The EU AI Act meets MDR

Everything AI-enabled medical device manufacturers need to know.

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Introduction

For over 30 years, medical devices have been regulated at the European level, with a well-established infrastructure ensuring their safety and efficacy. The introduction of the Medical Device Directives (MDD)[1] and later the Medical Device Regulation (MDR)[2] has created a framework for managing the risks associated with medical technologies.

Recent advancements in Artificial Intelligence (AI) are driving a **digital transformation across the healthcare sector**. AI is increasingly embedded in medical devices, ranging from AI systems to detect breast cancer during mammograms[3], wearable patient monitoring solutions for virtual patient care[4], to autonomous robotic surgeons[5]. While these advances present significant benefits to patients, they also raise new risks and safety concerns. For example, biased data, often due to underrepresentation of minority groups in medical datasets, can lead to inaccurate or misleading diagnoses for these populations. This can result in disparities in treatment, potentially jeopardizing patient safety and exacerbating discrimination in healthcare[6].

The European Union (EU) considered that the existing EU legal instruments that do directly regulate medical devices such as the MDR and the General Data Protection Regulation (GDPR), are not sufficient to handle specific challenges posed by AI models and systems. In this context, the European Commission recently published the **Artificial Intelligence Act** (AIA)[7], a Regulation that aims to harmonize AI rules across the EU and create an ecosystem of trust in AI by aligning its use with European values, fundamental rights, and principles.

This whitepaper explores the key aspects of the AIA and MDR that manufacturers of AI-enabled medical devices need to understand. It focuses on the interplay between these regulations, the classification of AI systems, the conformity assessment process, the roles of economic operators, and additional requirements coming from the AIA for high-risk AI enabled medical devices. Manufacturers will gain insights into how to integrate AIA requirements into their existing MDR compliance frameworks and prepare for the challenging landscape of AI regulation.

The new legislative framework

The AIA is a **horizontal regulation**, meaning it applies across all sectors and industries, not just one specific field. This approach ensures that AI models and systems, no matter in which domain they fall under, follow a consistent set of rules. The AIA aims to provide clarity and promote uniform regulation of AI technologies across the EU, creating a fair competitive field and equal opportunities for businesses.

The AIA and MDR align with the EU's New Legislative Framework (NLF) for CE marking, which aims to improve the internal market by enhancing product safety, boosting conformity assessments, and clarifying CE marking. The NLF includes Regulation (EC) 765/2008[8], Decision 768/2008[9], and Regulation (EU) 2019/1020[10]. **Decision 768/2008, in particular, sets a common framework for product marketing and serves as the template for future product harmonization laws.** Currently, 27 pieces of harmonization legislation, including the AIA, MDR, Toy Safety Directive, Low Voltage Directive, and Machinery Regulation, are based on this template, which is why they often share similar structures.

The AIA should be seen as a complementary legislation to existing product safety laws[11]. In fact, the AIA clarifies in Article 2(9) that its rules should be applied without prejudice to existing Union legal acts related to consumer protection and product safety.

The intention of the AIA is to avoid inconsistencies when applying several EU laws at the same time. For this reason, the principle *lex specialis* vs *lex generalis* is to be applied, whenever we have a matter regulated by two different rules. This means that, the more specific rule will 'win' over the more general one. In this regard, we understand the **AIA to be considered as *lex generalis***, which will set general requirements to the use and risks of AI while the **MDR should be considered *lex specialis***, which contains more specific requirements with respect to the safe use of AI in medical devices.

This approach should ensure that products covered by both the AIA and MDR are not subjected to conflicting regulatory requirements.

AI Act & MDR scope interplay

At the EU level, medical devices, including those with AI, are primarily regulated under the MDR. The MDR aims to guarantee a high level of health and safety of medical devices while supporting innovation[13].

According to the MDR, a medical device means '*any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes', for example, 'diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease*'[14]. Software can also be part of a medical device, improving the device functionalities. Depending on the **intended purpose of the software**, we need to differentiate the following:

- **Medical Devices Software (MDSW[15])** '(...) *is software that is intended to be used, alone or in combination, for a purpose as specified in the definition of a "medical device" in the medical devices regulation* (...)'[16]. Bear in mind that Software as a Medical Device (SaMD) is the term used by the IMDRF Guidance[17].
- **Software driving or influencing the use of a device** means '*software which is intended to drive or influence the use of a (hardware) medical device and does not have or perform a medical purpose on its own, nor does it create information on its own for one or more of the medical purposes described in the definition of a medical device* (...).' In other words, software that is considered a part/component or an accessory to the medical device. Under the MDR, an accessory is defined as '*an article which, whilst not being itself a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable the medical device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device(s) in terms of its/their intended purpose(s)*'[18]. Software in a Medical Device (SiMD) is the term used by the IMDRF Guidance[19].

In this whitepaper, we will adopt the terminology from the Medical Device Coordination Group (MDCG) guidance on the qualification and classification of software under Regulation (EU) 2017/745 (MDR) and Regulation (EU) 2017/746 (IVDR).

In short, whether a device, including software, is a medical device under the MDR, it will depend upon two criteria: **1) the objective element of (at least) one of the medical purposes enlisted in Article 2(1) MDR, and 2) the subjective element of the manufacturer intended to use the software for a specific medical purpose.**

Manufacturers should first assess whether their software qualifies as a medical device under these criteria. If the software is classified as a medical device, it must comply with the MDR.

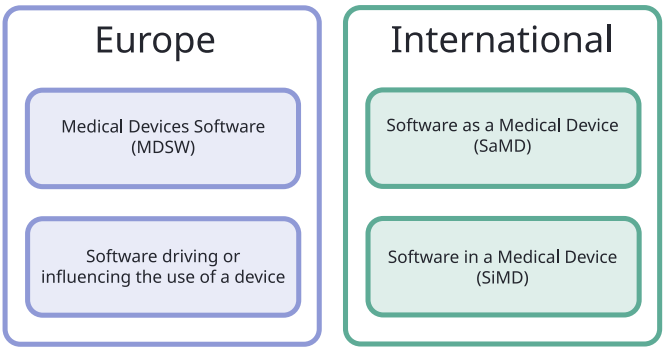


Fig. 1. Software terms between MDCG and IMDRF guidance

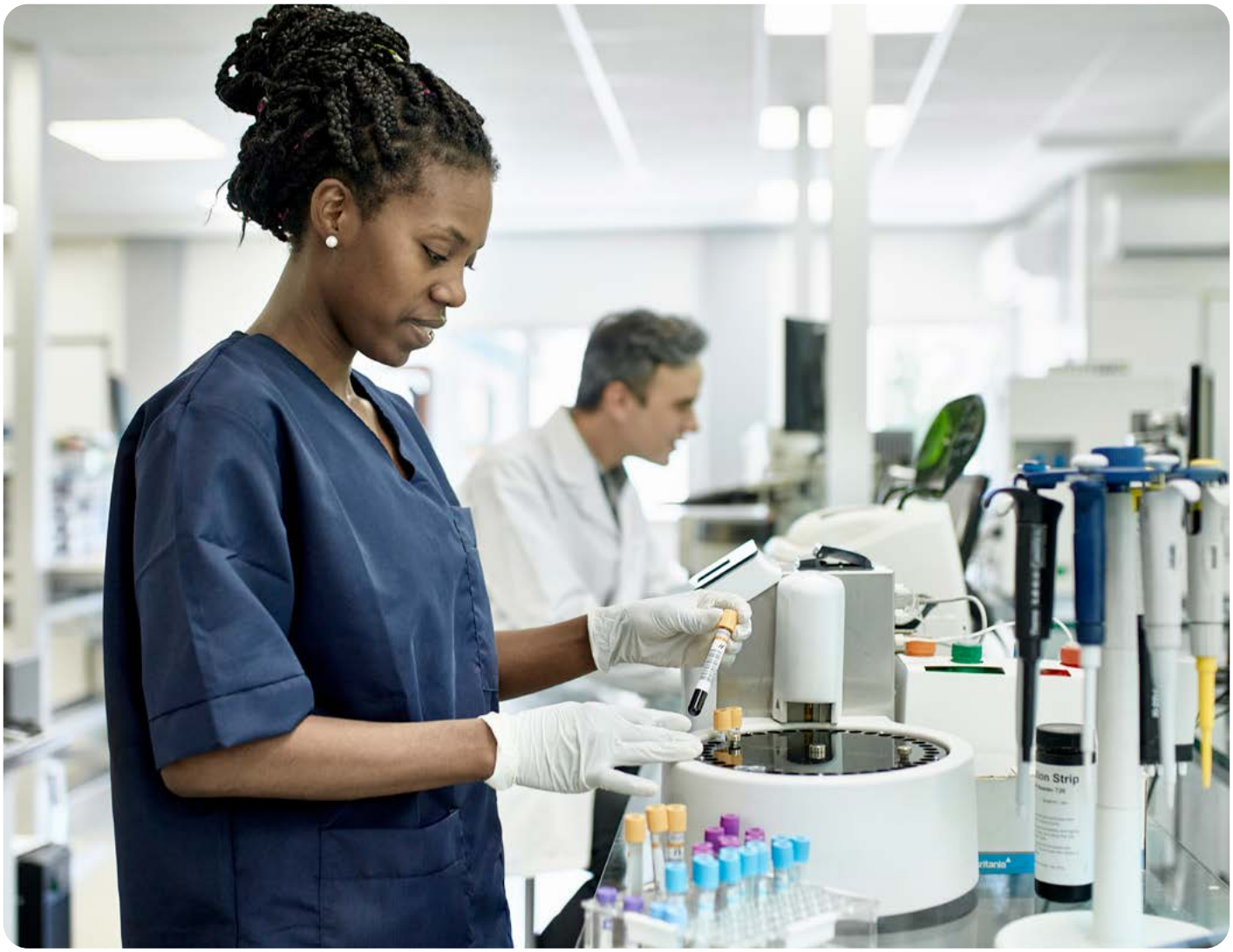
Intersection of MDR and AIA

The next consideration is **whether the MDSW or Software driving or influencing the use of a device includes AI, as defined by the AIA**. If the software qualifies as a medical device and includes AI, it must also comply with the AIA.

The definition of what is AI has been a controversial topic during the whole EU legislative process, the key thing was to differentiate AI from traditional based computer systems.

According to the AIA, an AI system is '*a machine-based system 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*;'[20].

The key criteria that differentiate an AI system from simpler traditional software systems or programming approaches are: (i) inference, (ii) autonomy, and (iii) adaptiveness.



Recital 12 AIA further elaborates on this definition and states that '***inference***' refers to '*the process of obtaining the outputs, such as predictions, content, recommendations, or decisions, which can influence physical and virtual environments, and to a capability of AI systems to derive models or algorithms, or both, from inputs or data*.'

The techniques that enable inference for AI include '*machine learning approaches that learn from data how to achieve certain objectives, and logic- and knowledge-based approaches that infer from encoded knowledge or symbolic representation of the task to be solved*,' with either implementation going '*beyond basic data processing' and enabling 'learning, reasoning or modelling*.' The recital also explains that '***autonomy***' means that AI systems have '*some degree of independence of actions from human involvement and of capabilities to operate without human intervention*', whereas '***adaptiveness***' refers to '*self-learning capabilities, allowing the system to change while in use*.'

Now that we have a definition, it is important to understand how AI systems can be presented to the market. AI systems can either:

1. be used on a **stand-alone basis**, outside of existing product safety laws, or
2. serve as a **component of a product**, whether physically integrated (embedded) or serving the functionality of the product without being integrated (non-embedded)[21].

For an AI system to be evaluated within the scope of product safety law, such as the MDR, it must be associated with a medical device product, as described in the second option. As we will see better in the following section, to fall under the scope of the AIA, the AI system must either function as a safety component of a product or the AI system is '*itself a product*'.

In summary, we have seen that the regulation of medical devices in the EU, particularly under the MDR, aims to ensure that medical devices, including those incorporating AI, meet stringent safety and performance conditions.

Whether an AI system is classified as a medical device depends on its intended medical purpose and function. If an AI application qualifies as a medical device, it must comply with the MDR; if it also falls under the definition of AI within the AIA, it may be subject to its regulation as well. Understanding this scope is the first step for manufacturers and providers to ensure full compliance with applicable EU regulations.

AIA classification and its interplay with MDR

Under the MDR, medical devices are classified based on their intended purpose and inherent risks. Article 51 MDR introduces four risk classes: Class I (lowest risk), Class IIa (medium risk), Class IIb (medium/high risk), and Class III (highest risk).

The class of a device is decided according to 22 rules[22] and within this list, **Rule 11** explicitly classifies MDSW[23] based on the risk it poses to patient safety. Once the class of a device is identified, the manufacturer will need to follow the applicable general safety and performance requirements (GSPRs) set out in Annex I.

This system ensures that devices with higher risks undergo stricter regulatory checks, while lower-risk devices face less regulatory burden. Moreover, the purpose of the classification is to guide manufacturers in selecting the appropriate conformity assessment pathway for a medical device. A conformity assessment under the MDR is the process by which a medical device's compliance with the regulatory requirements is evaluated before it enters the EU market.

Similar to the MDR, **the AIA follows a risk-based approach: the higher the risk, the stricter the rule**. Four risk classes are used: 'unacceptable risk'[24], 'high risk'[25], 'limited risk'[26] and 'minimal risk'[27] [28]. General Purpose AI systems (GPAI) are subject to specific obligations that vary depending on factors such as whether the model is open source, its computing power, and the size of its user base[29].

Fig. 2. Risk classification in the AIA

The bulk of the AIA relies on both, the requirements that high-risk systems shall satisfy, and the obligations for the economic operators involved in their lifecycle.

According to Article 6 AIA, two classes of high-risk systems can be identified:

1. **Stand-alone AI systems listed in Annex III**. It is important to note that these systems are not covered by existing product safety laws. This category includes software used in healthcare that does not fall under the MDR. For example, AI systems that play a crucial role in the management and prioritization of emergency calls and services are classified as high-risk AI systems under Annex III[30].

2. **AI Systems covered under Annex I, Section A**. These are classified as high-risk if they meet both criteria:
   a. they are intended to be used as a **safety component of a product** or the AI system is i**tself a product** covered by Union harmonization legislation listed in Annex I Section A, such as the MDR, and;
   b. the product whose safety component pursuant to point (a) is the AI system, or the AI system itself as a product, is required by the Union harmonization legislation to undergo a **third-party conformity assessment**, before being placed on the market or put into service.

We recognize that the term AI system being '*itself a product*' can refer to an independent AI medical device that performs a medical purpose and is intended to be placed on the market or put into service. Therefore, **MDSW qualifies as '*itself a product*'** when the AI software functions independently of any other device[31].

However, when the **MDSW drives or influences a (hardware) medical device** and also serves a medical purpose[32], the AI component will only be regarded as a '*safety component*', if it is specifically intended to perform a safety function. In both cases, the MDSW would qualify as high-risk under the AIA if classified as Class IIa or higher under the MDR.

On the other hand, **AI-software driving or influencing the use of a medical device** – if intended to perform as an accessory or part/component of a product[33] – falls under the AIA's high-risk category only if it drives safety functionalities, otherwise, it is classified as non-high risk.

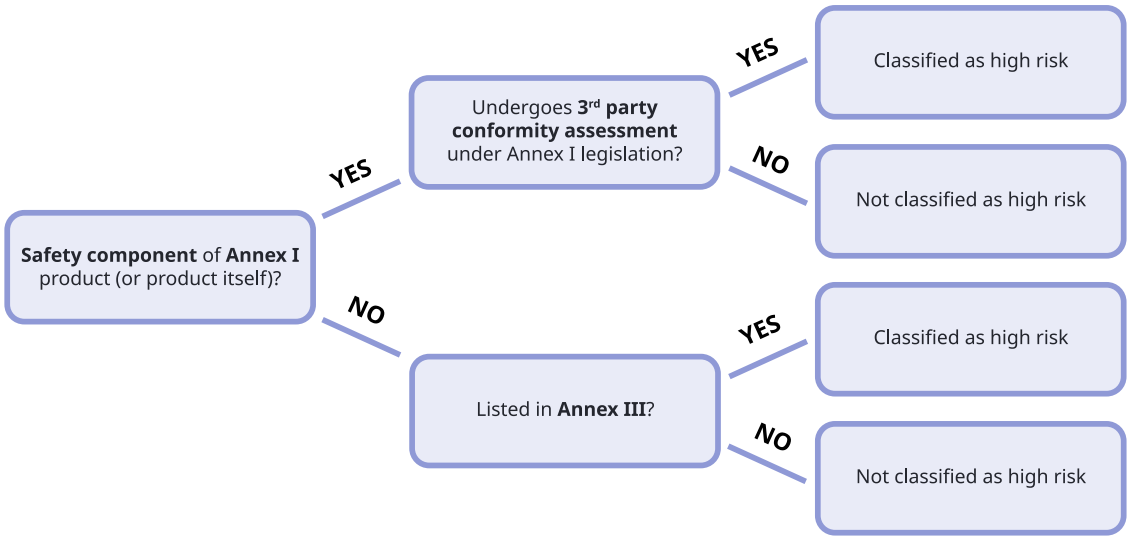


Fig. 3. Article 6 (1) AIA, risk classification of products covered under Union Harmonization Legislation

To summarize the key aspects, we can outline the following categorization scenarios regarding AI-enabled medical devices:

1. **MDSW that is '*itself a product*' having its own intended medical purpose**: In this case, the MDSW itself is an AI-based system, such as software for automated CT image segmentation aimed at the early diagnosis of specific cancer types. Here, the AI functions as the core medical device with a direct diagnostic purpose.

2. **MDSW where AI is a safety component with a medical purpose**: In this scenario, the AI drives or influences a (hardware) medical device and acts as a safety-enhancing component with a medical purpose. An example is an insulin pump system with a glucose monitoring software, where an AI-based algorithm predicts blood sugar trends using continuous glucose monitoring data. The AI component plays a safety role by adjusting insulin delivery to prevent adverse glycemic events.

3. **AI-software driving or influencing the use of a medical device, where AI is a safety component without a medical purpose**: Here, the AI component ensures the operational safety of the system but does not directly serve a medical purpose. For example, an AI monitoring system that oversees hardware performance in a surgical robot enhances the system's reliability and safety but does not contribute directly to medical decision-making or treatment.

The European Commission plans to release guidelines early in 2025 to clarify their expectations on classification of AI systems in more detail[34].

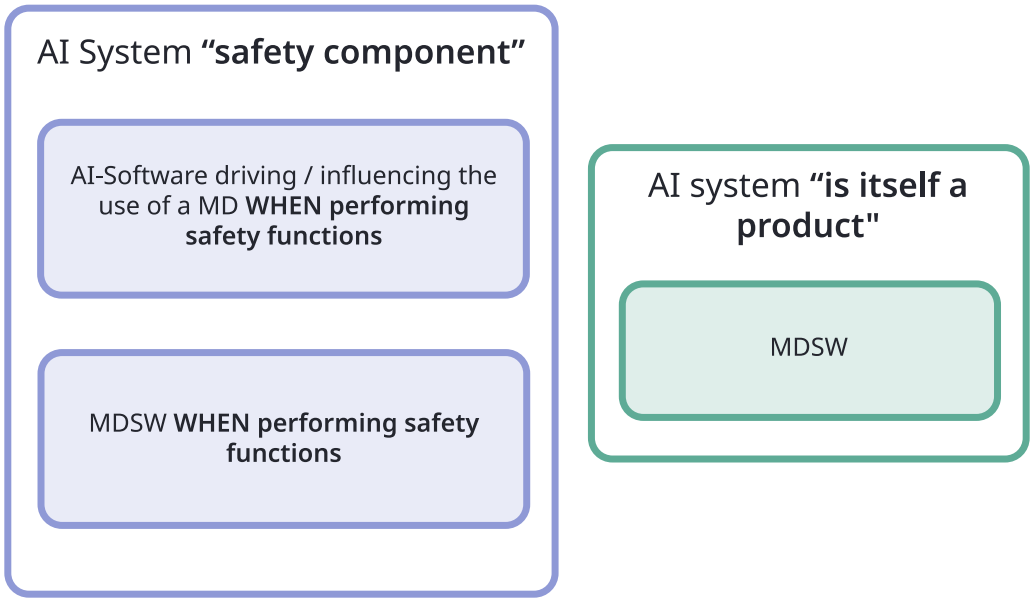


Fig. 4. Differentiation between AI systems as a 'safety component' of a product and AI systems being 'itself a product'

Misconceptions when classifying AI-enabled medical devices

A common misconception is to think that all AI medical devices will automatically qualify as high-risk under the AIA just because it has some form of AI in it. However, we are of the view that this is not accurate for two reasons:

1. It is true that when we talk about **MDSW that is '*itself a product*'**, if it is classified as Class IIa or higher under the MDR, requiring mandatory third-party conformity assessment, it is automatically deemed high-risk under the AIA.

   However, when it comes to **MDSW that drives or influences a (hardware) medical device**, if the AI is not intended to perform a safety function, it will not be classified as high-risk, even if the device requires mandatory third-party conformity assessment under the MDR. The MDR does not explicitly define '*safety component*'[35], however, the definition of safety component that we find in article 3(14) AIA can apply to medical device components.

   In the context of **AI software driving or influencing the use of a device**, while such AI system may not have a medical purpose -it is just an accessory-, they can potentially be considered a '*safety component*' if, again, the AI is intended to perform a safety function [36].

   It is clear from the above that additional interpretative guidance from the Commission is needed, especially regarding the definition of a '*safety component*' under the MDR.

2. Not all AI-enabled medical devices require third-party conformity assessment under the MDR. For example, some Class I medical devices may incorporate AI and maintain its classification under the MDR. In this scenario, the AI-enabled Class I device will not be classified as high-risk under the AIA. However, it is important to note that, if, for example, MDSW has been classified as Class I in accordance with MDR Rule 11, but then provider has integrated AI-functionality, then the risk classification can be changed to a higher class (e.g. Class IIa).

   It is also important to note that certain Class I medical devices, such as those with a measuring function, sterile devices, and reusable surgical instruments, require conformity assessment by a third party for those specific aspects. If these devices are enhanced with AI, they will be classified as high-risk under the AI Act.

It is crucial to emphasize that **risk classification under the AIA does not change the risk classification under the MDR**. In particular, recital 51 AIA specifies that the classification of an AI system as high-risk under the AIA should not necessarily mean that the product whose safety component is the AI system, or the AI system itself as a product, is considered high-risk under the MDR.

One might wonder why AIA risk classification matters if it does not affect MDR risk classification. The reason is that the **AIA risk classification determines which AI systems must adhere to additional obligations and requirements specified by the AIA, in addition to MDR requirements**. If an AI medical device is not classified as high-risk under the AIA, then the AIA's high-risk requirements do not apply.

Both the MDR and the AIA follow a risk-based approach for its classification rules, and their scheme should be seen as complementary rather than affecting each other directly. The MDR determines the level of regulatory scrutiny based on the device's risk classification. On the other hand, the AIA builds on this classification to assess whether the AI device is considered high-risk under its own criteria, adding extra requirements beyond those of the MDR.

Economic operators

There two primary economic operators recognized under the AIA scope are providers[37] and deployers[38] of AI systems. The AIA also introduces specific obligations for importers, distributors, deployers and authorized representatives of providers.

This distribution of roles is loosely aligned with the established categories of economic operators under the MDR.

Providers under the AIA are entities that place AI systems on the market or put them into service. For example, a company that places on the market or puts into service an AI-based diagnostic imaging software will act as both a "provider" under the AIA and a "manufacturer" under the MDR. **Thus, in this paper, when referring to an AI provider, we are talking about an AI-enabled medical device manufacturer.**

Deployers under the AIA are responsible for using AI systems in accordance with their intended purposes. At first glance, this role may appear similar to that of "users" of medical devices under the MDR.

However, the responsibilities of users primarily involve following instructions for use, maintaining devices and reporting any issues. In contrast, deployers under the AIA have broader obligations that encompass the ethical implications and societal impact of AI technologies. These responsibilities include conducting fundamental rights impact assessments, ensuring transparency in AI operations, and adhering to reporting requirements[39]. Non-compliance can result in penalties or restrictions on the deployment of AI systems.

Something important to bear in mind is Recital 87 AIA, which states that when a high-risk AI system functions as a safety component of a medical device and it is not placed on the market independently from the medical device, the medical manufacturer will be the one ensuring that the overall final product complies with both regulations, the MDR and the AIA.

Additional requirements for high-risk AI systems

The AIA recognizes that a single AI system may fall under different Union harmonization laws. In the case of a **medical device with AI, it could pose risks not fully addressed by the MDR, requiring the coordinated application of multiple EU regulations**[40].

The AIA seeks to ensure consistency, prevent duplication, and minimize additional burdens when applied alongside the MDR. It allows manufacturers to incorporate the necessary compliance measures for the AIA into the existing procedures and documentation required by the MDR.

This enables **manufacturers of AI-enabled medical devices to streamline their processes by integrating AIA requirements into their MDR submissions**. While the MDR takes precedence as the *lex specialis* for medical devices, manufacturers must still meet the additional AIA requirements, which can be addressed within a unified compliance process[41].

The requirements for high-risk AI systems and manufacturers of AI-enabled medical devices are specified in Chapter III, Section 2 and 3 AIA. When comparing the requirements of both, MDR and AIA regulations, at a broad level (see table 1 on next page), significant overlap is evident in areas such as Risk Management, Technical Documentation, Quality Management Systems (QMS), and Post-Market Surveillance (PMS). This overlap suggests some degree of interoperability between the two regulations. However, a detailed clause-by-clause analysis is needed to identify any new or additional requirements introduced by the AIA. **Even where requirements appear similar, differences may exist at a more granular level.**

In the following section, we will address the most important points that will lead to an adjustment of the AI-enabled medical devices' QMS.

Table 1 - Overview of relevant AI Act requirements for AI-enabled medical devices manufacturers

AI Act – High-risk AI providers obligations
Quality management requirements
Risk management system
Data and data governance
Post-market surveillance
Systems for reporting serious incidents and malfunctions
Technical documentation requirements
Product requirements
Automatically generated logs
Accuracy, robustness, and cybersecurity
Human oversight
Transparency and provision of information
Accessibility requirements
Declaration of conformity
CE mark

Quality management requirements

Article 17 AIA mandates that providers of high-risk AI systems implement a robust QMS. This requirement will sound familiar to medical device manufacturers, since it is essentially the same obligations prescribed under MDR. **High-risk AI providers must establish and maintain documented policies, procedures, and instructions to ensure compliance.**

Below is a table summarizing the key components that must be included in the QMS:

Table 2 - List of QMS Requirements

Regulatory compliance strategy
Design control and design verification
Quality control and assurance procedures
Testing and validation
Technical specifications (harmonized standards)
Data management systems
Risk management
Post market surveillance
Serious incident reporting
Communication with relevant authorities
Record keeping procedures
Resource management (security-of-supply) and accountability management

There are certain aspects of the AI QMS that are unique to the needs of AI systems. For example, data management, risk management, and testing and validation of AI algorithms require specific attention. Data management, in particular, must ensure that data used in AI systems is secure, accurate, and compliant with data protection laws[42] [43]. This is critical given AI's reliance on large datasets.

The AIA recognizes the unique challenges faced by SMEs and includes provisions for the development of **simplified QMS frameworks**[44]. These simplified systems, which will be developed by the Commission, aim to make compliance more accessible for smaller organizations while maintaining the safety and effectiveness of their AI systems.

For AI-enabled medical devices, the AIA allows manufacturers to integrate its specific QMS requirements into their existing MDR QMS framework[45]. Since medical device manufacturers typically adhere to the ISO/IEC 13485 standard, they may wonder if adopting an additional AI-specific QMS, such as ISO/IEC 42001, is necessary. It is important to note that while manufacturers can voluntarily choose which standards to follow, the mandatory requirements are to incorporate the relevant AIA's Article 17 obligations into their current system[46].

Risk management

The development and deployment of AI systems come with a wide range of risks, including algorithmic bias, data security vulnerabilities, a lack of transparency, and potential issues with faulty model updates. For companies in the AI value chain, it is essential and required by regulatory requirements to manage risks holistically – from identification and analysis to mitigation and continuous monitoring. This applies not only across the AI and data lifecycle (data, algorithms, model performance, cybersecurity) but also from economic, legal, and ethical perspectives . The capacity to reliably identify, accurately assess, and adequately respond to risks is especially critical in high-stake environments, like in this case, the health sector.

Within the AIA, the requirements on risk management[48] are particularly important. To mitigate the risks associated with high-risk AI systems, providers are required to comply with the requirements outlined in Chapter III sec 2 AIA[49]. However, the AIA acknowledges that even full compliance with the requirements may not reduce all risks to an acceptable level[50]. This is where Article 9 comes into play. This article requires providers of high-risk AI systems to identify any remaining risks and implement additional measures to mitigate them.

Pursuant to Article 9, a risk management system needs to be "*established, implemented, documented and maintained*". It also emphasizes that risk management for AI systems must be an ongoing and iterative process throughout the system's entire lifecycle. **This involves the continuous identification and analysis of known and the reasonably foreseeable risks to health, safety, and fundamental rights.**

The risk management of an AI-enabled medical device will require reorganization to address new objectives related to fundamental rights. While the MDR has traditionally focused on safety and performance-related risks, the AIA introduces a broader scope of protection, ensuring more comprehensive safeguards for the fundamental rights of individuals, as outlined in the EU Charter of Fundamental Rights[51].

However, variations in how member states define and protect fundamental rights can influence the risk assessment process, as the standards for safeguarding human rights may differ across jurisdictions[52]. Examples include algorithms discriminating against people with dual nationality and low income[53].

Providers are required to estimate and evaluate these risks, including those arising from misuse, and to implement targeted measures to mitigate them[54]. MDR requires to reduce risks as far as possible, while AIA requires elimination or reduction as far as technically feasible. Risk management measures shall be taken in such a way that as few interactions as possible occur[55], but also that residual risks are still considered acceptable[56]. To identify risks, high-risk AI systems must undergo regular testing, including under real-world conditions, to ensure they meet established safety and performance standards[57].

Special attention must also be given to addressing risks that affect vulnerable groups, particularly individuals under the age of 18[58].

Article 9 will be supported by future harmonized international standards on risk management methodologies. Currently, there is no specific, defined approach, concerning fundamental rights.

Something relevant for AI-enabled medical device manufacturers is that they can integrate AI risk management into their existing risk management processes under the MDR. However, compliance with ISO 14971:2019 alone is insufficient, as this standard does not address risks related to business operations, society, or the environment. ISO/IEC 23894 expands on these areas, outlining where they should be considered within an organization's risk management activities.

Additionally, BS/AAMI 34971:2023, Application of ISO 14971 to Machine Learning in Artificial Intelligence - Guide, provides guidance on incorporating AI systems into ISO 14971-based risk management. It is also important to note that ongoing work on the EN standard is focused on addressing the requirements of Article 9 of the EU AIA.

Data and data governance

Data plays an essential role in the AI context, as there is no AI without data. Data being of the highest quality is paramount to ensure that AI is trustworthy. For this reason, Article 10 AIA stands as one of the key requirements that high-risk AI systems are expected to fulfil.

Article 10 introduces new obligations to AI-enabled medical devices compared to MDR requirements as it introduces specific data governance and management practices tailored to AI systems. Unlike the MDR, which primarily focuses on safety and performance aspects, the AIA emphasizes detailed management of training, validation, and testing data. This includes careful consideration of design choices, data collection methods, preparation, bias prevention, and addressing any data gaps or shortcomings[59]. The data used must be relevant, representative, and '*to the best extent possible, free of errors and complete in view of the intended purpose*'[60].

Given the extensive amount of data required to properly train, validate, and test an AI models or systems, it will be difficult to determine when training is 'complete' according to the AIA. This issue is particularly significant for AI-enabled medical devices, where the sensitive nature of the data involved may have a more profound impact on the development process compared to other industries[61].

In this context, the AIA's requirements for handling special categories of personal data (genetic, health, biometric data) under strict conditions for bias monitoring and fundamental rights protection go beyond the MDR's scope, which does not specifically address these data management challenges for AI systems[62].

Data governance measures under the AIA must work in tandem with key EU regulations such as the General Data Protection Regulation (GDPR), the Data Act, the Data Governance Act and the future European Health Data Space Regulation (EHDS). These laws, part of the broader European Strategy for Data, collectively shape the framework for data management and protection.

To sum up, the AIA mandates that organizations implement comprehensive data management practices. This includes documenting these processes, procedures, and technical details as part of their Quality Management System[63] and Technical Documentation[64].

Additionally, aligning these practices with GDPR and other EU data laws ensures robust data protection, enhances transparency, and fosters trust in AI systems.

Post-market monitoring system

The post-market monitoring system (PMS) serves as a critical component in the regulatory framework for high-risk AI systems, ensuring their ongoing compliance with legal requirements. The AIA mandates providers to establish and document an appropriate PMS based on a PMS plan **to continuously monitor the performance, safety, and compliance of high-risk AI systems throughout their lifecycle**.

In addition to the requirements outlined in MDR articles 32, 61, and 84, as well as the MDCG on post-market surveillance and vigilance, and ISO/TR 20416 – Article 72 AIA requires providers the active and systematic collection of data, specifically related to the AI system's performance. This includes data from deployers as well as from other sources, emphasizing continuous monitoring throughout the AI system's operational life. Moreover, this article also mandates the analysis of the AI system's interactions with other AI systems, which is very relevant given the interoperable and interconnectable nature of many AI applications. This requirement excludes the analysis of sensitive operational data from deployers that are law enforcement authorities[65].

Something relevant for AI-enabled medical devices, is that manufacturers are allowed to integrate the additional PMS requirements of the AIA into the existing PMS surveillance framework stipulated by the MDR[66]. However, this integration is not just about adding new requirements, it involves adapting the monitoring surveillance system to specifically address the unique characteristics of AI systems. In particular, the AIA requires manufacturers to use a standardized AI PMS template that will be provided by the European Commission[67].

This template is expected to cover those aspects not addressed by the current MDR framework. Finally, for AI-enabled medical devices the responsibility for market surveillance will continue to reside with the authority designated under the MDR. This approach ensures that enforcement of PMS requirements is conducted by authorities familiar with the specificities of medical devices. However, Member States can decide to appoint an alternative authority for overseeing AI-specific requirements, as long as they ensure coordination between relevant bodies[68]. It is important to note that the enforcement procedures outlined in the AIA will not be applicable to AI-enabled medical devices, as the procedures established under the MDR will take precedence[69].

PMS requirements outlined so far are not fully detailed, providers will need to wait for the Commission to release the AI PMS template, which will specify the list of items that need to be covered in the PMS. However, there are additional PMS requirements hidden in the AIA that worth noting[70].

Risk management is a crucial part of the PMS plan for high-risk AI systems, as new risks to health, safety, and fundamental rights can emerge after the system is placed on the market or put into service. Consequently, organizations may need to establish a PMS that systematically evaluates market data and addresses these emerging risks[71].

High-risk AI systems are also required to automatically log events throughout their entire lifecycle, which we believe is vital for effective PMS[72]. These logs help track system performance, quickly identify issues, and enable efficient risk management. They also enhance transparency and accountability, allowing authorities to verify compliance with the AIA and investigate incidents if needed.

Furthermore, the AIA mandates that high-risk AI systems must be subject to human oversight while in use. This ensures that risks, such as bias or system errors, can be continuously monitored and addressed by human operators when necessary[73]. Some authors argue that the post-market monitoring plan should further specify the level of human oversight, the information to be collected, and the actions required to address potential system failures[74].

Additionally, deployers play a key role in ensuring the ongoing safety and performance of AI systems. They are responsible for actively monitoring the AI system based on the provider's instructions, identifying risks to health, safety, or fundamental rights, and reporting these to the provider or distributor and relevant market surveillance authorities[75]. Authors further suggest that the specific responsibilities of deployers should be clearly outlined in the PMS plan. This should also include details on communication between the involved parties in the value chain and with relevant authorities[76].

In conclusion, although medical device manufacturers are familiar with PMS requirements under the MDR, they must ensure that their system also meets the key requirement of **enabling continuous assessment of the product's conformity**.

Systems for reporting serious incidents and malfunctions

Article 73 AIA outlines the reporting obligations for providers of high-risk AI systems, focusing on serious incidents.

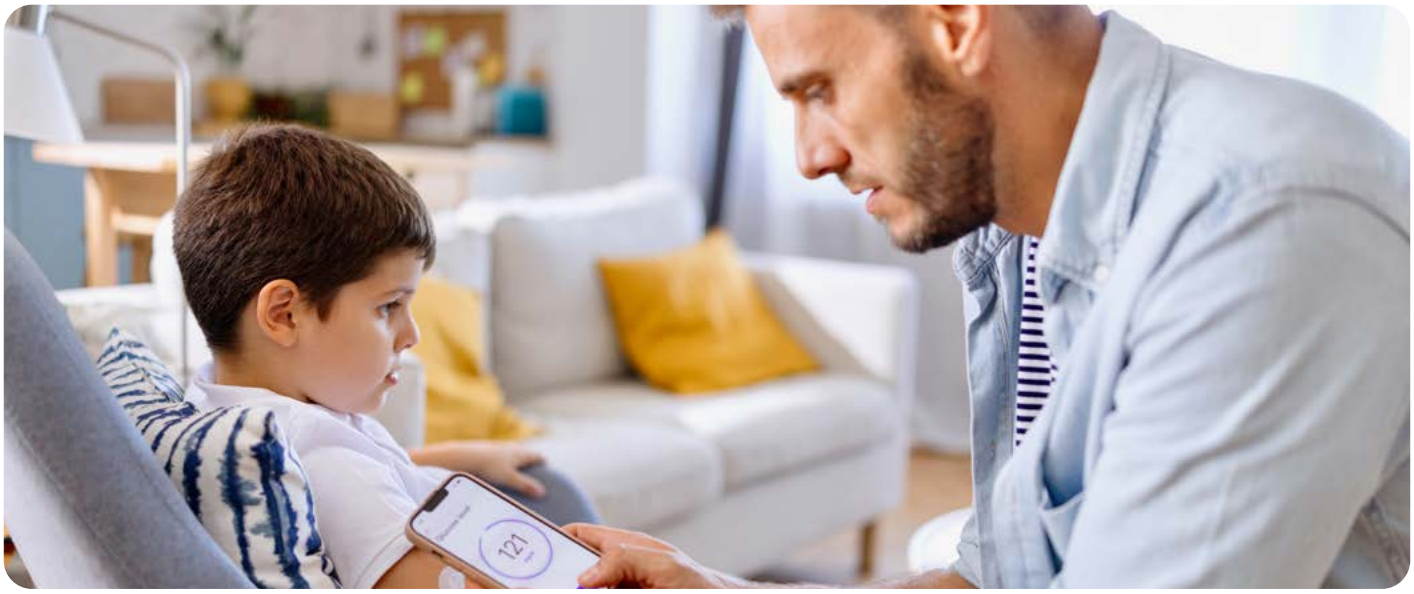
The AIA defines serious incidents as those that '*directly or indirectly led, might have led or might lead to (…) (a) the death of a person, or serious harm to a person's health; (b) a serious and irreversible disruption of the management or operation of critical infrastructure; (c) the infringement of obligations under Union law intended to protect fundamental rights; (d) serious harm to property or the environment*'[77].

Providers must report such incidents to the market surveillance authorities in the member state where the incident took place. The reporting must occur within 15 days after the provider establishes a causal link between the AI system and the incident, or suspects such a link, with faster timelines for more severe cases, such as deaths or widespread infringements. In those cases, reporting must occur immediately and no later than 10 days for fatalities or 2 days for widespread incidents or a serious incident regarding the management and operation of critical infrastructure.

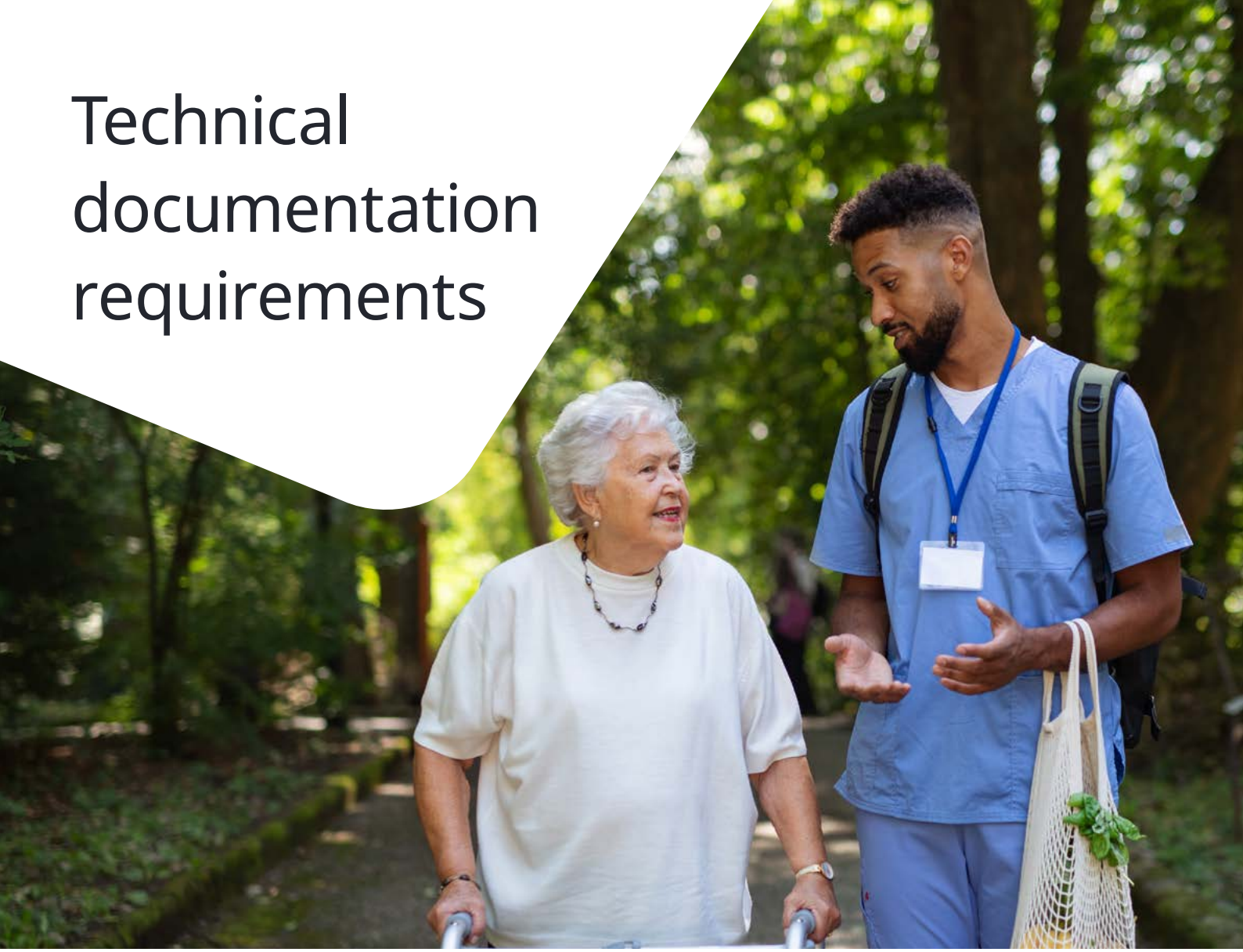
For high-risk AI systems that are safety components of devices, or are themselves devices covered by the MDR, the notification of serious incidents would be limited to '*the infringement of obligations under Union law intended to protect fundamental rights***'**[78] [79] **(e.g., discrimination, bias, privacy breaches).**

This means that incidents related to traditional health or safety risks of medical devices only need to be reported under the MDR, not the AIA. While AIA reporting is required only if the AI-enabled medical device infringes fundamental rights like privacy or non-discrimination, areas that the MDR does not directly regulate. Manufacturers will need to evaluate whether their current reporting systems need adjustments to ensure they do not miss AI-specific risks, such as violations of fundamental rights, which may not be directly linked to health (e.g., biased diagnostic recommendations).

In this case, the notification will have to be made, '*to the national competent authority [NCA] chosen for that purpose by the Member States where the incident occurred*'[80] and not to the market surveillance authority, as stated in Article 73 (1) AIA. This means that, instead of managing two separate reporting pathways, manufacturers of AI-enabled medical devices will primarily deal with NCAs for AIA incident notifications. This is crucial because medical device manufacturers are already accustomed to reporting safety incidents through their established channels under the MDR.



Technical documentation requirements



As we introduced in section 2, the NLF regime, in particular Decision 2008/768, provides a standardized approach to product legislation. This Decision requires, among other things, to have technical documentation in place to demonstrate that the product is compliant with EU safety, health and environmental standards, essential for its placement on the market[81]. While each NLF regulation has its own specific checklist of required technical documentation, there are notable similarities across them. In this section, we will examine the technical information required for AI systems.

Article 11 AIA is the provision that requires providers of high-risk AI systems to prepare and maintain up-to-date technical documentation that, at a minimum, includes the elements specified in Annex IV. This documentation must be kept for at least 10 years after the AI system is placed on the market or put into service and must be available to national competent authorities upon request[82].

Article 11 (2) AIA also allows manufacturers of AI-enabled medical devices to create a **single set of technical documentation** that fulfils the requirements of both the AIA and the MDR. Therefore, it is expected that medical device manufacturers will rely on this provision to adapt their existing MDR technical documentation system to add the information required in Annex IV of the AIA.

There are concerns that the stringent documentation requirements could be difficult for smaller companies and startups. To alleviate this burden, the AIA allows these entities to submit the required elements in Annex IV in a simplified format[83].

The Commission will create a **simplified technical documentation form** specifically for small and micro-enterprises, which Notified Bodies (third party bodies, see section 10) are required to accept. Companies will need to go to EU Recommendation 2003/361/EC to see whether they qualify as SME or micro enterprise.

In Annex IV we find the set of technical documentation essential for demonstrating compliance with the AIA. It includes details on system descriptions, development processes, performance monitoring, and risk management (See table 3).

Table 3 - Technical Documentation Requirements

AIA Annex IV Sections	AIA comments & observations
1. General Description **2. Detailed Description**	Both MDR and AIA require detailed descriptions of the medical device/AI system, manufacturer/provider's name and its purpose. AI Act focuses on the internal functioning of the AI system, version, interaction with hardware/software, how it was designed and developed, system architecture, data requirements, human oversight, pre-determined changes and validation/testing procedures.
3. Monitoring & Control	The AIA requires monitoring the information of the AI system's performance, capabilities and limitations, including accuracy for specific users on which the system is intended to be used. It should also outline potential unintended outcomes to health, safety, fundamental rights, necessary human oversight measures, the technical measures used to help deployers interpret results and details on input data.
3. Performance Metrics	Related to the above point, the AIA emphasizes on ongoing performance metrics and accuracy, or potential discriminatory impacts.
4. Risk Management	The AIA requires to consider risks to the health, safety and fundamental rights of persons and unintended outcomes. Risk assessment against fundamental rights is not covered under the MDR.
5. Description of Changes	The AIA requires updates to documentation if there have been changes to the AI system but also documentation of pre-determined changes for those high-risk AI systems that continue to learn after being placed on the market or put into service.
4. Harmonized standards	Presumption of conformity with AIA requirements when conformity with harmonized standards is evident, is also present in the AIA.
5. Declaration of Conformity	Declaration of Conformity should cover all applicable legislations.
6. Post Market Monitoring	The AIA post-market surveillance focuses on continuously collecting, documenting and analyzing relevant data gathered on the performance of the AI high-risk system during their lifetime. This analysis also include interaction with other AI systems. (More information in section 7.3.)

From the table on the previous page, it is apparent that the AIA imposes more rigorous documentation and monitoring requirements, going beyond what is required by the MDR. While both regulations demand detailed descriptions and continuous documentation, the AI Act places a stronger emphasis on the internal functioning and lifecycle management of AI systems, particularly in areas such as data governance, performance monitoring, and risk management. In other words, the AIA focuses more on how the high-risk AI systems have been developed and how they perform throughout their lifetime[85].

It is evident that design and development decisions for AI systems should be meticulously documented and integrated into a comprehensive QMS. This proactive approach supports compliance with the AIA, while enabling the traceability and transparency of high-risk AI systems, both during operation and post-market surveillance[86].

Finally, it is important to note that **Technical Documentation requirements may be updated over time**, as Article 11 of the AIA allows the Commission to modify them as needed through delegated acts[87].

Product requirements

The MDR's GSPRs do not fully address the unique challenges posed by AI. As a result, the AIA introduces new requirements for AI-enabled medical devices to ensure they protect individuals' health, safety, and fundamental rights.

Automatically generated logs

High-risk AI systems shall be designed in a way that it **automatically records events (logs)** relevant for identifying national-level risks and substantial modifications throughout the system's lifecycle[88] Article 12 AIA explains that it is primarily about recording events that are relevant for the following: a) identifying risks or substantial modifications in the AI system's behavior that could cause risks or harm; b) helping monitor the system after it is released to make sure it stays safe and functions correctly (facilitating post-market monitoring); and c) tracking how the AI system works to ensure it continues to follow safety rules during operation. While the MDR mandates post-market surveillance and vigilance requirements, it does not mandate automated logging, which is essential for monitoring AI behavior over time.

Accuracy, robustness, and cybersecurity

The MDR includes requirements for device safety and performance, including cybersecurity aspects, however, it does not fully address the dynamic nature of AI systems, such as the need for ongoing **accuracy, robustness and adaptative cybersecurity measures**[89].

Article 15 AIA states that high-risk AI systems must be designed to be accurate, reliable, and secure throughout their entire lifecycle. They should be resistant to errors, faults or inconsistencies that may occur within the system or the environment in which the system operates, due to its interaction with natural persons or other systems.

The robustness of high-risk AI systems can be achieved through technical redundancy, which may include backup or fail-safe plans. AI systems that keep learning after being released must avoid biased outputs with appropriate risk mitigation measures. The system's security should also prevent unauthorized changes or exploitation. Cybersecurity measures for high-risk AI systems should match the specific risks they face.

These measures should help prevent, detect, and handle attacks that attempt to manipulate the training data set (data poisoning), or pre-trained components used in training (model poisoning), inputs designed to cause the AI model to make a mistake (adversarial examples or model evasion), confidentiality attacks or model flaws[90].

Human oversight

The AIA mandates to design high-risk AI systems so that deployers can implement **human oversight**[91]. Human oversight is a mechanism to prevent or minimize the risks to health, safety or fundamental rights that may emerge when a high-risk AI system is used as intended or under conditions of foreseeable misuse[92]. Here, contrary to the MDR, the AIA recognizes that AI systems may operate with a degree of autonomy that needs additional safeguards to allow for human intervention.

Simply put, natural persons oversighting the system must be able to understand what is happening in the product and interpret the output. In addition, this person must be able to step in and intervene in the high-risk system's operation or safely shut down the system if needed.

Transparency and provision of information to deployers

The MDR requires **transparency** by device labelling and instructions for use, but the AIA introduces additional transparency obligations specific to AI systems. High-risk AI providers have transparency obligations towards AI deployers with a view to enable the latter to '*interpret the system's output and use it appropriately*'[93].

This includes providing detailed instructions for use, such as the system's intended purpose, accuracy, performance, data input specifications, and human oversight measures, along with technical documentation[94] that covers the AI's general logic, design choices, training data, and potential discriminatory impacts. Deployers must use this information when conducting Data Protection Impact Assessments (DPIAs) to comply with the transparency requirements of the AIA[95].

However, such transparency obligations apply only to high-risk AI systems; for non-high-risk AI systems, transparency requirements are limited to communicating the presence of AI, as outlined in Article 52, such as in the case of deepfakes.

Accessibility

Often overlooked, article 16(l) AIA specifies that high-risk AI systems must comply with accessibility requirements outlined in two specific EU accessibility directives (2016/2102 and 2019/882)[96]. Thus, these systems should be designed so that all deployers and other intended user, including those with disabilities, may easily access and use them. Compliance involves integrating features such as readable interfaces, alternative text for images, and compatibility with assistive technologies.

It is important to note that the MDR does not specifically address accessibility for AI-enabled medical devices, therefore, manufacturers will need to integrate the accessibility requirements to ensure inclusivity for all users.

Declaration of conformity

Another key requirement is for the provider to draw up a written machine readable, physical or electronically signed **EU declaration of conformity** for each high-risk AI system and keep it at the disposal of the national competent authorities for 10 years after the high-risk AI system has been placed on the market or put into service. For AI-enabled medical devices, the AIA allows to issue a **single declaration of conformity** covering all applicable laws. The declaration must include the information specified in Annex V of the AIA[97], including a statement of conformity with the GDPR.

AI database and registration

Similar to EUDAMED for medical devices, there will also be an EU database for high-risk AI systems in the future. However, it is important to clarify that only high-risk AI systems listed in Annex III (except for critical infrastructure) will need to be registered in this upcoming database[98]. **This means that AI-enabled medical devices must be registered under EUDAMED instead**.

CE Mark

AI providers must affix the CE mark on the device, its packaging, or accompanying documentation, along with the identification number of the Notified Body responsible for conformity assessment[99]. For AI-enabled medical devices there will be a **single CE mark indicating that the device complies with both regulations, the AIA and MDR**[100].

Conformity assessments & Notified Bodies

To ensure a high level of trustworthiness, the AIA states that high-risk AI systems are only allowed on the EU market after they have undergone and passed a conformity assessment[101]. This process enables providers to demonstrate that their high-risk AI systems meet the requirements specified in Chapter III, Section 2 AIA[102]. If a product meets all relevant requirements, a declaration of conformity[103] is issued, and the "CE" marking[104] is applied. Once the CE marking is affixed, the system can be deployed and freely circulated within the EU internal market.

In industries such as medical devices, the conformity assessment process is already well-established. To reduce administrative burdens and avoid duplication, the AIA allows high-risk AI systems covered by Union harmonization laws, such as the MDR, to use the existing conformity assessment process from that law, while also incorporating the specific requirements of the AIA[105].

Article 43 AIA outlines the different conformity assessments routes. The appropriate assessment route will depend on the specific Annex applicable to the high-risk AI system (See Figure 5).

When it comes to AI systems not classified as high-risk, these routes of conformity will not be applicable. However, these non-high-risk AI systems are still subject to important obligations. While these requirements are less stringent, they remain critical for ensuring transparency, accountability, and safety.

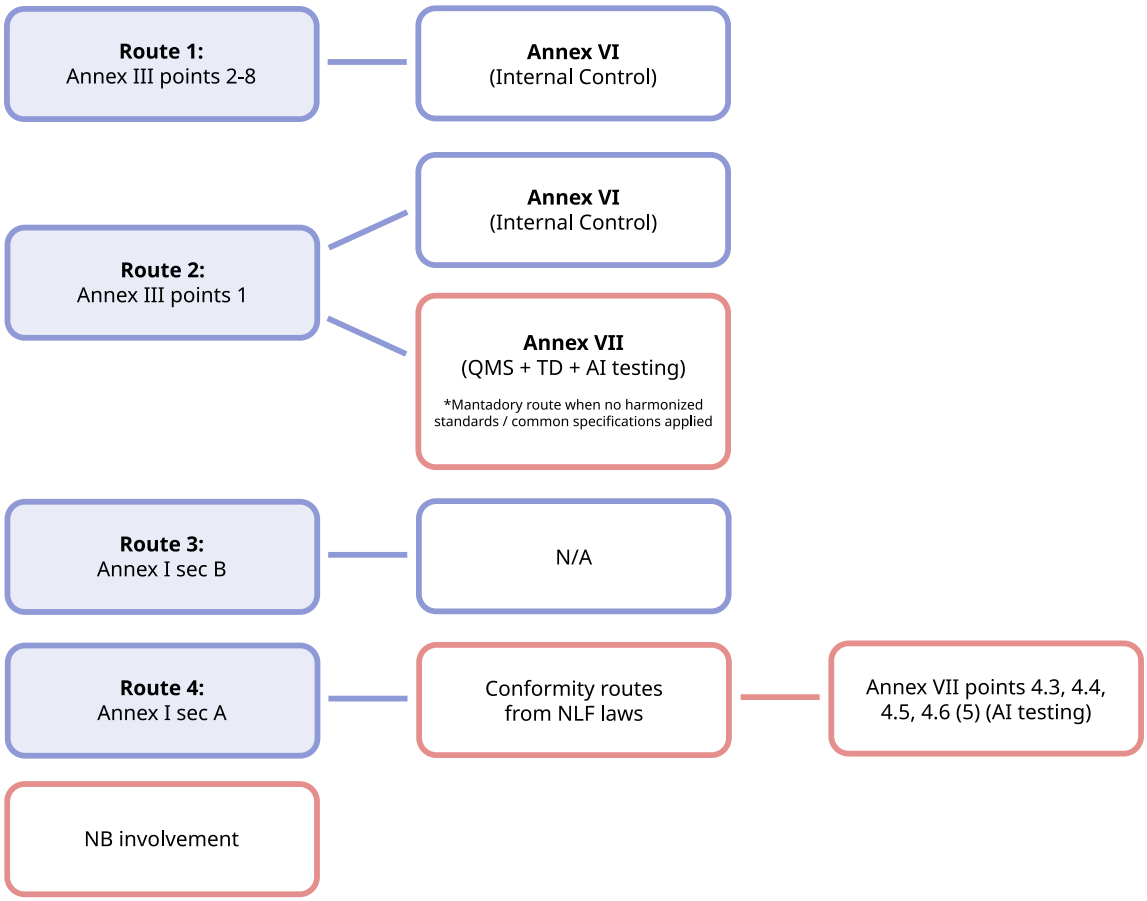


Fig. 5. AIA conformity assessment routes

Route 4 is the one applicable to high-risk AI enabled medical devices. According to Article 43 (3) AIA, for high-risk AI systems covered by Union harmonization legislation listed in Section A of Annex I, providers must follow the relevant conformity assessment procedures already required by those laws. The specific requirements in Section 2 of Chapter 4 AIA must also be included within the assessment. Additionally, Points 4.3, 4.4, 4.5, and the fifth paragraph of Point 4.6 in Annex VII AIA are applicable (datasets testing, see more in section 10.1).

This means that the responsibility for third-party conformity assessments lies with conformity assessment bodies, known as "Notified Bodies," which are designated by "notifying authorities" established by member states[106]. In some cases, public authorities can also serve as Notified Bodies[107]. These bodies are tasked with evaluating the QMS and technical documentation which must be included in the provider's application[108].

In particular, the responsible Notified Body for the AI assessment is the one that has been designated under Union harmonization legislation if they fulfil the obligations set out in Article 43 (3), second paragraph. These obligations are around Notified Body independence[109], professional integrity[110] and having sufficient internal competence of personnel in AI[111], which should have been assessed during its designation under Union harmonization legislation.

In the context of the MDR, this means that **MDR-designated Notified Bodies will be the ones controlling the conformity assessment procedure of AI enabled medical devices**, ensuring that the specific requirements from the AIA and relevant Notified Body testing are integrated. However, MDR Notified Bodies can only perform AI assessments if they meet the obligations outlined in Article 43 (3), second paragraph. Since these obligations should have been evaluated during the initial designation of the MDR Notified Bodies, **many will likely need to request an extension of their scope**. This extension is necessary to ensure they have appropriate internal AI competencies. The AIA demands not only technical AI expertise but also legal, administrative, and scientific knowledge to effectively carry out these conformity assessments[112].

August 2025 is dictated (Art 113(b)) as the date of applicability for Chapter III sec 4, on Notifying Authorities and Notified Bodies. Under this section of the AIA (Art. 28 and 29), it is mandated that Member States should have in place at least one notifying authority for Conformity assessment bodies to be able to submit an application.

Finally, it is important to note that the AIA allows Notified Bodies to conduct necessary tests on AI systems and request access to trained models, including their relevant parameters[113]. **This requires MDR Notified Bodies to have competent AI personnel and adequate testing facilities to perform such assessments**.

Notified Body testing

As discussed earlier, sections 4.3, 4.4, 4.5, and the fifth paragraph of section 4.6 in Annex VII focus on testing procedures.

The MDR Notified Body is responsible for examining the QMS and technical documentation of AI-enabled medical device systems to ensure compliance with the AIA. To do this effectively, the Notified Body may need access to training, validation, and testing datasets, potentially through remote means. The Notified Body may require additional evidence or tests from the provider and, if unsatisfied, may conduct its own tests. If all other methods to verify compliance have been exhausted, the Notified Body can also access the AI system's training models and parameters, provided this access complies with intellectual property and trade secret laws.

It is important for providers to establish clear agreements detailing how and when this access will be granted. These contracts should outline the process for providing access to technical documentation and data, including necessary security measures to protect sensitive information. This is particularly important if the manufacturer does not own the datasets used for training or testing. In such cases, the provider must ensure that contracts with dataset owners include provisions for granting the Notified Body access.

Notified Body certificate

When a Notified Body conformity assessment is required, **the AI provider will need to lodge an application with a Notified Body of their choice**, to examine the QMS and the technical documentation of the AI system/s that the provider intends to place on the market or put into service. As stated in section 10 in the case of AI-enabled medical devices, the MDR-designated Notified Bodies will be the ones controlling the conformity assessment procedure.

The provider's QMS for AI-enabled medical devices must undergo **initial examination and continuous surveillance** by the Notified Body, as per article 17 AIA[114]. The provider's application should include contact details, relevant documentation, and a written declaration that **the same application has not been lodged with another Notified Body**. The Notified Body will assess compliance with Article 17 AIA and notify the provider of its decision[115]. To ensure ongoing compliance with the terms and conditions of the approved QMS, the Notified Body will conduct regular audits. **The Notified Body may also perform additional tests on AI-enabled medical device system and will provide audit reports to ensure the QMS remains adequate and effective**[116]. It is crucial to emphasize the need for MDR Notified Bodies to have competent AI personnel and appropriate testing facilities to conduct these assessments effectively.

In addition, the application to the Notified Body shall also cover the **assessment of their AI system's technical documentation**, which the Notified Body will review and provide a decision along with an explanation[117].

If the AI system meets the requirements outlined in Chapter III, Section 2, the MDR Notified Body will issue a **Union technical documentation assessment certificate** which has a limited time validity and can be suspended or withdrawn by the Notified Body[118] [119]. This certificate will include the provider's name and address, the conclusions of the assessment, any conditions for the certificate's validity, and essential data for identifying the AI system[120].

Although the intention of the AIA is to reduce overlaps between sectorial legislations and the AIA, it remains unclear whether AI-enabled medical devices will be covered by a single certificate for both the MDR and AIA regulations or if the Union technical documentation assessment certificate will be issued separately only for the AI part. Further guidance on this matter is undoubtedly necessary.

Changes to AI systems

One of the key advantages of AI-enabled medical devices is their ability to learn and enhance their performance through real-world experience. These devices have the potential to revolutionize healthcare by extracting valuable insights from the extensive data generated daily in medical settings. However, **the adaptability of AI also presents certain challenges**[121].

Specifically, these challenges arise from the continuous training of AI models in post-marketing settings. This includes algorithms that are locked or unlocked. Locked AI systems do not undergo retraining or updates after their initial deployment. As a result, they do not adapt to new data or changing conditions. However, unlocked AI systems are designed to be continuously retrained and updated with new data over time. This capability allows them to learn from real-world experience and adapt to new information even after they have been distributed[122 123].

Despite the benefits of continuous adaptation, unlocked AI systems come with risks. Continuous updates can alter the system's intended use or modify its classification, which may impact its performance or regulatory status[124 125]. To manage these risks, the AIA imposes stringent obligations on providers regarding changes to AI systems.

Managing changes under the AIA

According to the AIA, any **intended change to the approved QMS** or the list of AI systems covered by it must be brought to the attention of the Notified Body by the provider. For AI-enabled medical devices, this requires contacting the MDR-designated Notified Body.

The MDR Notified Body will then examine the proposed changes and determine whether the modified system still satisfies with article 17 AIA, or if a reassessment is required. Once the examination is complete, the Notified Body will notify the provider of its decision, including a reasoned assessment of the changes[126].

Moreover, **any changes to the AI-enabled medical device that could impact its compliance with the AIA, or its intended purpose must be assessed by the MDR Notified Body that issued the Union technical documentation assessment certificate**. The provider is responsible for informing the Notified Body of any such changes, or if they become aware of changes that may affect the system. The Notified Body will then decide whether the changes require a **new conformity assessment** or can be addressed by **issuing a supplement to the original certificate**. Where the changes are approved, a supplement to the Union technical documentation assessment certificate will be issued to the provider[127].

However, there is an exception to this. The AIA indicates that those changes occurring to the algorithm and the performance of AI systems which **continue to 'learn' after being released on the market (unlocked AI systems) should not be considered 'substantial modification' if these have been pre-determined by the provider and assessed during the conformity assessment**[128]. In other words, the provider will need to specify how their AI system will change while continuously learning in post-market settings. In this case, a new conformity assessment will not be required.

Defining significant changes and substantial modifications

A critical question for AI-enabled medical device manufacturers is understanding **what constitutes a "change"**. The AIA uses the terms significant change and substantial modification interchangeably. Recital 177 clarifies that the concept of significant change under the AIA is equivalent to substantial modification[129]. This could potentially create conflicts with how substantial modification is understood under other sector-specific laws, such as the MDR.

However, Recital 84 AIA addresses this issue, stating that sector-specific laws should take precedence over the AIA when more specific provisions exist. For instance, Article 16(2) of the MDR, which outlines certain changes that should not be considered modifications of a medical device, still applies to high-risk AI-enabled medical devices under the MDR.

Implications for other AIA actors

The AIA also includes provisions that impact distributors, importers, and other third parties. Any third party that makes a substantial modification to a CE marked high-risk AI system or changes the intended purpose of a non-high-risk AI system, turning it into a high-risk one, **will be considered the provider under the AIA and therefore assume all the relevant obligations**[130]. For example, repurposing an AI system for medical purposes could result in the actor who made the substantial modification being reclassified as both the provider under the AIA and the manufacturer under the MDR, requiring compliance with both sets of regulations.

Documenting Pre-Determined Changes

Another key consideration for manufacturers is how to **properly plan for and document pre-determined changes**. According to Annex IV, Section 2(f) AIA, the technical documentation of the provider must include details on the pre-determined changes to the AI system and its

performance, along with information on the technical solutions used to ensure continuous compliance. However, further guidance is needed on what constitutes pre-defined changes.

An example of such guidance is the **Predetermined Change Control Plan (PCCP) for Machine Learning-Enabled Medical Devices**[131] by the U.S. Food and Drug Administration (FDA), Health Canada, and the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA). This document identifies 5 guiding principles for predetermined change control plans for machine learning-enabled medical devices (MLMD). These guiding principles are voluntary and offer best practices to monitor the performance and the potential risks that come with retraining models.

Although the AIA aligns closely with the FDA's guidance, detailed and specific guidelines for manufacturers would be helpful to ensure clear and effective compliance with the AIA's requirements, particularly for AI systems that continue to learn after-market release.

Conclusion

In conclusion, the integration of AI into medical devices brings transformative potential to healthcare, improving patient outcomes and creating new possibilities for diagnostics and treatment. However, it also introduces new risks and regulatory challenges. While the MDR has long provided a framework for regulating medical devices, the rapid advancements in AI have necessitated additional safeguards, which the AIA aims to provide. The AIA and the MDR form a complementary regulatory framework, that together ensure the safety, efficacy, and ethical deployment of AI-enabled medical devices in the European market.

The AIA introduces a risk-based approach to AI, focusing on high-risk systems and ensuring their compliance with stringent requirements for data governance, transparency, and fundamental rights.

For manufacturers, understanding how these two regulations intersect is crucial. Compliance with both the MDR and AIA, will ensure that AI-enabled medical devices not only meet safety and performance medical standards but also uphold fundamental rights and European values for AI technology.

As AI continues to evolve, manufacturers must remain proactive in adapting their compliance strategies, integrating the specific requirements of the AIA into their existing MDR framework. By staying informed and compliant with these complex regulations, AI-enabled medical device manufacturers will be well-positioned to contribute to the future of healthcare.

Authors

Inma Perez Ruiz - Regulatory Lead - AI Notified Body

Sarah Mathew - Regulatory Lead - AI Notified Body

Alex Zaretsky - Regulatory Lead - AI Notified Body

Aris Tzavaras - Head of AI Notified Body

Practical use cases

In this section, we explore three hypothetical examples to illustrate how different AI-enabled medical devices navigate the conformity assessments under the MDR and AIA.

Each example outlines the relevant device classifications, economic operators, and legal obligations that must be met under these regulations. The scenarios reiterate the concepts detailed in this whitepaper as well as highlight the complexities in choosing the correct route to market.

Disclaimers:

1. Any similarities with existing MDs or manufacturers provided in the examples below are coincidental; the devices chosen are hypothetical examples by BSI.
2. The information presented in the examples below is limited and may not be sufficient to undergo an actual assessment under both MDR and AIA legislations. Therefore, the conclusions drawn might not be representative of real word AI enabled MDs.

Peace of Mind LLC

Background information
Peace of Mind LLC. has created an app for adult patients who have been diagnosed with moderate to severe depression. The mobile app uses real-time biometrics and lifestyle activities of the diagnosed person to suggest activities, either physical (i.e. exposure therapy treatments, exercise, etc.) or to be completed on the mobile device, to assist in alleviating the symptoms of depression. This app recommends these activities based on two in-house built deep learning models that are integrated within the app. The app is only available with a healthcare professional's prescription in the EU.

MDR classification
What are the legal obligations for this entity and its product? As Peace of Mind LLC. has developed the app along with the two deep learning models, it is the product manufacturer. This product would be considered Class IIb medical device due to Rule 11 of the MDR as it is software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes. However, why would this device be a IIb device? If the activities suggested to the patient may possibly cause a "a serious deterioration of a person's state of health or a surgical intervention, in which case it is classified as class IIb". The classification must always consider the worst-case scenario.

AIA classification
Whether AIA is applicable to the device depends on 2 main factors:

1. Is the system used considered an AI system under the AIA definitions?
2. Is it high-risk under AIA? Is the AI enabled medical device a product on its own or a safety component of a MD that undergoes 3rd party conformity assessment?

For the first question, the AIA definition is general, it does not directly address AI technologies. However, the AI technology described above falls under the general definition as it is a machine-based system that for explicit objectives makes an inference. Taking into consideration recital 12, machine learning approaches such as deep learning are considered AI. Therefore, the AI techniques used in this example are considered AI systems, and therefore AIA is applicable. It is worth noting that more details about the models would be needed to rule out this as general-purpose AI.

For the second question, as this is a product on its own, that requires 3rd party conformity assessment under MDR (Class IIb) this is considered a high-risk AI system per Article 6 (1).

Under the AIA, since Peace of Mind LLC. developed the app and intends to place it on the market, they are considered an AI provider.

With the identified classification and economic operator, this organization has obligations both under the MDR and AIA. The device will need to undergo a conformity assessment with one Notified Body under the MDR and an assessment for Chapter III, Section 2 requirements of the AIA. The Notified Body must be appropriately designated under both the MDR and AIA.

If this is a MD to be marketed in EU following August 2027, CE marking and certification must be in place before placing the product on the market.

If the MD is intended to be placed on the market prior to August 2027, then the AIA requirements are not applicable, and the initial assessment should be performed under MDR requirements. However, in this case, significant changes following Aug. 2027 should be assessed against both MDR and AIA.

Radiopic Limited Power

Background information
The Dutch organization Windy Tree Hospital Consortium implants the Radiopic Limited's Powertini devices to treat certain types of focal seizures through sensing and modulating electrical stimulation in an area(s) of interest in the brain. The device's operation is built on a static AI Machine learning system. The AI system drives the operation of the device and the failure of which may compromise the safety of the patient.

MDR classification
Under the MDR, these products would be considered Class III medical devices due to Rule 8 since it is an active implantable.

AIA classification
Whether AIA is applicable to the device depends on 2 main factors:

1. Is the system used considered an AI system under the AIA definitions?
2. Is it high-risk under AIA? Is the AI enabled medical device a product on its own or a safety component of a MD that undergoes 3rd party conformity assessment?

As in the previous example, for the first question, the AIA definition is general, it does not directly address AI technologies. However, the AI technology described above falls under the general definition as it is a machine-based system that for explicit objectives makes a decision to modulate brain electrical stimulation that influences the patient. Taking into consideration recital 12, machine learning approaches are considered AI. Therefore, the AI techniques used in this example are considered AI systems, and therefore AIA is applicable.

It is important to note that static AI systems fall under the scope of the AIA even though they do not continue to learn in the field. Static systems are expected to be retrained after a period of time in order stay relevant to their affected domain.

The second question is more difficult to address. This is not a "stand-alone" Software product, as AI is embedded into the MD functionality. Therefore, the question is whether this is a safety component. MDR does not make any reference on "safety components", while the AIA defines (Art 3 (14) a safety component as "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". Following the AIA definition the AI system should be considered as a MD safety component, as the failure/malfunctioning of which might endanger the health of the patient.

As Class III products are required to undergo a 3rd party conformity assessment under the MDR the risk classification per the AIA would be as a high-risk AI system per Art. 6(1).

Radiopic Limited is considered the AI provider for the product, while Windy Tree Hospital Consortium, while utilizing the devices in a professional capacity, would be considered as an AI deployer. The AI provider of this high-risk AI system as well as being the product manufacturer for the device, must undergo a conformity assessment with an appropriately designated Notified Body under the MDR and an assessment for Chapter III, Section 2 of the AIA.

If this is a MD to be marketed in EU following August 2027, CE marking and certification must be in place before placing the product on the market.

If the MD is intended to be placed on the market prior to August 2027, then the AIA requirements are not applicable, and the initial assessment should be performed under MDR requirements. However, in this case, significant changes following Aug. 2027 should be assessed against both MDR and AIA.

Windy Tree hospital consortium will need to comply with Article 26 Obligations of deployers of high-risk AI systems of the AIA. As the date of applicability for Article 6(1) is Aug. 2027, the above obligations are mandatory following this date.

Reality Vieux

Background information
Reality Vieux is a French company that develops an AI system software application that uses Convolutional Neural Networks and AI Deep Learning models to provide estimates to clinicians on the likelihood of presence of carcinomas through magnetic resonance imaging or computed tomography scans. It is intended to be placed on the market in the EU in Q4 of 2026.

MDR classification
Under the MDR, the product is considered "software as a medical device" and is classified under rule 11. Considerations of rule 11 and MDCG 2019-11, to classify the MD under MDR classification, should take into account the following:

- Is the MD diagnosing carcinomas? The system should be considered a clinical decision support system (CDSS), as it provides "opinion" on the likelihood of presence of a disease. Clinicians makes the final diagnosis, taking into consideration AI system recommendation.
- Is the MD driving clinical management? Not directly. The "opinion" of the CDSS is considered among other clinical factors by the clinician to decide the need of additional diagnostic or treatment steps. However, CDSS aid in the patient diagnosis as it helps predicting diseases potentially in early stages.
- Is the patient situation critical or serious? Under the assumption that the diagnosis of carcinomas will require major therapeutic interventions, patient situation should be considered critical. However, if clinical claims include early diagnosis, the patient situation might be considered serious as early diagnosis or treatment is important to avoid unnecessary interventions.

The information provided in this example for the MD is not sufficient to come to a verdict on MDR classification. Other factors that need to be considered are:

- Performance metrics used and their values: How may the performance metrics affect treatment and patient situation? As an example, consider an MD system with high False Negative (FN) rate or False Positive (FP) rate. Suggestions produced by such system heavily affect a percentage of patients' disease diagnosis and future treatment (unnecessary in the case of high FP).
- Risks identified and mitigations: Although this system is a CDSS, the risk of clinicians' overreliance to MD suggestions is not to be ignored. Risk mitigation strategies need to be assessed for their effectiveness prior to deciding on whether is supporting or clinician's might rely on the system for the diagnosis.

For this example, we will classify the device as a class IIb considering the scenarios of MD driving clinical management (aids in diagnosis) and patient situation is critical (requires major therapeutic interventions).

AIA classification
Whether AIA is applicable to the device depends on 2 main factors:

1. Is the system used considered an AI system under the AIA definitions?
2. Is it high-risk under AIA? Is the AI enabled medical device a product on its own or a safety component of a MD that undergoes 3rd party conformity assessment?

For the first question, the AIA definition is general, it does not directly address AI technologies. However, the AI technology described above falls under the general definition as it is a machine-based system that for explicit objectives makes a recommendation. Taking into consideration recital 12, machine learning approaches such as deep learning and Convolutional Neural Networks are considered AI. Therefore, the AI techniques used in this example are considered AI systems, and therefore AIA is applicable.

For the second question, as this is a product on its own, that requires 3rd party conformity assessment under MDR (Class IIb) this is considered a high-risk AI system per Article 6 (1).

Reality Vieux is the AI system provider under AIA. As the MD is intended to be placed on the market prior to August 2027, then the AIA requirements are not applicable, and the initial assessment should be performed under MDR requirements. However, in this case, significant changes following Aug. 2027 should be assessed against both MDR and AIA by the MDR Notified Body.

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21. Recital 12, AIA.
22. Annex VIII, Chapter III, MDR.
23. The classification of software that drives or influences the use of a medical device will mirror the classification of the medical device it interacts with. For stand-alone MDSW, the classification will be based on Rule 11 Annex VIII MDR.
24. Article 5, AIA.
25. Article 6, AIA.
26. Article 50, AIA.
27. Recital 165 & Article 95, AIA.
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36. Cepeda Zapata, K.A., Patil, R., Ward, T., Loughran, R., & McCaffery, F., "Analysis of the Classification of Medical Device Software in the AI Act Proposal," 2024, p.8. Available at: [PDF] Analysis of the Classification of Medical Device Software in the AI Act Proposal | Semantic Scholar
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97. The Commission is empowered to adopt delegated acts in accordance with Article 97 in order to amend Annex V by updating the content of the EU declaration of conformity set out in that Annex, in order to introduce elements that become necessary considering technical progress.
98. Article 49, AIA.
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108. The provider must apply to an accredited notified body. This application should include all the documents and information specified in Annex VII.
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BSI Group
389 Chiswick High Road
London, W4 4AL
United Kingdom

+44 345 080 9000

bsigroup.com