GMED LNE GROUP Newsletter

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Version Française

"AI ACT": WHAT REQUIREMENTS AND DEADLINES FOR MEDICAL DEVICES?

On July 12, 2024, Regulation (EU) 2024/1689 was published in the Official Journal of the European Union. This "Regulation on Artificial Intelligence" or "AI Act" marks a new stage in the certification of medical devices (MDs) using this technology. The European Commission has chosen a horizontal approach to legislating on artificial intelligence, and medical devices are one of the areas covered by this text. The medical industry is already well prepared, as it is familiar with the approach and requirements: quality management systems, risk management, technical documentation, etc. Preparing for the application of this regulation will therefore involve adapting practices to the new normative and regulatory requirements linked to artificial intelligence.

A Classification

Like Regulations (EU) 2017/745 (MDR) and (EU) 2017/746 (IVDR), the "AI Act" requires the qualification of products as artificial intelligence systems (AIS) and then their qualification according to their level of risk.

Products, which must comply with the MDR or IVDR and whose compliance must be assessed by a third party, fall directly into the high-risk AIS category (Article 6-1). Class I MDs and Class A in vitro diagnostic medical devices (IVDMDs) will not then have to comply with the same requirements, only with transparency obligations.

According to Article 6-1, if the AIS is a safety component of a medical device, and even if it is independent of it, it will be classified as a high-risk AIS, since patient safety depends on its performance and reliability.

B Requirements and assessment

The following paragraphs deal only with high-risk AIS, as specific requirements apply to them.

Articles 47-3 and 48-5 state that medical devices incorporating AIS may have a single EU declaration of conformity and a single CE marking for the MDR (or IVDR) and the AI Act, as well as all other applicable EU legislation. This makes it possible to establish a single technical documentation and quality management system. Both will have to be adapted for conformity assessment under these two Regulations (Articles 11-2 and 17-3 of the AI Act). The specific requirements of each regulation and any other applicable legislation must be met.

There are many similarities between the two regulations, and as described above, the approach is similar. For example, both require the establishment of a risk management system to identify, assess and implement actions to eliminate or reduce risks. The AI Act emphasizes technology-specific risks, such as training data bias and cybersecurity. Both regulations also call for the implementation of post-market surveillance to identify and track failures and incidents.

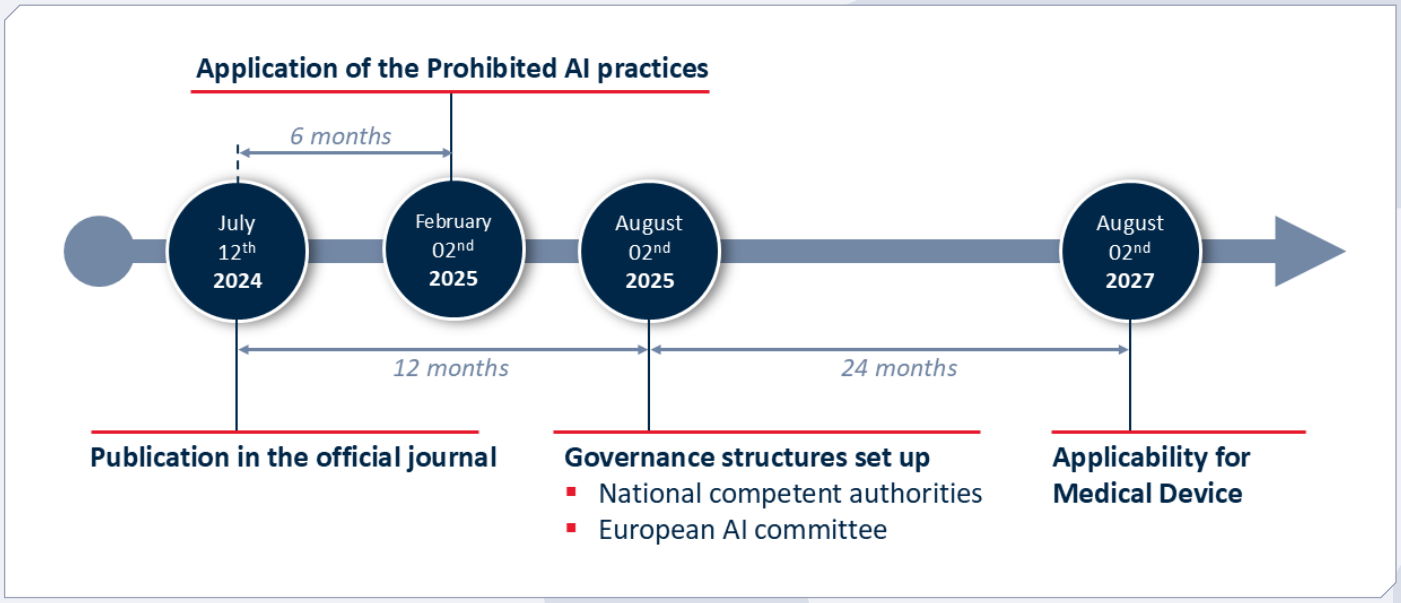
In the case of AIS, this should also enable the maintenance and deployment of updates. The AI Act specifically requires the presence of event logs to trace activity and facilitate this post-market monitoring.

Other requirements are specific to the AI regulation but are more technical than documentary. For example, the design of the AIS must include means of human supervision. This requirement is a risk control measure whose application and scope will depend on the autonomy and impact of the AIS on patient safety. The regulation also specifies requirements for AIS transparency. This means, among other things, that users must be informed not only of the product's performance, but also of its limitations and potential biases.

As with other software, AIS will be able to rely on lifecycle management practices. However, issues specific to AI technology will need to be considered to meet safety and performance objectives. The quality of training, validation and test datasets is a cornerstone of AIS performance and relevance. Particular attention must therefore be paid to their selection and processing. Technical documentation should include statistical descriptions of these data sets, to demonstrate their suitability for AIS specifications and the control of biases, for example.

C Transitional provisions

Article 113 defines the dates of application of the AI Act. As the text came into force on August 2, 2024, the next applicable deadlines for MD are described in the visual below:



Conclusion

The publication of the "AI Act" is an important milestone, as it is the world's first text regulating artificial intelligence. Many points remain to be defined and clarified.

GMED is already taking part in the study of these regulations, notably through the creation of a dedicated working group which participates in various European standardization committees to keep abreast of developments introduced by the "AI Act". In this way, GMED can best support manufacturers who are integrating or will integrate AI into their devices.

The publication of guidance documents and harmonized standards as defined in Article 40 is also expected to provide guidelines on the content of technical documentation.

MD manufacturers will have to include in their device technical documentation and quality management system, the means of managing the risks specific to the presence of AIS. These changes will have to comply with the new regulation by August 2, 2027, at the latest. Until then, GMED encourages manufacturers to anticipate and plan for the implementation of the AI Act requirements.

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Apply the requirements of the Regulation (UE) 2017/745 on medical devices
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[ONLY FOR GMED CUSTOMERS]

The format and content of the technical documentation to be provided for the assessment of your medical device

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