

THE EU MEDICAL DEVICES REGULATION AND THE EU AI ACT: A SHORT COMPARISON



TWO DIFFERENT FRAMEWORKS

In April 2021, the European Commission proposed the Artificial Intelligence Act, which is now debated in the EU parliament. The AI Act (AIA) is the EU's first attempt to create a comprehensive AI regulatory framework and aims to ensure the **protection of fundamental rights** in this field. AI applications used in healthcare are often 'medical devices' and are thus regulated under the EU Medical Devices Regulation (MDR).

In its current version, the AI Act only regulates **AI medical devices** that are subject to the MDR. Other health-related AI applications fall outside the scope of the AI Act. However, also the MDR is not fully adapted to the risks posed by AI. While both the AI Act and the MDR are risk-based, the comparison below shows the differences in assessment criteria. For **AI medical devices**, the AI Act provides improvements for fundamental rights but also needs some specifications to fill the gaps left by the MDR.

Fundamental rights include inter alia the right to life, the right to privacy, as well as the prohibition of discrimination. Such rights are enumerated in various human rights instruments, such as the European Convention on Human Rights.

The increasing use of AI threatens such fundamental rights. AI systems are trained on the basis of large databases, which are too often low-quality and full of biases. When used within AI systems, this can lead to discrimination. In the healthcare context, these biases or AI errors may lead to patient harm.

The Medical Devices Regulation	The AI Act
<p>Art. 51 of the MDR divides medical devices into four classes based on a different level of risk according to their intended purpose: “low risk” devices are listed in Class I, medium risk devices in Class IIa and Class IIb, and all high-risk devices in Class III.</p>	<p>The AIA distinguishes between AI applications that present I) an intolerable risk, II) a high risk, and III) a low or negligible risk. It generally considers devices regulated in the MDR to be “high risk”.</p>
<p>Medical devices are classified according to some specific criteria: duration of contact with the patient, the invasiveness, type of operation and anatomical site on which the device acts.</p>	<p>Art. 6 AIA lists two conditions for the assessment of high-risk medical devices: they must be used as a safety component of a product, or are a product, and they are required to undergo a third-party conformity assessment under the MDR.</p>
<p>For medium- and high-risk devices, manufacturers are required to conduct a conformity assessment that includes an audit of a notified body.</p>	<p>Article 17 also requires a conformity assessment: examination, test and validation procedures must be carried out before, during and after the development of the high-risk AI system.</p>
<p>Human oversight is not required and attention to data quality is only present in the post-market clinical follow-up procedure.</p>	<p>Human oversight as a risk management measure on high-risk medical devices is provided in Article 14. The quality of data must be “relevant, representative, free of errors and complete” and AI systems are subject to data governance and management practices.</p>

In short: one of the primary issues with the **MDR** is that a lot of **AI applications are not covered**. **Many AI applications utilised in the healthcare industry are therefore excluded**, including various lifestyle and health apps. This means that the AI Act’s rules for high-risk AI also do not apply.

The MDR is more concerned with establishing technical standards for risk assessment to preserve physical safety than with preventing potential discrimination due to the use of medical devices. In that sense, it is not a patient’s rights instrument.

On the other hand, although the **AIA** guarantees better protection of the fundamental rights of patients in the field of health, it still has some shortcomings. In particular, the AIA deals with *AI in general* and does **not provide for specific measures in the health sector**, which means that the list of high-risk AI devices in Annex III does not include a specific section on “healthcare”. Considering the possibility of AI-based medical devices causing diversity and discrimination

problems, such as worse health outcomes for ethnical and racial minorities or women, it is necessary to improve the **transparency** of algorithms and the **quality of data** collected, and to establish a **human rights impact assessment** for all AI-based medical devices. With the new proposal of the AI Act still at the negotiation table, there is an opportunity to implement stronger protections for fundamental health rights in the AI Act.

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