Congenius

Congenius Whitepaper

Artificial Intelligence Act Regulation (EU) 2024/1689

Revision 2 – February 2026

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Overview

This updated overview reflects Regulation (EU) 2024/1689 and related guidance / standards as available until mid-2025.

Following the EU Commission's proposal in April 2021 for a Union-wide regulation on Artificial Intelligence (AI), the **European Artificial Intelligence Act** has applied since **1 August 2024.**

As the world's first legal framework on AI, the AI Act is **directly applicable in all 27 EU Member States**, but with a phased system of **transitional periods** and certain exceptions to the rules concerning implementation date.

The AI Act introduces a uniform framework across all EU Member States, based on a **four-tier model of risk classification** for AI applications related to their potential impact on health, safety, and fundamental rights. This risk-based approach classifies AI under **unacceptable risk**, **high risk**, **specific transparency risk**, or **minimal risk**.

Regulatory requirements for each AI system correspond with their risk classification – spanning prohibition for those systems classified under "unacceptable risk", to voluntary codes of conduct for those that fall under "minimal risk".

The AI Act applies to public and private actors looking to place their AI systems on the European Union market, or where the system impacts people located in the EU, with certain exemptions in place for activities that take place before the AI system is released onto the market, and for systems exclusively designed for military, defence, or national security purposes.

The legal obligations of the Act can affect both system providers and system deployers, and as such, a smart first step for companies is to **identify all AI applications used and rate the respective risks** according to the four risk categories, focusing first on high-risk AI systems currently in use or planned. For medical technologies, this should align with the latest MDCG guidance on the interplay between the AI Act and the MDR / IVDR (MDCG 2025-6).

The following page provides further guidance on the **four risk categories,** which are **based on the intended purpose** of the AI system.

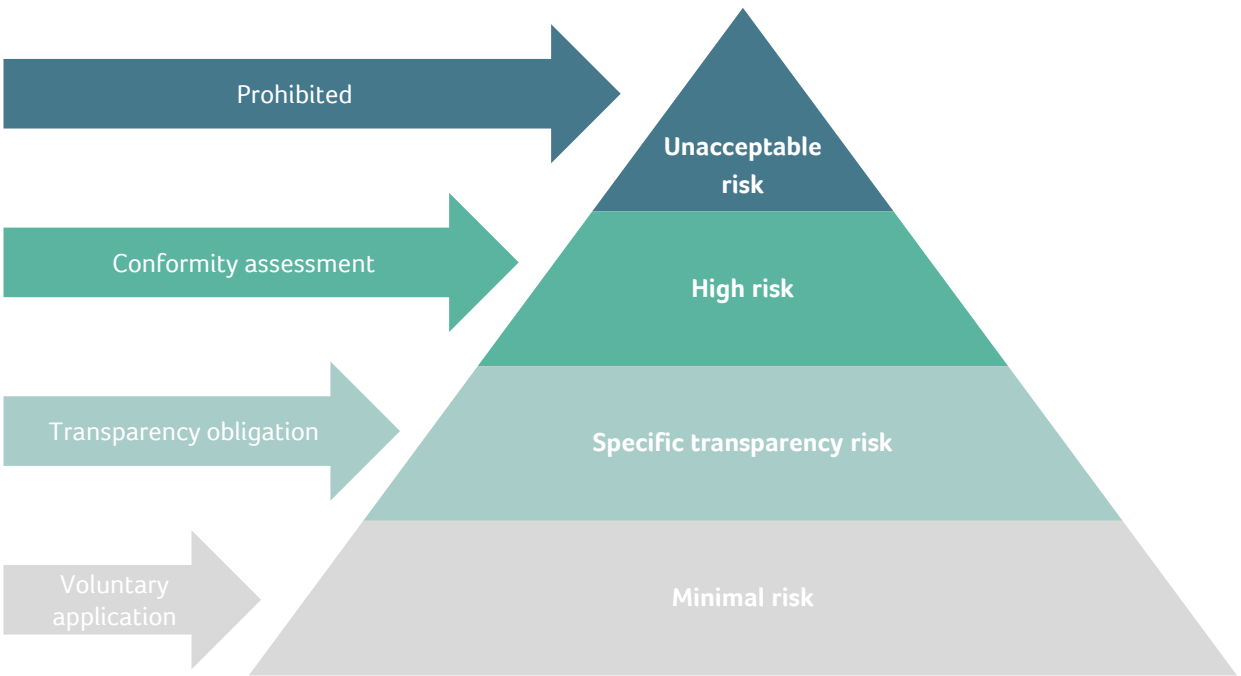
Overview | Risk classification

Unacceptable risk | Includes harmful uses of AI that violate fundamental rights and are prohibited, e.g., AI that exploits human vulnerability, or facilitates social scoring, individual predictive policing, emotion recognition in the workplace / in education institutions, and biometric categorisation.

High risk | Includes AI systems that could potentially create an adverse impact on human safety or fundamental rights, e.g., AI that assesses access to medical treatment, employment, or housing, and AI systems that operate robots, drones, or **medical devices**. AI systems with a high-risk rating must comply with multiple requirements and undergo a third-party conformity assessment.

Specific transparency risk | Includes certain AI systems which do not meet the specified criteria for the two higher tiers but still require transparency due to a risk of user manipulation (e.g., via chatbots or deep fakes). This tier is particularly relevant for patient-facing conversational tools, where users must be clearly informed that they are interacting with an AI system.

Minimal risk | Includes most AI systems that can be developed and used according to the existing legislation without additional legal obligations. Providers of this category of AI system may voluntarily apply the requirements for trustworthy AI and adhere to voluntary codes of conduct.



Transition periods

The risk-based and graduated regulatory approach that characterises the AI Act is also reflected in the structure of the transitional periods. Essentially, **the higher the risk classification of the AI, the earlier the provisions of the AI Act apply**.

From 2 February 2025

The **provisions on prohibited practices** have applied since 2 February 2025. The EU Commission has issued guidance on the scope and interpretation of these prohibitions, and providers should ensure that their systems do not fall within the banned practices.

From 2 August 2025

The **rules on governance and the obligations for general purpose AI** became applicable on 2 August 2025. These rules are complemented by the new EU-level AI Office and AI Board, as well as the broader "digital omnibus" adjustments to the EU digital regulatory framework.

From 2 August 2026

General applicability for most of the AI Act provisions takes effect from 2 August 2026, by which time multiple accompanying measures such as delegated acts, guidelines, and harmonised standards will have been published.

From 2 August 2027

The **obligations for high-risk AI systems classified as such because they are embedded in regulated products** listed in Annex II of the AI Act, will apply from 2 August 2027. For medical devices and in vitro diagnostic medical devices, these obligations are expected to be implemented primarily through the existing MDR / IVDR conformity-assessment routes, with AI-specific checks integrated into those processes.

Note: **Grandfathering rules** (for those AI systems already placed on the market) remain an area of legal uncertainty and are being further clarified through Commission guidance and sector-specific FAQs. Manufacturers should monitor new guidance closely when planning upgrades or significant changes to existing AI systems.

How will medical device manufacturers be impacted?

Is my AI system high risk?

Under the AI Act and the latest MDCG FAQ on the interplay with MDR / IVDR, medical device AI is considered high risk when both of the following are true:

- The AI system is a safety component of a medical device or constitutes a medical device in itself; and
- The device (or safety component) is subject to third-party conformity assessment under the MDR or IVDR

In MedTech, this typically includes **AI that is part of Class IIa, IIb, or III medical devices, or Class B–D IVDs**, where a Notified Body is involved. Not all software used in healthcare is automatically high-risk under the AI Act; the classification depends on both MDR / IVDR status and the applicable conformity-assessment route.

AI systems can also be high risk under Annex III if they are intended for certain high-impact use cases such as education, employment, law enforcement, or migration management. For healthcare organisations, this second route is less common than the medical device route but may still apply to specific HR or public-sector deployments.

How will medical device manufacturers be impacted?

Is my AI system high risk?

Is my AI system embedded as a safety component?

A safety component is defined in the AI Act (Article 3(14)) as a **component of a product or AI system that performs a safety function, or whose failure or malfunction could endanger the health and safety of people or property**. This definition can apply to medical device components such as an AI algorithm that alerts users to potential abnormal behaviour in a medical device, monitors a surgical robot, detects potential hacking attempts in a software medical device, or prevents radiation overdose in a CT scanner.

These AI systems can be considered safety components even if they do not directly contribute to the medical device achieving its intended medical purpose. If such a safety component is subject to Notified Body assessment under MDR/IVDR, it will generally qualify as a high-risk AI system under the AI Act.

Is my AI system a product in itself?

To distinguish whether your AI system is a product in itself, you need to consider the **intended purpose of your medical device.**

If the AI in your medical device contributes to the device achieving its intended purpose – i.e., your device relies on the AI system to perform its diagnostic or therapeutic function, then the AI system would be a product in itself and, where the device requires Notified Body involvement under MDR / IVDR, would be classified as high risk under the AI Act.

How will medical device manufacturers be impacted?

What are the regulatory considerations for my high-risk AI system?

Conformity Assessment

Before placing your high-risk AI system on the EU market, it must undergo a conformity assessment to demonstrate its compliance with the mandatory requirements for trustworthy AI.

This assessment must be repeated if the system or its purpose are substantially modified. For medical devices and IVDs, the sectoral MDR / IVDR conformity-assessment route will usually serve as the primary mechanism to also verify AI Act compliance, rather than requiring a completely separate AI-specific assessment.

Medical devices and in-vitro medical devices that incorporate an AI system will continue to undergo conformity assessments according to the current procedures under the MDR and IVDR. Where the device includes high-risk AI, Notified Bodies that are also designated under the AI Act will integrate AI-specific checks (e.g., data governance, human oversight, logging, and fundamental-rights risk management) into their existing audits.

Providers may be required to make training, validation, and testing datasets, along with AI models, available for testing, which has implications for data-licensing and contractual arrangements.

Notified Bodies will be evaluated by Competent Authorities for their expertise in AI, enabling them to issue CE certificates under existing procedures and the AI Act for high-risk systems. Bear in mind however, that not every Notified Body may seek or obtain AI Act designation, so you may need to verify the status of your current Notified Body and, where necessary, plan for an alternative.

How will medical device manufacturers be impacted?

What are the regulatory considerations for my high-risk AI system?

Quality Management & Technical Documentation

Providers of high-risk AI systems must implement quality and risk management systems to ensure compliance with the AI Act requirements.

In a similar way to risk management, the requirements for quality management and technical documentation under the AI Act can be integrated into your existing systems and documentation - significantly reducing duplicated effort. Compliance with the quality management requirements of the AI Act involves alignment with a standardised Quality Management System according to ISO 13485, augmented by AI-specific governance and risk-management processes (e.g., data governance, model lifecycle control, robustness, and bias management).

The European standardisation organisations CEN and CENELEC were mandated to develop standards supporting the AI Act's high-risk requirements. Several horizontal AI standards (e.g., for AI risk management and AI management systems) are now available or close to publication, and further sector-specific standards are in development.

For medical device manufacturers, these AI standards will complement established sectoral standards such as IEC 62304, IEC 82304-1, and IEC 81001-5-1 and should be referenced in the QMS and technical documentation where relevant. The MDCG has now issued guidance (MDCG 2025-6) to clarify the interaction between the AI Act and the MDR / IVDR, offering practical guidance on quality management and technical documentation in the absence of a complete set of harmonised AI standards.

How will medical device manufacturers be impacted?

What are the regulatory considerations for my high-risk AI system?

Post-Market Surveillance & Lifecycle Management

The EU Commission has stated that market surveillance authorities will conduct regular audits and facilitate post-market monitoring to ensure compliance throughout the lifecycle of AI systems.

Providers should establish and document a post-market monitoring system proportionate to the nature of the AI technologies and the risks of their high-risk AI system. For medical device AI, this monitoring should be closely integrated with MDR / IVDR post-market surveillance and clinical / performance follow-up, including specific tracking of model performance, bias, robustness, and potential model drift over time.

Where appropriate, manufacturers may make use of AI Act “real-world testing” provisions in combination with MDR / IVDR clinical investigations or performance studies, following the approaches outlined in MDCG 2025-6.

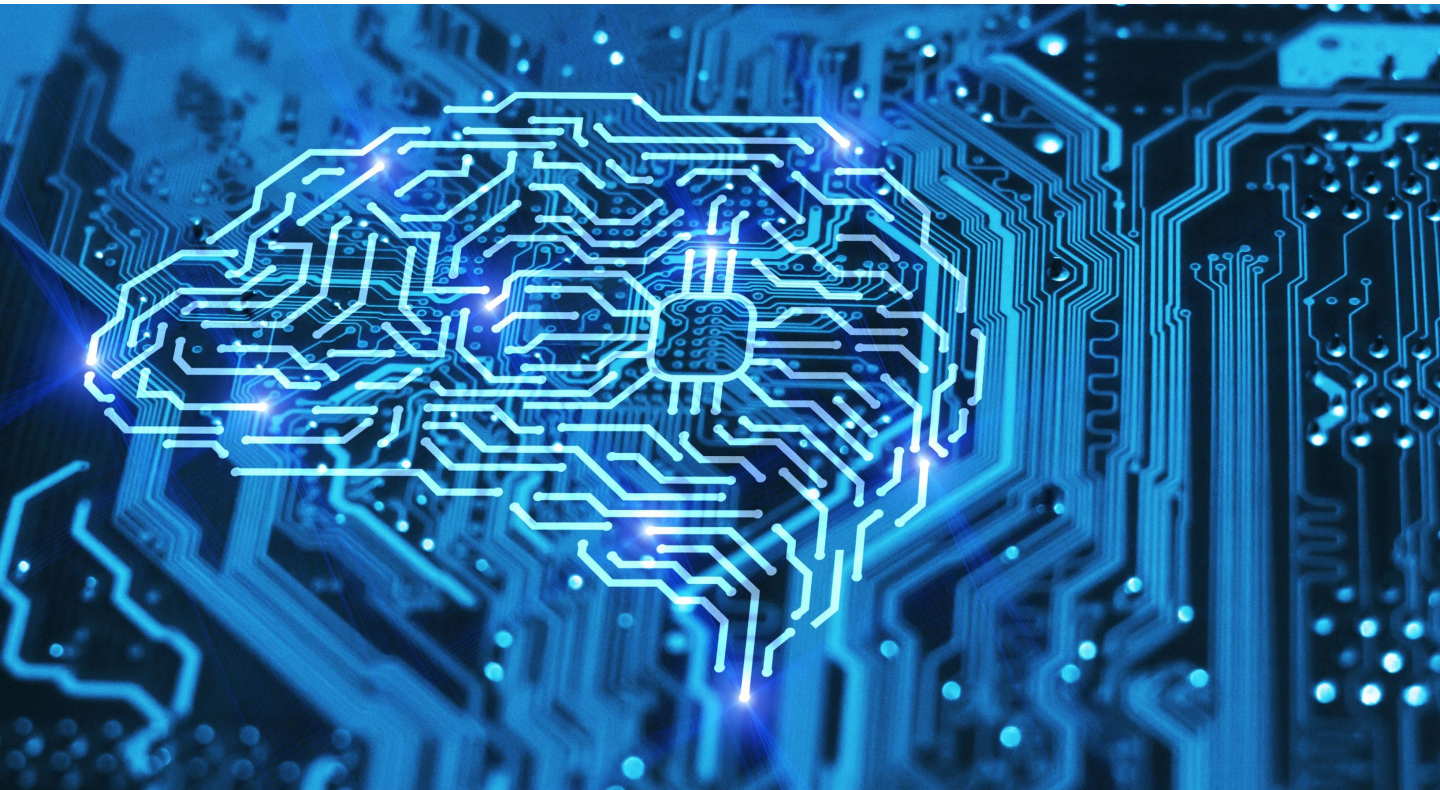
How will medical device manufacturers be impacted?

General purpose AI (GPAI) and foundation models

Since 2 August 2025, providers of general-purpose AI systems, including many foundation and large language models, must comply with specific AI Act obligations such as transparency on training data and registration of certain models in an EU database.

There are Commission templates and guidance to support the preparation of training-data summaries and documentation for these systems. Medical device manufacturers that fine-tune or integrate such GPAI models may assume “deployer” obligations under the AI Act and should ensure appropriate contractual and technical controls are in place.

This includes clarifying responsibilities for risk management, data governance, logging, and user information when general-purpose AI is embedded into medical device software or support tools.



What does this mean for Swiss legislation?

The Swiss Federal Council is aiming to "harness the potential of AI whilst minimising the risks it poses to society".

In November 2023, the Federal Council tasked the Federal Department of the Environment, Transport, Energy and Communications (DETEC) with identifying potential approaches to regulating AI by the end of 2024, involving all federal agencies responsible in the legal areas affected.

Based on the analysis, on 12 February 2025, the Swiss Federal Council issued a concrete mandate for the Federal Administration to draft legislative amendments for an AI regulatory proposal. The draft legislation is expected to remain interoperable with the EU AI Act and the Council of Europe AI Convention, and is anticipated to be ready for public consultation by the end of 2026.

For Swiss medical device manufacturers placing AI-enabled products on the EU market, full compliance with MDR / IVDR and the EU AI Act is required regardless of the future shape of Swiss-internal AI rules.

Key actions for medical device manufacturers

- Establish an **inventory of AI systems** and classify them under the AI Act using the MDCG 2025-6 criteria
- **Integrate AI-specific requirements** (Articles 9-15 AIA) into existing MDR / IVDR quality management, risk management, and technical documentation processes
- Confirm whether your **Notified Body is seeking or has obtained designation** under the AI Act for high-risk systems and plan accordingly
- **Plan data governance, logging, and post-market monitoring processes** that address AI-specific risks such as bias, robustness, adversarial threats, and model drift

Congenius

Should you have a regulatory challenge related to AI, get in touch with our team today.

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