Dear readers,

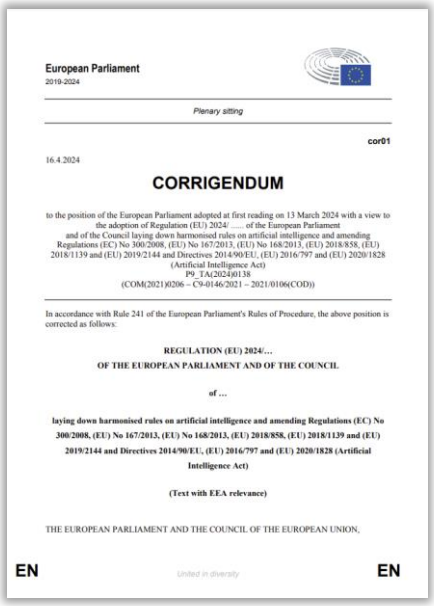
on May 21st 2024, the European Union adopted the AI Act after three years of consultation and discussion.

The EU AI Act sets new standards for the use of artificial intelligence, particularly in sensitive areas such as healthcare. For companies that integrate AI into their medical devices and healthcare services, it is crucial to know and implement the new requirements. In this issue, we provide you an overview of the most important requirements of the EU AI Act, its impact on the healthcare sector and look beyond Europe into how regulators are approaching AI in the US and China.

Your Flying Health team wishes you an enjoyable read!

The EU AI Act at a glance

The EU AI Act is the first comprehensive regulation of artificial intelligence (AI) globally. The flagship project is intended to serve as part of the European Union's digital strategy to promote the development and usage of safe AI applications.
The aim of the regulation is to ensure the safe use of AI systems that can bring benefits through automation, while preventing potential disadvantages and harmful outcomes.
Innovative products in the healthcare sector are also affected by the regulation. Medical devices from risk class IIa upwards that use AI will be regulated by the AI Act and must meet additional requirements as part of the conformity assessment in the future.



European Parliament
2019-2024

Plenary sitting

cor01

16.4.2024

CORRIGENDUM

to the position of the European Parliament adopted at first reading on 13 March 2024 with a view to the adoption of Regulation (EU) 2024/ ..... of the European Parliament and of the Council laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act)
P9_TA(2024)0138
(COM(2021)0206 – C9-0146/2021 – 2021/0106(COD))

In accordance with Rule 241 of the European Parliament's Rules of Procedure, the above position is corrected as follows:

REGULATION (EU) 2024/...
OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of ...

laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act)

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

EN EN

Risk-based approach
The EU AI Act regulates specific applications based on their risk and not the technology in general.

AI Act comes into force in mid-2024
From 2026, the impact of the AI Act on the industry will be clearly noticeable; medical devices will have to fulfil the additional requirements three years post enactment.

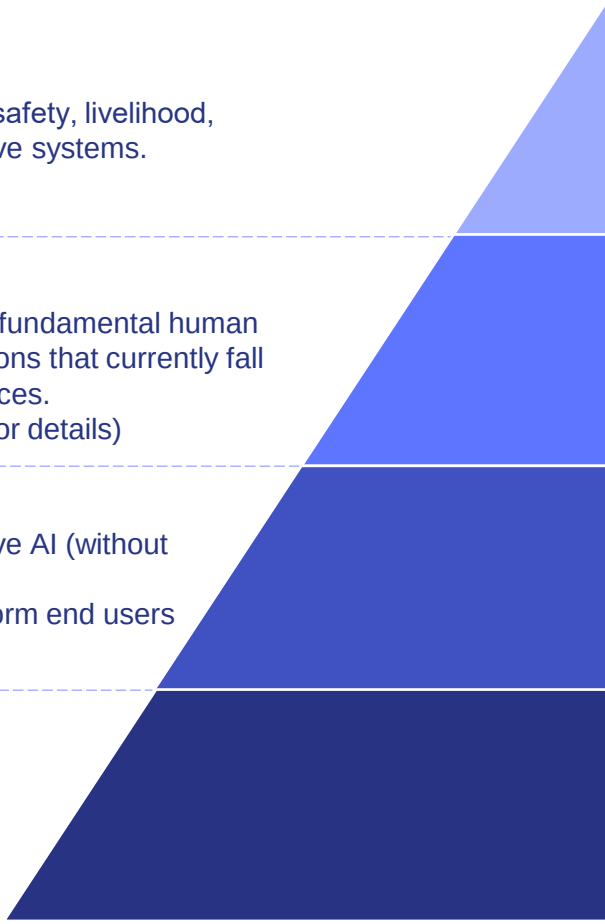
Promoting AI research and development
Development of test environments and sandboxes at a national level to train AI models.

Source: Flying Health | Artificial Intelligence Act EU, 19/04/2024

What does the EU AI Act regulate?

The risk-based approach classifies AI applications into four tiers

The AI Act does not regulate AI as a technology in general, but sets out measures and rules for specific AI applications. This is not intended to hinder the research and development of AI systems. AI systems are divided into four categories according to their risk



Unacceptable Risk
Systems that are considered a direct threat to a person's safety, livelihood, fundamental rights, i.e. subliminal techniques or exploitative systems.
Measures: Prohibited

High Risk
Systems with a high risk for health, education, safety and fundamental human rights, e.g. biometric categorisation. Additionally, applications that currently fall under EU product safety regulations such as medical devices.
Measures: Various additional requirements (see page 4 for details)

Limited Risk
Systems that interact with humans, i.e. chatbots, generative AI (without systemic risk)
Measures: Transparency and information obligations: inform end users that they are interacting with an AI system

Minimal Risk
Spam filters, AI-based video games
Measures: Largely unregulated, voluntary codes of conduct

Prohibited AI applications (Unacceptable Risk)

- Cognitive behavioral manipulation
- Exploitation of vulnerable groups
- Untargeted scraping of biometric data and facial images
- Emotion recognition
- Social scoring
- Predictive policing

Infringement may lead to fines of up to 35million Euros (or max. 7% of annual revenue)

Source: Flying Health | Artificial Intelligence Act EU, 27/06/2024; Europäisches Parliament, 19/06/2024

ChatGPT and Co. have their own guidelines

The regulations for general purpose AI (GPAI) include systems such as GPT-4, DALL-E or Midjourney. AI models that have been trained with a large amount of data and can be used for a variety of purposes (Link). GPAI models are categorized according to their systemic risk (based on the computing effort) and must primarily meet additional (technical) documentation requirements. (Link).

Does every medical device fall under the „high risk“ category?

The AI Act regulates products that are already covered by EU product safety regulations (Annex I of the AI Act). This also includes the MDR (Medical Device Regulation) for medical devices or the IVDR (In-Vitro Diagnostic Regulation) for in-vitro diagnostics. (Link)
However, two conditions must be met for classification in the "high risk" category:

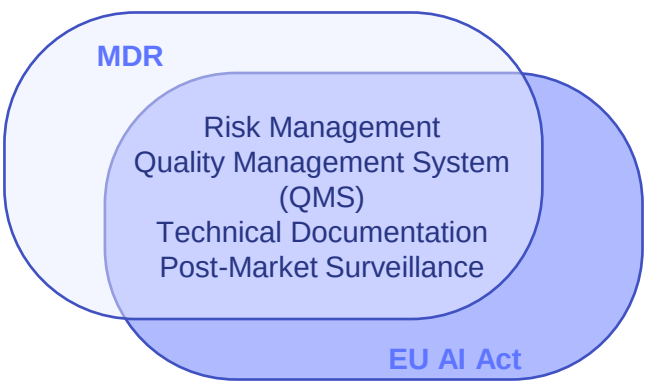
CE Device regulated under MDR or IVDR	**AND**	Conformity assessment carried out by a notífied body → min. risk class IIa

This means that products in risk class I (currently the majority of DiGAs, for example) are not regulated by the EU AI Act. (Link)
Nevertheless, following the future norms and standards of the AI Act is sensible for all applications, as this is the current state of the art with regard to the safe development of AI.

Medical devices of higher risk classes are subject to additional requirements

The AI Act increases the conformity assessment requirements for regulated medical devices (see page 4). There is a large overlap of requirements between the MDR and the AI Act. The MDR requirements for risk management, technical documentation and quality management, for example, are being supplemented. Additional processes relating to the AI model are necessary, particularly in software development, in order to cover the further development of the model. The topic of "data governance" will also become more important for medical device manufacturers with the AI Act. (Link)

Single conformity assessment procedure based on the MDR and the EU AI Act



The AI Act does not introduce an additional assessment procedure, but rather supplements the existing conformity assessment. Ideally, notified bodies can evaluate the device in accordance with both the MDR and the EU AI Act.

? There are still question marks over the specific interaction between the MDR and the AI Act. For this reason, there are already working groups at the European level that are looking into integrating the requirements of the two regulations.

High-risk AI applications must fulfil additional requirements

For the "high risk" category, the AI Act specifies precise requirements for AI applications. In addition to further requirements for the technical documentation and the quality management system, both familiar from the MDR, technical requirements are also specified for the product itself (see overview below). An EU database will be set up for the registration of these high-risk systems to ensure a high transparency.

Technical Documentation
The implementation of all processes and requirements of the AI Act must be recorded in the technical documentation. Annex IV shows where special features and necessary extensions arise as a result of the AI Act.

Quality Management System

Risk Management System
Introduction of a risk management system focussing on the fundamental rights of individuals. The risk management system from the MDR and GDPR is unlikely to cover all areas of the AI Act.

Post-Market-Surveillance (PMS) & Vigilance
Within the framework of the AI Act, the PMS must above all perform a continuous conformity assessment. MDR vigilance systems only need to be extended to cover violations of the Charter of Fundamental Rights of the EU.

Data Governance
Establishment of suitable processes, e.g. for the collection & preparation of data, conceptual decisions and assumptions made. There are also specific requirements for the data used for training and validation.

Product Requirements

Human Oversight
The product must make it possible for anomalies or misbehaviour to be detected and stopped by a human supervisor in the software or by the user himself.

Automatically Generated Logs
In line with their claim and intended purpose, AI systems must log actions automatically. This additional system monitoring enables the tracing and analysis of critical situations.

Robustness, Accuracy and Cyber Security
All three areas have additional technical requirements to ensure the quality and safety of the system. The entire product life cycle must be taken into account, particularly in the case of self-learning, dynamic systems.

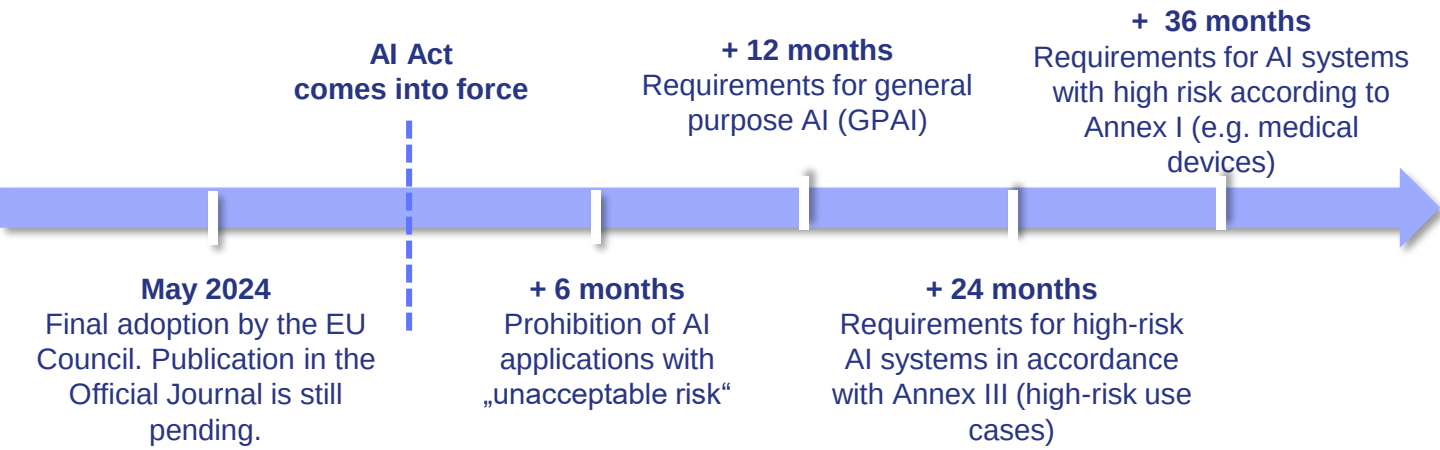
Transparency and information for deployers and users
Users and downstream distributors must receive instructions for use. This is primarily about creating transparency regarding the security and risks of the system.

Note: This is a selection of the most important requirements and not a complete list.

Source: Flying Health | Artificial Intelligence Act EU – Kapitel III, 19/04/2024

The AI Act will be implemented gradually

In spring 2024, the European Parliament voted on the AI Act after a three-year legislative process. The AI Act will come into force 20 days after its publication in the Official Journal of the EU, which is still pending. A transitional phase applies until mid-2027 during which the requirements for AI systems will be gradually implemented.



Source: Flying Health | Artificial Intelligence Act EU – Timeline of Developments, 28/06/2024

Some countries were skeptical during the legislative process

During the legislative process, several member states repeatedly criticised the planned regulation. Their main concern was that the introduction of a comprehensive AI regulation, including general purpose AI, would curb the innovation potential within the EU. (Link)

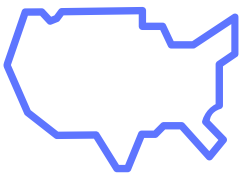
- Criticism: not innovation-friendly and too low hurdles for the use of biometric recognition with concerns about its use for surveillance (Link)
- AI-driven companies and the research community had urged politicians to agree for fear of a standstill and the need for legal certainty
- Federal Ministry for Digital and Transport agreed on compromise after initial rejection

- Overly restrictive regulation, especially for the so-called general-purpose AI models, such as GPT-4
- Discrimination of EU start-ups in competition with China and the US (Link)

- Criticism of exemptions from applications used for military or defence purposes
- Governance system gives the European Commission too much power in terms of implementation of the regulations (Link)

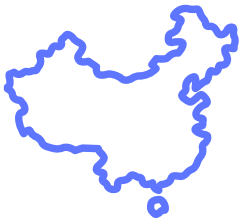
Cultural differences influence the use of data and AI regulation

The EU AI Act introduced the world's first comprehensive regulation of AI. Legislative initiatives have also been launched in the USA and China to maintain a balance between the benefits of AI and the potential risks. However, the approach differs significantly (Link). While the EU has introduced a comprehensive regulation across all industries (similar to the GDPR), the US has so far relied primarily on sector-specific principles and voluntary compliance (Link). China, on the other hand, has been pursuing an iterative approach to regulating AI since 2017. Instead of a single all-encompassing regulation, various aspects of AI are gradually being addressed and regulated. So far, the focus has primarily been on generative AI and the balance between promoting innovation and maintaining state control (Link).



Broad use of data
&
Limited regulation of AI at a sector level

Strict data protection laws
&
Comprehensive regulation of AI



Data protection laws similar to EU principles
&
Iterative regulation of AI for specific aspects

The FDA uses existing procedures to review and approve AI solutions

In the US, the existing approval processes for medical devices are used for the AI-driven medical devices without the need for a separate regulation. Instead, there are various guidelines and basic principles for AI, combination products or other emerging innovative solutions that complement the existing approval pathways. In the US, 882 medical devices based on AI/ML systems have received an FDA approval to date. (Link)

FDA

Premarket clearance
510k

De Novo Classification

Premarket approval

Source: Flying Health | FDA, 19/04/2024 | FDA, 19/04/2024 | FDA, 19/04/2024 | FDA, 19/04/2024