The European Association of Medical devices Notified Bodies

Team-NB Position Paper

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European Artificial Intelligence Act

About Team-NB

TEAM-NB (The European Association for Medical Devices of Notified Bodies) is an association representing notified bodies (NBs) active in the certification of medical devices[1] under EU regulations. Our main objectives are promoting high standards of conformity assessment, ensuring harmonised implementation of the MDR/IVDR, and facilitating dialogue between NBs, regulators, industry, and other stakeholders.

Background

The European Commission Artificial Intelligence (AI) Regulation (Regulation (EU) 2024/1689), in the following "AI Act" or "AIA" has entered into force on 01 August 2024. The AI Act is designed horizontally to cover most business sectors and introduces a risk-based approach to determine the level of scrutiny on AI systems being placed on the Union market or being used in the Union. Use of AI systems as a safety component of or as a medical device or *in vitro* diagnostic[2] (MDAI) is considered high-risk according to the AI Regulation, if a conformity assessment would be required according to risk classification under Medical Device Regulation (EU) 2017/745 (MDR) or In Vitro Diagnostics Regulation (EU) 2017/746 (IVDR) (AIA Art. 6(1)).

According to Article 113 (c) (AIA), the high-risk scope under Article 6(1) will become applicable on 02 August 2027. From that date onwards, newly introduced or legacy medical devices undergoing a significant change (Art. 111 (2)) and fulfilling the aforementioned conditions (i.e. requirement for third party conformity assessment and use as safety component or as a device itself) will have to comply with the provisions of the AI Act.

The members of Team-NB publish this position to express their opinion regarding the implementation and application of the EU AI Act, with a focus on the interface and overlap with MDR and IVDR.

[1] If not indicated otherwise, the term 'medical device' includes '*in vitro* diagnostic medical device'.

[2] For the purpose of this document, an 'AI system in or as medical devices or *in vitro* diagnostics' is 'medical device AI' or 'MDAI'.

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Summary

This position paper provides an overview of the Team-NB perspective on the challenges of the AI Act with particular attention to its implementation.

Because of the tight timelines for implementation, we welcome a coordinated approach between member states for the designation and oversight of NBs, being currently under discussion. The proposed pathway referring to Article 43(3) and making use of the existing software-related codes[3] to include AI Act requirements enables notified bodies to assess MDAI in an efficient manner without compromising due scrutiny. Although Article 30 foresees designation of AI NBs in a horizontal manner (i.e. across different business areas), this pathway may be too time consuming and complicated to establish enough NBs for MDAI to meet industry demands in a timely manner. However, we observe with some concern that not all member states might be ready on 02 August 2025 with established national implementing laws and designating authorities. Delays are likely to cause a shortage of designated NBs, when the high-risk scope of the AI Act becomes applicable on 02 August 2027.

Conformity assessment of MDAI will follow the procedures established under MDR and IVDR (Art. 43(3)). This will allow both, manufacturers and NBs to focus on new requirements of the AI Act. As there is already substantial expertise and experience on both sides, we foresee the challenges of the conformity assessment of high-risk MDAI to be of administrative and legal nature.

Particularly, a common understanding of the AI Act's definitions of 'AI system' and 'safety component' is crucial to the scope. Likewise, the terms 'substantial modification' and 'significant change' require clear definitions for life-cycle management of MDAI. With the Commission guideline on the AI system definition, we see an important first step. Yet, additional clarity will be needed for all stakeholders, especially when it comes to specific knowledge- or logic based approaches as either AI or non-AI models.

While safety and performance remain central for medical devices, the AI Act makes distinct provisions for the compliance with fundamental rights like privacy, data protection, non-discrimination, and human dignity. These principles need to be incorporated into manufacturers' risk assessments and products. Further guidance on fundamental rights in this context will help harmonise approaches and expectations. Also, embedding principles of fundamental rights into standards (compliance by design) may support effective compliance with the AI Act's requirements.

The AI Act and MDR/IVDR have requirements for post-market surveillance and vigilance. This means that there is some risk relating to duplication of administrative efforts as well as compartmentalisation of information. By ensuring interoperability between surveillance systems and databases, full oversight may be maintained and administrative burden reduced.

It is a widely acknowledged fact that the availability of high-quality data is pivotal for training, validation and testing of AI systems. While this challenge is foremost one of developers of AI systems, NBs will have responsibilities regarding conformity assessments through GDPR-compliant access to manufacturers' data sets and, if necessary, also to high-quality, well-documented, and independent datasets for additional testing of MDAI. Whilst a fully implemented European Health Data Space (EHDS)

[3] Regulation 2017/2185

may be particularly helpful we must acknowledge that this won't be the case for the applicability of the high-risk scope of the AI Act. Finding timely and practical solutions to these data challenges will be necessary.

Timelines for the finalisation of harmonised standards under the AIA are already delayed. Efficient development and conformity assessment of innovative MDAI relies greatly on their availability. Although their absence may not be insurmountable given the framework which considers state of the art, not being able to rely on harmonised standards will cause compliance issues and costs for developers and assessors of MDAI such as notified bodies.

In summary, the implementation of the AI Act in the medical device sector hinges on successful completion of these challenges. Clear definitions, timely national laws, availability of designating authorities, robust data security, integrated reporting systems, consideration of fundamental rights, and availability of harmonized standards are essential for smooth and effective conformity assessments and ensuring access to advanced medical technology.

Designation of Notified Bodies

Background: The AI Act offers different routes for conformity assessment bodies to assess AI systems. First, conformity assessment bodies can apply for full designation according to Article 30 which is primarily to be understood in context of Article 6(2) (Annex III). There are several provisions in the AI Act to make this pathway as smooth as possible (e.g. avoiding duplicate documentation of requirements for notified bodies) Yet, it is to be expected that this process will take considerable time. Designating authorities have to be established on member state level by 02 August 2025 (Article 70 (2)). Second, Article 43 (3) allows the conformity assessment of high-risk AI systems under the respective specific Union harmonisation legislation (listed Annex I as referred to in Article 6(1), incl. MDR and IVDR) covering specific requirements of the AI Act as part of the established conformity assessment procedures. Both designation routes (1. Full designation according to AI Act (Annex III); 2. Extended designation under other Union harmonisation legislation (Annex I)) require national implementing laws in all member states. Formally, notified bodies may only pursue a designation for assessing high-risk AI systems when these national laws are established as required by the AI Act.

Opinion: We greatly welcome the discussions on member state level to establish a pragmatic way to implement the AI Act following the second option described above. Particularly, the proposed approach to extend the scope of software codes established by Regulation 2017/2185 to cover additional requirements of the AI Act appears to offer a fast and easy route to enable conformity assessment of AI systems in medical devices without compromising the scrutiny on notified bodies.

With increasing concern, we observe recent discussions, that designations according to this second option shall not be possible. This position is in contradiction to Article 43(3) and bears the imminent risk of notified bodies not being able to pursue their obligations in a timely manner. A limited availability of NBs at the time of applicability of the AI Act for medical devices is likely to be the consequence.

Furthermore, we'd like to highlight, that not all member states are diligently proceeding with national implementing acts, that are required to establish a legal basis for any conformity assessment according to the AI Act. We acknowledge that potential delays are due to specific national political constellations. Yet, this poses a substantial risk to innovative AI systems throughout the Union and a balanced competition between notified bodies. Notified bodies are preparing for the applicability of the AI Act, but it should be noted that actual designation procedures will require additional time after national implementing laws have come into force. Consequently, we see the risk of notified bodies not being readily available well in advance of the applicability of the high-risk scope of the AI Act (i.e. 02 August 2027). Depending on the practical interpretation of the overall scope of the AI Act (see 'Definitions'), we'd like to make aware of the inherent risk of a major disruption of the medical device software (MDSW) market.

We strongly believe that the swift designation of notified bodies is pivotal to the implementation of the AI Act. Any delays on European or member state level will likely cause backlogs in assessing innovative medical devices and thus prevent healthcare professionals and patients having access to cutting edge medical technology.

Conformity Assessment Procedure

Background: In accordance with Article. 43 (3), an integrated process for conformity assessment of medical devices including or consisting of AI systems is required.

Opinion: AI methodologies in medical technology are readily being used and assessed for years. Consequently, notified bodies and industry have gathered considerable experience and built expertise in this field. AI systems are considered medical device software and are assessed accordingly within the current framework, i.e. for conformity with relevant GSPRs. Given the existing capacities for the assessment of AI in medical devices and ongoing efforts to increase these to meet industry demand, we expect a smooth building of capacities on the AI Act by notified bodies.

When the high-risk scope of the AI Act is applicable on 02 August 2027, medical devices using AI in accordance with Art. 6(1) are to be compliant with the AI Act. Particularly the following points will require additional attention by manufacturers as well as notified bodies (list is not exhaustive):

- Ensure a high level of protection of fundamental rights in addition to health and safety (Art. 1)
- Risk and quality management systems compliant with Articles 9 and 17 respectively,
- Stringent provisions ensuring human oversight over AI systems need to be in place (Art. 14),
- Appropriate logging needs to be in place (Art. 12)
- If deemed necessary, NBs may access training, validation and testing datasets of AI systems Annex VII, 4.3),
- If technical documentation does not provide clear evidence for compliance with the AI Act, NBs may carry out additional testing on their own or commission tests (Annex VII, 4.4 and 5.3),
- If tests and audit are not sufficient, NBs may access source code of AI systems (Art. 74 (13)(a)).

Although the overall requirements for MDAI under the MDR/IVDR regulatory framework are already at a considerably high level and ensure a robust compliance framework, the AI Act adds substantial requirements (see above). Yet, we believe, that administrative aspects represent a greater challenge to the implementation of the AI Act. Thus, it will be crucial to follow a well-coordinated approach between member states, that are in charge of notified body oversight, and the Eurupean Commission.

Definitions

Background:

Article 3

(1) ‘AI system’ means a machine-based system that is designed to operate with varying levels of autonomy and that may exhibit adaptiveness after deployment, and that, for explicit or implicit objectives, infers, from the input it receives, how to generate outputs such as predictions, content, recommendations, or decisions that can influence physical or virtual environments;’

[…]

(14) 'safety component' means a component of a product or of an AI system which fulfils a safety function for that product or AI system, or the failure or malfunctioning of which endangers the health and safety of persons or property;

[…]

(23) 'substantial modification' means a change to an AI system after its placing on the market or putting into service which is not foreseen or planned in the initial conformity assessment carried out by the provider and as a result of which the compliance of the AI system with the requirements set out in Chapter III, Section 2 is affected or results in a modification to the intended purpose for which the AI system has been assessed;

[…]

Opinion: These definitions are crucial for understanding the scope of the AI Act, as they define (1) the overall scope of the AI Act, (14) the scope of high-risk AI systems, and (23) the need for post-market change reporting.

(1) We appreciate the adoption of a wording for the 'AI system's' definition that follows the OECD definition. We believe this will allow for an easier global harmonisation and help avoiding diverging positions on the nature of AI between major markets. For good reasons, this covers a wide scope to allow for interpretation according to future technological developments in the field of AI.
We believe the clarifying guidance[4] by the European Commission is of great value for a consistent understanding of the legal definition of AI systems. Also, we appreciate the need for flexibility for case-by-case decisions which is foreseen by this guideline. However, the pivot of the AI Act's definition of AI systems 'inference' might require additional elaboration, e.g. by more detailed and sector specific guidance making use of examples. Unclear constraints of the definition might well cause an overflow of the definition to include entities that are traditionally not considered AI systems (e.g. many logic- or knowledge-based systems).

(14) Another critical aspect for understanding the impact of the AI Act is the term 'safety component'. In the current discourse, we observe a certain divergence of opinions on what uses of AI systems qualify as safety component. Our understanding of the term is that the AI system as a part of a medical device always bears the risk of 'endanger[ing] the health and safety of persons'. Obviously, this will always be the case, if the AI system *is* the medical device. The definition of a 'safety component' in the AI Act, allows the conclusion that a potential malfunction of an AI system always constitutes a 'device deficiency' according to MDR, Art. 2 (59). However, a more pragmatic interpretation appears to be more appropriate for practical reasons.
Since the high-risk scope of the AI Act and also medical 'device deficiencies' directly relate to this term, clarifying guidance would be highly appreciated.

[4] Commission Guidelines on the defintion of an artificial intelligence system established by Regulation (EU) 2024/1689 (AI Act), C(2025) 924 final, published 06 February 2025

(23) Likewise, understanding of 'substantial modifications' will be needed; according to recital 177, it can be understood as equivalent to the term 'significant change' which is used by AI Act and MDR/IVDR. However, 'significant changes' lack a formal legal definition in the latter context and have been subject to disputes. The guidance required by Article 96 (AIA) could be a good opportunity to establish a harmonised interpretation of 'substantial modifications' and 'significant changes'.

We'd like to highlight, that the ease of implementation of the AI Act greatly depends on the interpretation of the above mentioned and other definitions. Notably, this will affect the number of products requiring an extended conformity assessment covering the requirements of the AI Act or re-assessment following changes of the device.

Fundamental Rights

Background: In Article 1, the AI Act makes a very prominent reference to the protection of fundamental rights, with reference to the Charter [5] including democracy, the rule of law and environmental protection. While ensuring a high level of safety and health is already the focus of MDR and IVDR the topic of protection of fundamental rights is an additional focus provided by the Act (EU) 2024/1689.

Opinion: Though for medical devices the aspects of safety and health appear generally to be most important, fundamental rights (e.g. privacy, data protection, non-discrimination, or human dignity and autonomy) will also have to be considered. Medical device manufacturers will need to adapt their approaches and take in consideration the relevant factors in their risk assessments and in consequence in their products. The guidance to be provided on the matter of fundamental rights will be an important orientation for harmonising approaches and expectations.

Reporting and Vigilance

Background: The AI Act requires registration and safety reporting (e.g. registration acc. to Art. 71 AI Act; safety reporting acc. to Art. 73 AI) in a similar fashion to MDR and IVDR. New databases and IT systems are to be established under the oversight of the AI Office.

Opinion: Given the existing/to be established reporting routes under MDR/IVDR, the new requirements of the AI Act bear the risk of duplicating administrative efforts and partitioning information in independent reporting systems. In line with the approach to be used for conformity assessments (see above), it would be highly desirable that reporting requirements of the AI Act are fully integrated into the existing routes for medical devices. If an integration is not feasible and to avoid partitioned vigilance information spread over several systems, interoperability of respective databases (i.e. information mirrored to the respective other system) is a minimum requirement. In this way, it would be guaranteed both regulatory frameworks having full oversight and not missing any critical information.

[5] CHARTER OF FUNDAMENTAL RIGHTS OF THE EUROPEAN UNION (2016/C 202/02)

Data and Data Governance

Background: Availability of high-quality data is key for the quality of an AI model or system and is therefore important in the development of many AI devices, most relevantly those employing machine learning techniques. Consequently, the EU AI Act imposes various requirements on data and data governance that directly impact conformity assessments of high-risk AI systems (Art. 10). E.g. 'Training, validation and testing data sets shall be relevant, sufficiently representative, and to the best extent possible, free of errors and complete in view of the intended purpose. […]' (Art. 10(3)). To verify the adequacy of the data used by developers, conformity assessment may require access to those in many cases. Additionally, NBs must verify that AI system providers have implemented robust data governance practices, including traceability and compliance with GDPR (Regulation (EU) 2016/679).

For the purpose of conformity assessment, notified bodies may require full access to training, validation and testing data sets used by the manufacturer (Annex VII, 4.3). Also, additional testing of AI systems by notified bodies may be required during assessment of technical documentation (Annex VII, 4.4). The availability of high-quality, well-documented and independent data sets is essential for such additional tests.

Opinion: We see two critical challenges with regard to data for Notified Bodies:

- In many cases, NBs will have to access training and testing datasets used by developers to assess conformity of devices. This will require appropriate data security measures and compliance with GDPR by both, medical device manufacturers and notified bodies. E.g. security of data when accessed remotely by or being transferred to NBs must be ensured as well as appropriate data protection agreements have to be in place that allow this access by a third party. Practically, this might prove to demanding for both sides.
- The availability of a sufficient amount of high-quality, well-documented and independent datasets for notified bodies will be a challenge. For example, the scarcity of this resource might cause problems for the independence of data from training data. To enable notified bodies to fulfil their responsibilities, easy access to data will be essential for verifying safety, performance, and fairness of AI-driven medical devices. We'd like to note that currently no easy pathway is established to guarantee access to independent test datasets.
  We expect the implementation of the European Health Data Space (EHDS)[6] will offer at least a partial solution for the increased demand for health data. However, the EHDS framework will not be readily available for the applicability of the high-risk scope of the AI Act, so that availability of data might pose a considerable barrier to the certification of AI in or as medical devices. Thus, finding pragmatic solutions to this problem should be a priority for all stakeholders.

[6] Regulation (EU) 2025/327 of the European Parliament and of the Council of 11 February 2025 on the European Health Data Space and amending Directive 2011/24/EU and Regulation (EU) 2024/2847, https://eur-lex.europa.eu/eli/reg/2025/327/oj/eng

Despite these challenges, it shall be noted that NBs' focus will remain on the assessment of quality management systems and technical documentation of MDAI (AI Act, Annex VII); and that further testing or scrutiny of data sets is not required by default.

Standardisation

Background: According to Article 40 of the AI Act, harmonised standards for AI systems are to be drafted. The European Commission issued a first request for such activities already in May 2023 to CEN and CENELEC.[7]

Opinion: Although standardisation requests have been made in advance, a delayed availability of harmonised standards is to be expected. Although such are not strictly necessary for the implementation, they would allow for a presumption of conformity with the provisions of the AI Act and hence an easier development and conformity assessment of devices including an AI system. If harmonised standards are not available well in advance of the applicability of the high-risk scope of the AI Act, conformity assessment will have to rely on a comparison with the state-of-the-art which will be more resource consuming than demonstrating compliance with a harmonised standard.

It should be noted that currently available horizontal standards on AI systems are not harmonised with the AI Act and are neither adequate for presumption of conformity nor may be considered state-of-the-art in their entirety.

Version history

This document is a full revision (Version 2) of the Team-NB Position Paper "European Artificial Intelligence Regulation" (06 Oct 2021) and supersedes the position "The designation of notified bodies under the upcoming Artificial Intelligence Act" (16 Dec 2022).

[7] C(2023)3215 – Standardisation request M/593, COMMISSION IMPLEMENTING DECISION of 22.5.2023 on a standardisation request to the European Committee for Standardisation and the European Committee for Electrotechnical Standardisation in support of Union policy on artificial intelligence