entry into force of this Act, for general purpose AI after 12 months and for high-risk AI after 3 years. For existing high-risk AI used within specific large-scale IT systems (listed in Annex IX) or intended to be used by public authorities, they will apply by the end of 2030 and four years, respectively.

Organizational Impact and Compliance

Non-compliance can lead to fines up to 7% of global turnover. Organizations are advised to establish AI governance and compliance strategies that incorporate this Act's requirements and broader ethical AI principles. They should also consider creating dedicated AI regulatory affairs roles to navigate this and forthcoming AI regulations.

After crossing the MDR goal line, manufacturers and software (MDSW) developers should focus their efforts on AI Act CE Marking