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AI in healthcare

Regulatory landscape

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AI in MedTech

From Innovation to Clinical Impact

1,600+ AI enabled medical devices authorized for marketing by the US FDA as of September 2026

A WHO/Europe report found that nearly three-quarters of EU countries were already using AI-assisted diagnostics, showing how AI is becoming part of everyday healthcare.

Key applications:
Medical imaging, diagnostics, patient monitoring, clinica l decision support and treatment planning.

Why is this market important?

- **Clinical value**: earlier detection and support for clinical decisions.
- **Operational value**: more efficient workflows and analysis.
- **Commercial opportunity**: AI-enabled software, connected devices and smarter medical equipment.

In the near future, the AI medtech market is expected to **grow rapidly**, driven by **advances in early disease detection**, **personalized treatments**, **AI-powered medical devices**, and more efficient healthcare delivery

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Why Do We Need AI Regulation?

AI creates opportunities — but also risks.

- **Fairness**: bias and discrimination
- **Safety**: reliability and security
- **Transparency**: understanding AI-driven decisions
- **Accountability**: who is responsible when things go wrong?
- **Sustainability**: high request of energetic and hydric resources

The challenge
protect people while enabling innovation

IMPOSE A REGULATORY FRAMEWORK IS ESSENTIAL

WHO expert group in 2021 issued a guidance 'Ethics and governance of AI for health' aimed at identifying set of core principles for safe and effective development of AI systems

In 2019, Organization for Economic Co-operation and Development (OECD) issued 1st intergovernmental standard on AI identifying 5 principles fostering trust in adoption of AI.



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How is it regulated?

EU and US in Focus

EUROPE

- First ever legal framework on AI, aims to provide AI developers and deployers clear requirements and obligations regarding specific uses of AI.
- Proposed AI Act is a horizontal legislation that follows New-Legislative Framework (NLF) approach. Sets high-level, **cross-sector, essential requirements**, while the detailed technical implementation is achieved **through harmonized sector-specific standards.**
- The EU AI Act is intended to cover all parties involved in the **Development, introduction, sale, distribution and utilization of AI systems** that are made available to consumers in the EU.
- Non-EU organizations are included in scope if they supply AI systems to EU consumers.

UNITED STATES

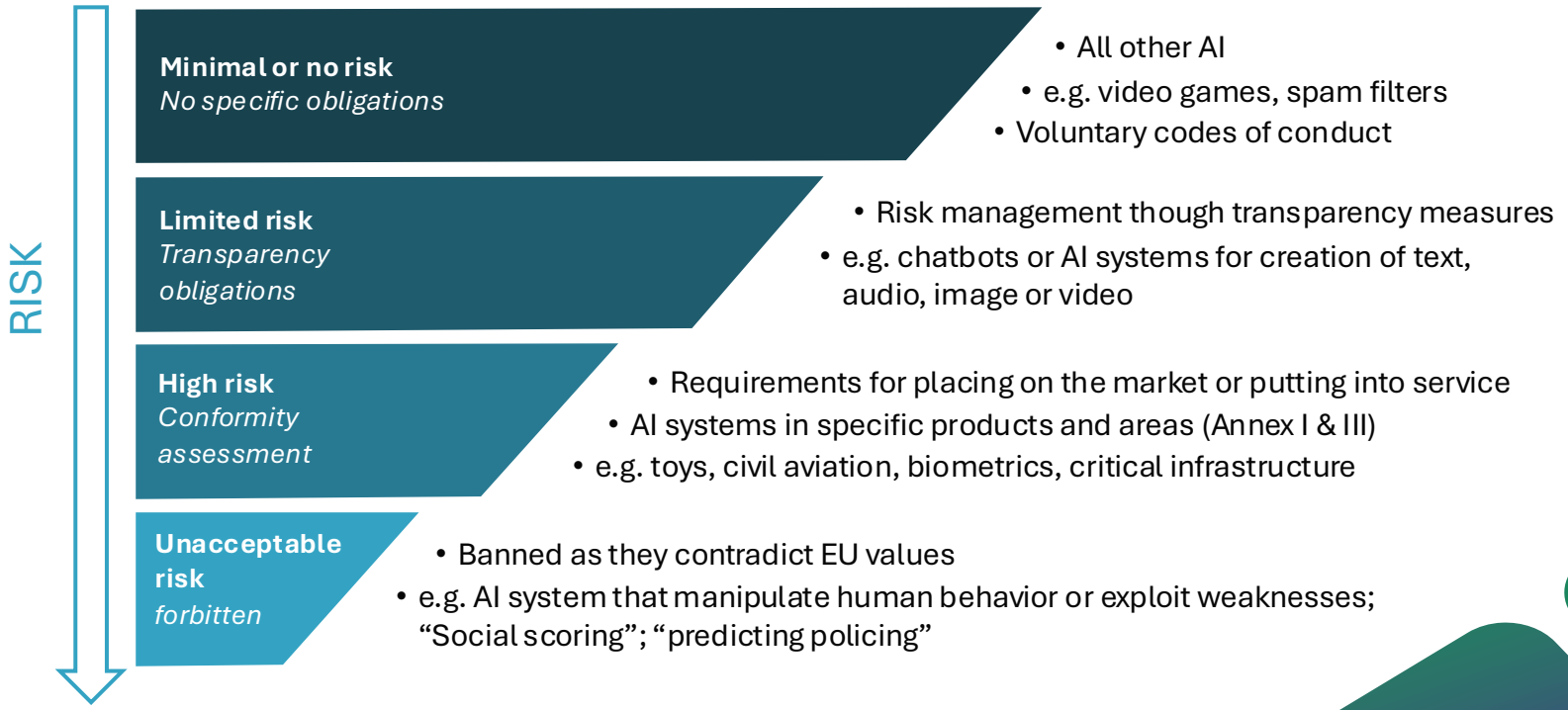
- The United States does not have a single, comprehensive federal AI law. Instead, AI governance relies on a decentralized, multi-layered approach. A national AI legislative framework was proposed by the White House in March 2026.
- States like California, Colorado, Texas, Utah, and New York have enacted rules covering high-risk deployments, algorithmic discrimination, AI watermarking, and data transparency.
- The US approach is decentralized and sector-dependent. The **FDA regulates AI-enabled medical device under existing medical device frameworks**, assessing safety and effectiveness though the applicable authorization pathway.

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The EU Approach

The EU AI Act (Regulation 2024/1689): A Risk-Based Framework

- Unlike EU MDR/IVDR, where there are pre-defined rules for determining the risk class of the medical device, **AI Act classifies the AI systems based on their use cases**.
- AI Literacy obligations apply to any risk class
- MDR and IVDR are currently included under Annex I Section A (subject to the full set of high-risk obligations)





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Current challenges in EU

- The limited availability of AIA harmonized standards. To date EN 18286:2026 is the first – and only – published European standard supporting AI Act compliance, focused on quality management systems. Formal harmonization and presumption of conformity depend on its OJEU citation.
- The unavailability of Designating Authorities, needed to accredit Notified Bodies for conformity assessments and certification, and
- The cross-legislation data challenges of MDAI (GDPR-compliance, Data Act, EHDS)

DIGITAL OMNIBUS WAS PROPOSED IN NOVEMBER 2025 AND PARTIALLY CAME INTO FORCE IN JUNE 2026

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AI Act Timeline



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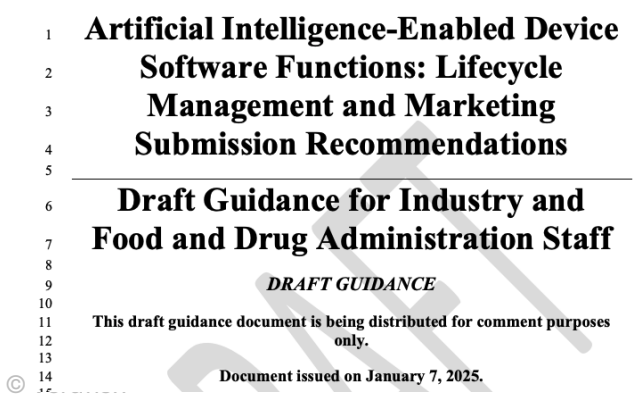
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The US approach

- The FDA combines the functions of a governmental regulatory authority and the body responsible for medical-device market authorization. In the EU, these responsibilities are split between public authorities and designated third-party conformity assessment bodies called Notified Bodies.

FDA regulation of AI-enabled medical devices:

- Lifecycle management: risk-based development, validation, performance monitoring and supporting evidence.
- Predetermined Change Control Plan (PCCP): can pre-speficy planned AI modification and their validation, allowing changes covered by an authorized plan without a separate submission for each change.
- Risk-based market access: applicable requirements depend on the device and pathway — 510(k), De Novo or PMA.
- Software exclusions: certain functions fall outside the device definition under the 21st Century Cures Act; other functions may be subject to FDA enforcement discretion.

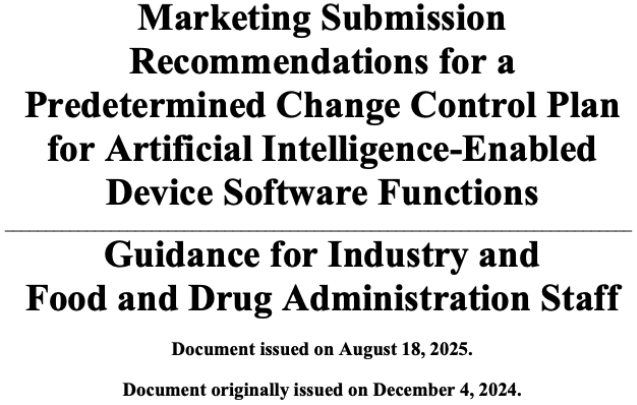

Artificial Intelligence-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This draft guidance document is being distributed for comment purposes only.

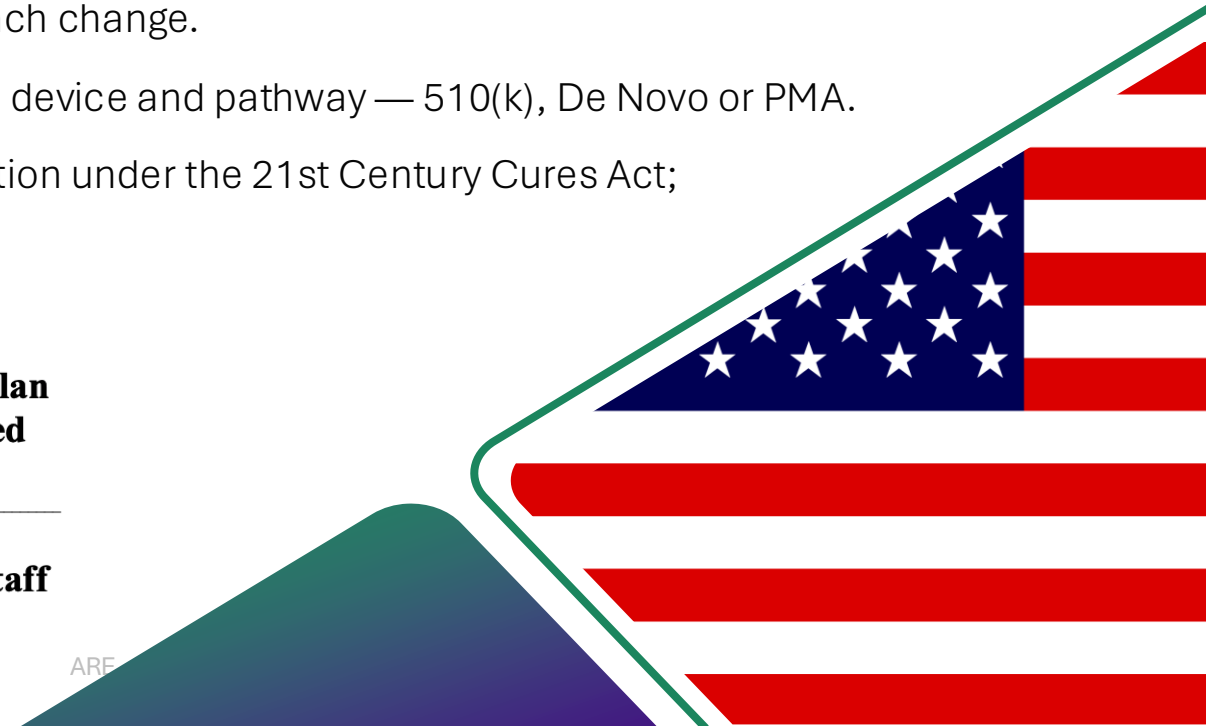
Document issued on January 7, 2025.


Marketing Submission Recommendations for a Predetermined Change Control Plan for Artificial Intelligence-Enabled Device Software Functions

Guidance for Industry and Food and Drug Administration Staff

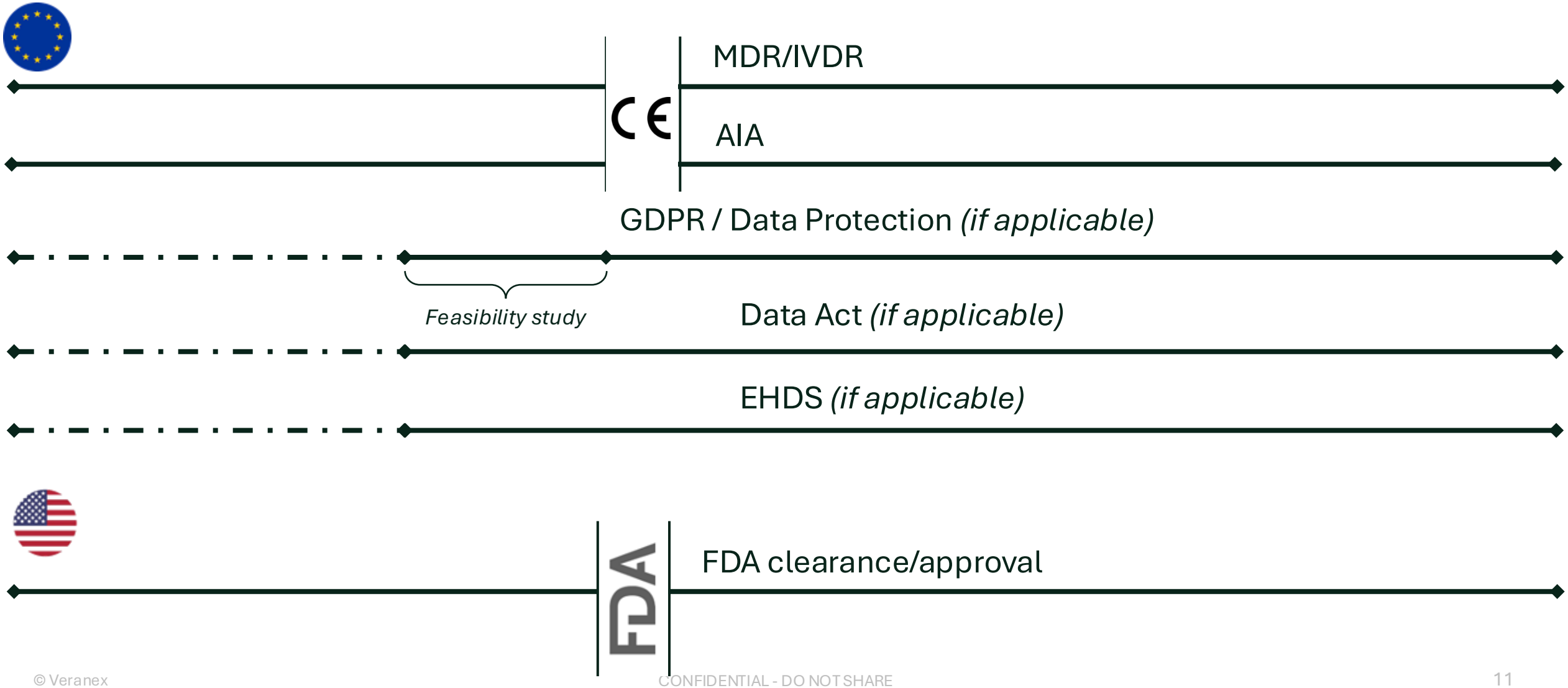
Document issued on August 18, 2025.

Document originally issued on December 4, 2024.



Pathway to market with respect to requirements

Device development | Place on the market | Post Market



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Key take at home messages

Different regulatory models

EU: a horizontal, risk-based AI Act alongside medical-device legislation (MDR/IVDR).
US: FDA medica device regulation, existing federal laws, agency policies and applicable state laws

Different regulatory pathways

EU: Notified Bodies assess conformity for devices requiri ng third-party assessment; Competent Authorities provide public oversight.
US: the FDA centrally performs regulatory review and appli cable medical-device market-authorisation functions.

AI lifecycle management matters in both markets

Risk management, performance validation, monitoring and controlled modifications are essential. In the US, FDA guidance addresses lifecycle management and Predetermined Change Control Plans (PCCPs); in the EU, applicable AI Act and medical device requirements must be considered together.

One product, two regulatory strategies

A single AI-enabled medical device may need different evidence, documentation and conformity or authorization pathway in EU and US. Regulatory planning should start early to reflect the intended use, risk classification and planned AI changes.

The EU and US share the objective of safe and effective AI in healthcare, but differ in how they organize regulation. For MedTech companies, understanding both pathways from the beginning is key to bringing AI innovations to market.

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Thank you

Any question?

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