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Horizontal Directives & Regulations Series

Artificial Intelligence Act Regulation (EU) 2024/1689

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By Jörg Dogwiler

Edited by Hannah Matthews

Overview

Following the EU Commission's proposal in April 2021 for a Union-wide regulation on Artificial Intelligence (AI), the **European Artificial Intelligence Act** took effect from **1 August** this year.

As the world's first legal framework on AI, the AI Act will be **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 will apply 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 would be to **generally identify all AI applications used and rate the respective risks** according to the four risk categories. Following this, efforts should be focused on the high-risk AI systems that are either currently in use or in the planning stages.

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

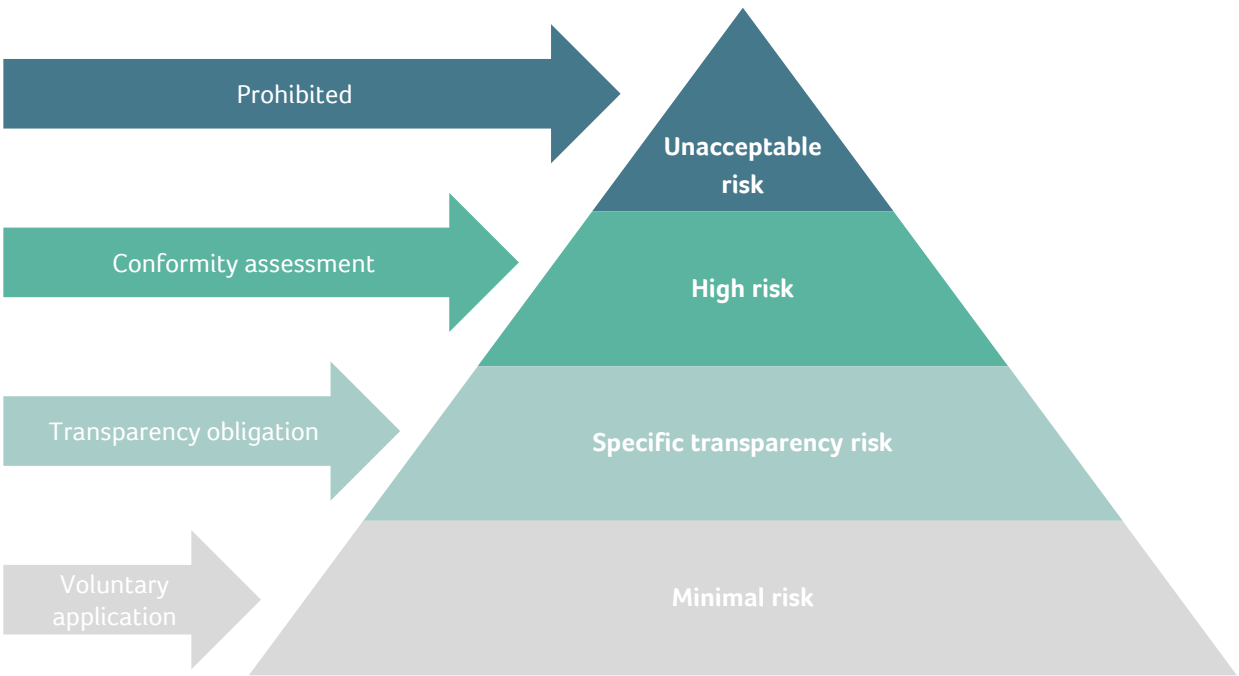
Overview | Risk classification

Unacceptable risk | Includes harmful uses of AI that violate fundamental rights and will therefore be 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 other two tiers, but still require transparency due to a risk of user manipulation (e.g., via chatbots or deep fakes).

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 upon which the AI Act is characterised 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 will apply**.

From 2 February 2025

The **provisions on prohibited practices** will apply from 2 February 2025. Before this time, the EU Commission will issue guidance on the prohibitions.

From 2 August 2025

The **rules on governance and the obligations for general purpose AI** become applicable from 2 August 2025.

From 2 August 2026

General applicability for most of the AI Act provisions will take effect from 2 August 2026. Before this date, numerous accompanying measures such as delegated acts, guidelines, and standards will be 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.

Note: Grandfathering rules (for those AI systems already placed on the market) are not yet clearly formulated in the AI Act, causing some legal uncertainty. It's expected that the European Commission will follow up on this with guidelines in the coming months.

How will medical device manufacturers be impacted?

Is my AI system high risk?

The classification of your AI system **depends on the function it performs**, and on the specific purpose and modalities for which the system is used. According to the EU Commission, AI systems can be classified as high risk in two cases:

1. If your AI system is embedded as a **safety component** in products covered by the existing product legislation (in Annex I of the AI Act) or **constitutes such products themselves** - for example, AI-based medical software.

2. If your AI system is intended to be used for a high-risk use case as listed in Annex III of the AI Act, e.g., in education, employment, law enforcement, or migration.

Is my AI system embedded as a safety component?

According to the AI Act (Article 3(14)), a safety component is defined 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 could still be considered safety components, despite not directly contributing to the medical device achieving its intended medical purpose.

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 in turn, classified as high risk.

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.

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. But in addition, Notified Bodies will also audit for compliance with the AI Act, including aspects such as data governance procedures, human oversight, logging, and risks related to fundamental rights.

You may also be required to provide your training, validation, and testing datasets, along with AI models, to the Notified Body for testing purposes if deemed necessary – so be sure to factor this into your contracts with any data providers.

Notified Bodies will be evaluated by Competent Authorities for their expertise in AI, enabling them to issue CE certificates under existing procedures. Bear in mind however, that not every Notified Body may develop the necessary expertise - in such cases, you may need to source an alternative Notified Body.

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.

The European standardisation organisation CEN and CENELEC have until the end of April 2025 to develop and publish standards for the high-risk requirements.

In the meantime, the MDCG has initiated the development of guidance to clarify the interaction between the AI Act and the MDR / IVDR, which is expected to offer practical guidance on Quality Management and Technical Documentation in the absence of additional standards.

Post-Market Surveillance

The EU Commission has noted 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 in a manner that is proportionate to the nature of the AI technologies and the risks of their high-risk AI system.

What does this mean for Swiss legislation?

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

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

The analysis, which will be led by the Federal Office of Communications and Europe Division of the Federal Department of Foreign Affairs (FDFA) will:

- ✓ Build on existing Swiss law
- ✓ Identify possible regulatory approaches for Switzerland that are compatible with the AI Act and the Council of Europe Convention on Artificial Intelligence
- ✓ Consider the technical standards and the financial and institutional implications of the different regulatory approaches
- ✓ Involve legal, economic, and European policy clarifications
- ✓ Take place within the framework of the Interdepartmental Coordination Group on EU Digital Policy

Plateforme Tripartite and its administrative committee, the Competence Network for Artificial Intelligence at the Confederation and its legal competence hub, and the Federal Administration's working group on AI will also participate in the project.

The Federal Council intends to use the analysis as a basis for a concrete mandate for an AI regulatory proposal in 2025.

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Should you have a Regulatory challenge, please do get in touch – our team is ready and happy to help.

For more on the regulatory landscape relating to AI in medical devices, see this Congenius whitepaper.

And for the full series of articles on the latest horizontal directives & regulations, see here.

Congenius AG
Riedstrasse 1
CH - 8953 Dietikon

E: info@congenius.ch
T: +41 44 741 04 04

congenius.ch

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