A Review of the Artificial Intelligence Act Proposal and the Medical Device Regulation

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***Abstract*—The Artificial Intelligence Act (AIA) proposal is designed to regulate Artificial Intelligence (AI) systems intended to be placed on the market or put into service in the European Union (EU). The proposal covers different products, including Medical Devices (MD). It is expected that harmonisation will be achieved with the application of obligations and requirements in the AIA, ensuring the protection of human rights and the Union values. Nevertheless, there is a concern that conflicting scenarios may occur once the AIA is passed. This paper reviews the AIA, its possible implications for MDs, and prior work in line with the AIA.**

Keywords—Artificial Intelligence Act, Medical Device Regulation, Software as a Medical Device, Medical Device Software, Artificial Intelligence

I. Introduction

The adoption of AI technologies has recently gained interest in the healthcare sector [1]. Many applications can be improved by embedding AI models into complex systems for prediction and classification [2]. In the MD domain, AI can enhance healthcare services and assist physicians, improving clinical workflow [1], [3]. Despite the benefits of AI, risks and socio-ethical considerations must also be considered [1], [2]. This paper explores the EU AIA and the Medical Device Regulation (MDR), considering the question – What are the implications of the AIA to the challenges of adopting AI into Medical Device Software? This work shall not be taken as a legal guideline but as a resource to inform colleagues of the upcoming AIA and possible implications for MDs. Additionally, as the proposal is still under review, this work must be revisited to consider the final version of the AIA.

This paper is divided into the following sections. Section II describes the MDR in brief. Section III introduces the AIA proposal in brief. Section IV discusses the challenges portrayed in previous work [4] and their relationship with the AIA. Lastly, in Section V, conclusions are drawn up.

II. The Medical Device Regulation

The legal instrument that regulates MDs in the EU is outlined in the MDR [5]. The MDR replaced the Medical Device Directive to modernise the regulatory framework, prioritising patients and device quality, reliability, traceability, and transparency [6], [7]. This instrument was enacted in May 2017 and became applicable in May 2021 [5]. The following subsections will explore the definition of a MD, its context in software, and a brief description of the Conformity Assessment (CA) process.

A. Medical Devices

A MD is any instrument, including software, intended to perform one or more medical purposes on human beings. MDs can range from sticky plasters to more sophisticated, complex systems like computed tomography scanners [8]. Software can also be part of a MD, vital in enhancing device functionalities [9]. Depending on the intended purposes of the software, a MD with software functions may be divided into [10]:

- **Software as a Medical Device (SaMD)**. This term refers to software intended to perform a medical purpose. This could be part of hardware or a stand-alone system [10]. The MDR does not refer directly to this term; however, the Medical Device Coordinated Group (MDCG) refers to this term as Medical Device Software [9].
- **Software in a Medical Device (SiMD)**. This term refers to software considered an accessory to a MD; in other words, software is not intended to perform medical purposes [10]. In the MDR, an accessory is defined as any instrument, including software, that supports additional functionalities to a MD, including driven systems (Article 2.2).

B. Medical Device Classes and Conformity Assessment

The MDR is a risk-based legislation outlining a device classification based on the vulnerability of the human body [9]. Article 51 introduces four device classes: Class I, Class IIa, Class IIb, and Class III. To assign a class to a MD, 22 rules must be inspected, as described in Annex III. Within this list, rule 11 is explicitly outlined for software. Nevertheless, this rule is not the sole criterion for SaMD and SiMD, as other rules shall also be considered to determine the appropriate class [9].

The role of a device class is to identify the CA pathway for a MD [11]. The CA is the process to demonstrate that a MD complies with the MDR, fulfilling mandatory requirements and obligations. The participation of a Notify Body (NB) in this process depends on the device class [6], [7]. Class I devices do not require a NB, and the manufacturer can perform a self-declaration. On the other hand, Class IIa, Class IIb, and Class III require a NB to be involved in the CA process. Additionally, for specific Class III, special agencies such as the European Medical Association are also required during CA procedures [7], [12]. Each class device, its associated risk, and its CA pathway are illustrated in Fig. 1.

The MDR indicates safety and performance requirements as outlined in Annex III. These requirements are related to the Risk Management System, Design and Manufacture of the MD, and Information Supplied with the MD. The compliance of these requirements is supported by harmonised standards or common specifications [6], [7]. Additionally, the MDCG has endorsed guidelines [13] to support manufacturers, i.e., to identify the device class [14].

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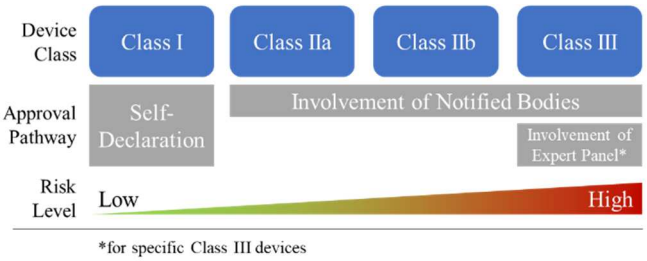

Fig. 1. The level of risk and approval pathway based on the device class [7].

III. The EU AI Act Proposal

In April 2021, the European Commission (EC) released a draft of the AIA proposal [15]. This instrument is intended to regulate and harmonise rules for AI systems in the Union Market [15]. It is the first proposal of its kind intended to regulate AI technologies across different industries and is likely to become a Global Standard [2]. The AIA could be enacted by 2023 and applicable by 2024 [15]. The following subsections will discuss the definition of AI systems, the risk classification, the requirements, and the CA outlined in the AIA.

A. Definition of AI Systems

In legislative frameworks, definitions are critical to allow the proper control of concepts to avoid uncertainty [16] and filter products under laws [17]. Hence, defining the term 'AI systems' is fundamental for its legal regulation [2]. However, determining a global meaning for AI systems has been challenging due to the vast involvement of disciplines such as Philosophy, Computer Science, and Linguistics [18]. Even more, the definition of AI has also followed different methods and approaches in rational, thinking, and behavioural dimensions [18] and in terms of its capability, i.e., weak or strong [19].

Despite the lack of a universally accepted definition of AI, its definition is necessary to control the term [17] and legal responsibilities [2]. The EC proposed a definition of AI systems aligned with the one established by the OECD [2]. AI systems in the AIA are defined as "… software … developed with one or more … [machine learning, deep learning, logic- and knowledge-based, and statistical] techniques and approaches … and can … generate outputs such as content, predictions, recommendations …" (Article 3). This definition in the AIA has started a discussion among experts [17]. On the one hand, some argue that the definition is too narrow as the rapid evolution of AI technologies might undermine it [17]. On the other hand, it was also criticised for being too broad, which may cover traditional software [17], a series of if-then rules where interpretation and debugging are easy to track the path taken through the code [9], [20]. The definition of AI systems in the AIA is still a subject of discussion within the EC, the Council of the EU, and the European Parliament [21].

B. Risk Classification

The AIA proposal outlines three risk classifications for AI systems [15], which are not explicitly stated. This classification system is generally illustrated as a pyramid [2], [15], as shown in Fig. 2. The AIA does not provide definitions for each risk classification but a set of conditions [15]:

- **Unacceptable risk (Article 5)**. This classification is assigned to AI systems that fall under prohibited practices. These AI systems are banned from the Union. In other words, placing unacceptable AI systems on the market or putting them into service is forbidden. This classification is represented in the red area in Fig 2.
- **High risk (Article 6)**. These AI systems must comply with the obligations and requirements of the AIA. This classification is represented in Fig. 2 in the yellow area. The AIA listed different products considered high-risk as follows [2]:
    - **Annex II**. AI systems that are part of existing regulations and will be regulated under the AIA. Section A outlines products part of the New Legislative Framework, such as toys and medical devices. Section B outlines products that are part of other regulations and directives, such as aircraft and marine equipment. These AI systems shall be a product itself or safety components.
    - **Annex III**. Specific AI systems that are not part of existing legislation and will be regulated under the AIA. Examples of specific AI systems that are considered high-risk are biometric identification of natural persons, worker management, and law enforcement systems. Other conditions for these systems are outlined in Article 6(3).
- **Non-high risk (Recital 81)**. These are AI systems that are not under the scope of the AIA. Hence, the requirements in the AIA are not mandatory but can be applied as Codes of Conduct (Article 69). This classification is represented in Fig. 2 in the green area.

When applicable, transparency obligations shall also be considered for AI systems. These obligations depend on whether the AI system contains impersonation and deception practices, as described in Article 52. This obligation has been portrayed as another risk classification, named limited risk [15]. Recital 70 states that transparency obligations can apply to high- and non-high-risk AI systems. This paper outlines transparency obligations as not mutually exclusive to either high or non-high-risk classification, as shown in Fig. 2, with a white bubble overlapping the yellow and green areas.

C. Requirements for High-Risk AI Systems

When an AI system is classified as high-risk, it is subject to seven requirements outlined in Chapter 2 of Title III. These requirements are Risk Management System (Article 9), Data and Data Governance (Article 10), Technical Documentation (TD) (Article 11), Record-Keeping (Article 12), Transparency and Provision of Information (Article 13), Human Oversight (Article 14), and Robustness, Accuracy and Safety (Article 15). Moreover, additional transparency obligations might also be applicable for high-risk AI systems, according to Article 52.

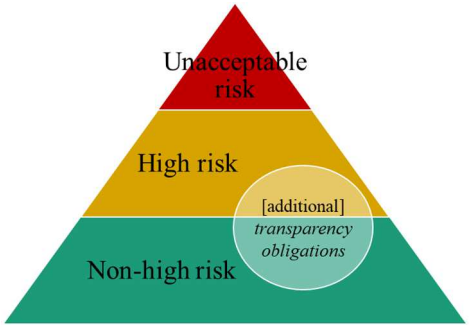

Fig. 2. Risk Classification in the Artificial Intelligence Act [15].

The AIA describes the seven requirements in a high-level approach, and the development of harmonised standards will be key to facilitate compliance [22]. The technical specifications for the requirements in the AIA are expected to be supported by international standardisation work [23]. The Joint Research Centre (JRC), as an independent work and contribution to European Standardisation Organizations, identified and analysed AI International Standards that can support the AIA [23], [24]. Their first report analysed ISO and IEC standards and their relevance based on scores [24]. Then, a second report on IEEE standards was released in 2023 [23]. In January 2023, the CEN-CENELEC Joint Technical Committee 21 on AI proposed a preliminary plan for standardisation work to support the AIA [25]. This plan considers ten ISO/IEC AI standards, including management systems, risk management, data quality, and security management. The JRC analysed these standards, finding partial support for the requirements of the AIA [25]. The remaining gaps are expected to be addressed by European Standardisation Organisations [25].

The requirements outlined in the AIA are not mandatory for non-high-risk AI systems. However, these can be applied as Codes of Conduct (Article 69). If applicable, transparency obligations (Article 52) must also be considered (Recital 70).

D. Conformity Assessment of High-Risk AI Systems

High-risk AI systems will be subject to CA procedures before being placed on the market or put into service (Article 19). The AI systems with existing legislation, as listed in Section A of Annex II, must follow their corresponding CA procedures (Article 43). However, for specific AI systems in Annex III, the CA procedures must be followed as indicated in Annex VI (based on internal control with no involvement of NBs) or Annex VII (based on the assessment of the Quality Management System and TD).

According to Article 43, for a high-risk AI system as a product itself, the provider shall ensure that the final product complies with the requirements of the AIA. Additionally, existing legislative requirements shall be applied alongside the AIA for AI systems under Section A in Annex II (Article 43). For a high-risk AI system as a safety component, which will not be marketed independently, the provider must ensure that the AI system complies with the AIA (Recital 5). At the same time, the final product must also adhere to its respective legislation (Recital 5).

Once an AI system is approved, it must bear a CE marking of conformity, which should always be visible and legible. As appropriate, this shall be affixed to the AI system, packaging, or documentation (Article 49).

IV. The MDR and The AIA Proposal

This section will explore the alignment of the AIA and the MDR, primarily on the classification pathways, requirements, and CA procedures. The scope of the discussion is around SaMD embedding AI systems performing medical purposes, also referred to as AI-based SaMD.

A. Classification of AI-base SaMD

It is assumed that MDs would fall under the AIA and be labelled high-risk [26]. Nevertheless, the classification of MDs in the AIA also depends on the intended use of the AI systems [27]. In the context of SaMD, AI systems intended to perform medical purposes will be classified as high risk in the AIA. In the context of SiMD, an AI system intended to perform as an accessory, i.e., to give additional functionality to a MD, will be classified as non-high risk. However, further analysis should be conducted on SiMD and AI accessories for driven or safe functionalities. Some of these systems may be classified as high-risk in the AIA when falling under the scope of other legislations, such as the Machinery Directive (Annex II). On top of these conditions, an essential condition for classifying an AI system is to ensure that its intended use does not fall under unacceptable practices [27].

With the upcoming introduction of the AIA, an AI-based SaMD will have two classifications, one from the AIA (risk classification) and another from the MDR (class device). According to Recital 31 in the AIA, the risk classification will not alter the device class assigned in the MDR. In other words, a higher risk in the AIA is not inherited into the device class. For instance, when a MD is identified as Class I in the MDR while high-risk in the AIA, its class device will remain unchanged. Therefore, the AI-based SaMD will concurrently be Class I (MDR) and high-risk (AIA). As such, it is essential to understand the purpose of the classification system in both the AIA and the MDR. The classification risk in the AIA is used to identify AI systems that must follow the obligations and requirements outlined in the proposal [15]. Whereas the device class in the MDR is to identify the CA pathway [11], as shown in Section II.B.

B. Requirements for High-risk AI-based SaMD and Conformity Assessment

When a MD is categorised as high-risk in the AIA, the requirements outlined in Chapter 2 of Title II shall be considered. Additionally, the obligations and requirements outlined in the MDR shall be contemplated alongside (Article 43). In other words, manufacturers must concurrently adhere to the requirements in the AIA (Chapter 2 of Title II) and the MDR (safety and performance requirements) for AI-based SaMD. Nevertheless, compliance with the requirements of the AIA and the MDR might bring additional challenges.

When examining the requirements of the AIA and the MDR at a title level, an overlapping behaviour is observed. As shown in TABLE I, these requirements are Risk Management System, TD, Quality Management System, and Post-Market Surveillance. This intersection suggests that interoperability will occur between the AIA and the MDR. However, it also implies potential duplication or inconsistency between the AIA and the MDR, which might challenge relevant MD stakeholders [26], [28]. For instance, the terms User, Provider, and Risk are inconsistent when their definitions in the AIA and the MDR are compared [28]. Therefore, further in-depth analysis at a clause level is needed to identify the level of harmonisation in both documents. This issue might also occur at a standard level. Different sets of harmonised standards will be designed to comply with the AIA and another set for the MDR. Hence, it is likely that standards also contain duplications or inconsistencies.

According to Article 19, a high-risk AI system will be subject to CA procedures before being made available in the Union or put into service. In the case of AI systems with existing legislation (Annex II), these must follow their respective CA procedures (Article 43). In the case of AI-based SaMD, the CA outlined in the MDR must be followed.

TABLE I. REQUIREMENTS IN THE AIA PROPOSAL AND THE MDR.

Requirements	AIA	MDR
Risk Management Systems	X	X
Technical Documentation	X	X
Quality Management System	X	X
Post-Market Surveillance	X	X
Accuracy, Robustness and Cybersecurity	X	
Data and Data Governance	X	
Human Oversight	X	
Record-Keeping	X	
Transparency and Provision of Information	X	
Clinical Evaluation and Investigation		X
Design and manufacture		X

V. CHALLENGES ASSOCIATED WITH THE ADOPTION OF AI IN MEDICAL DEVICE SOFTWARE

Based on the previous discussion, this section focuses on the question – What are the implications of the AIA to the challenges of adopting AI into Medical Device Software? The previous work [4] considered challenges in adopting AI into Medical Device Software related to the Development Life Cycle (DLC), continuous learning of AI models, transparency, and use of conflicting terminology. Please notice that recitals, articles, and annexes mentioned in this section are related to the AIA.

A. Different Development Life Cycle Frameworks

This challenge was described in the context of different development frameworks in traditional software and AI. Traditional software is generally referred to as computational statements with a series of if-else rules, transforming specific requirements into pre-defined outputs [20]. In the MD industry, methodologies implemented for the development of traditional software tend to follow a plan-driven approach [29], such as the V-Model, or incremental/evolutionary approaches, such as Agile Software Development practices [29], [30]. Nevertheless, this process is different in AI as processes tend to be data-driven [31]. AI learning algorithms are trained and tested with datasets, which may require prior processes such as understanding, collection, and preparation of data [31]. Therefore, traditional software DLC is about writing computational statements based on predetermined requirements, whereas AI is about experimenting to build a model based on data.

No explicit DLC methodology is indicated for AI systems in the AIA, like in the MDR. The TD requirement outlines the need to specify the steps and procedures carried out during the development process (Article 15). Manufacturers must describe, among other details, the development process of the AI system, data requirements, architecture, algorithms, and validation and testing procedures (Annex IV). Moreover, the Quality Management System is another obligation that mandates providers to document "… techniques, procedures and systematic actions to be used for the development … of the high-risk AI system …" (Article 17).

Different AI International Standards from the ISO and IEC might become harmonised to support the requirements of the AIA. The JRC, as an independent contribution to the European Standardisation Organisations, analysed AI International Standards from ISO, IEC, and IEEE to evaluate their relevance to the requirements of the AIA [23], [24]. Among these standards, "ISO/IEC 5338 – Life Cycle Framework for AI Systems" (draft) was included in the analysis performed by the JRC. This standard defines activities to support the life cycle of AI systems, including development processes and activities. The JRC inspected ISO/IEC 5338, finding that this standard may support the requirements in the AIA related to Data and Data Governance, Human Oversight, Accuracy, Risk Management System, and Quality Management System [24]. Other international standards related to the DLC of AI systems are "ISO/IEC 8183:2023 – Data Life Cycle Framework" (published) and "ISO/IEC 23053:2022 – Framework for AI Systems Using Machine Learning" (published).

B. Risks Associated with the Adaptability of AI

This challenge is related to the continuous training of AI models in post-marketing settings. This includes algorithms that are locked or unlocked [32]. Locked AI systems are not re-trained in post-marketing settings. Consequently, these systems do not adapt to, e.g., new data. On the other hand, unlocked AI systems are continuously retrained over time, adapting to, e.g., new data [32]. Nevertheless, unlocked AI-based SaMD might represent a risk as changes can affect its intended use or alter its device class [32], [33].

The AIA proposal indicates in the TD requirement that "… where applicable, a detailed description of pre-determined changes to the AI system and its performance…" (Annex IV.2), including continuous learning. The provider shall specify how the AI model and performance will change while continuously learning in post-market settings (Recital 66). These pre-documented changes are not considered substantial modifications[1], and a new CA will not be required (Recital 66).

Continuous learning of AI systems is also associated with other requirements in the AIA. For instance, Post-Marketing Surveillance is outlined as key for addressing risks from unlocked AI systems (Recital 78). Another example is the Robustness, Accuracy and Safety requirement (Article 9). This requirement indicates that continuously learning AI systems must be developed to mitigate bias from feedback loops (i.e., outputs used as inputs of future operations) to ensure robustness (Article 15.3).

Another requirement of the AIA associated with unlocked AI systems is TD. Despite minor gaps found, the JRC suggested that TD does not require a standard as it is clearly outlined in Annex IV [24]. Nevertheless, the JRC did not inspect or indicate the documentation of pre-defined changes as a gap within TD. In another report from the JRC [23], the standard "IEEE 7010 – Recommended Practice for Assessing the Impact of Autonomous and Intelligent Systems on Human Well-Being" was found to provide partial coverage of Risk management system, which was also linked to continuous learning [23]. Nevertheless, no more analysis was conducted regarding AI systems continuously learning in post-marketing settings.

Even though TD might not need a specific standard, guidelines should be provided for the appropriate documentation of pre-defined changes. An example of this is the guideline for Predetermined Change Control Plan (PCCP) for AI/ML-enabled Device Software Functions (draft) by the US FDA [34], [35]. The document outlines the

[1] Substantial modifications are elements in an approved AI system that change and affect compliance with requirements in the AIA (Article 3.23).

documentation required to describe future modifications in post-market conditions. In general, the components within the PCCP must contain a Detailed Description of Modifications (list of changes to the device), a Modification Protocol (activities that support those changes), and an Impact Assessment (benefit-risk for each modification and measures taken to ensure safety and performance of the device). When a device and its PCCP are approved, the PCCP is considered an authorised change on the device, and a new marketing submission is not required [35]. Despite the AIA following a similar approach as the PCCP, detailed guidance should be provided to manufacturers [34].

C. Achieving Explainability and Traceability in AI

This challenge is related to the condition of being transparent, which means the proper information is supplied. This can be associated with explainability and traceability. Explainability is understanding the internal procedures in an AI model [36], whereas traceability is the maintenance of requirements and appropriate documentation [37].

Transparency and Provision of Information requirement in the AIA indicates that information associated with high-risk AI systems must be provided (Article 13). Clause 1 outlines that sufficient information must be provided so the user can understand an AI system's output. According to the JRC, this requirement does not explicitly mandate explainable AI techniques, but other approaches can be used, such as documentation or user interfaces [23], [25]. Nevertheless, it is also suggested that explainable AI techniques should be applied to ensure an ecosystem of trust [23]. Despite current limitations in explainable AI, international standards may partially support explainability, like "ISO/IEC TS 6254 AI – Objectives and Approaches for Explainability of ML Models and AI Systems" (draft) and "IEEE P7001 – Transparency of Autonomous Systems" (draft) [23].

In the AIA, traceability can be related to TD and Record-Keeping. TD is outlined in Article 11, referring to documentation to demonstrate compliance with the requirements of Chapter 2 in Title III. The AIA indicates that only one TD shall be drawn up when an AI system is associated with another existing regulation (Article 11). Keeping a single TD may be challenging, as duplicated details may occur in the AIA and the MDR [28]. This situation may also impact the DLC documentation of AI-based SaMD. Hence, consolidation of TD in the AIA and the MDR is necessary.

The Record-Keeping requirement (Article 12) is related to creating, designing, and maintaining automated logs, allowing traceability of the AI system [18]. Some ISO/IEC standards may partially support the implementation of Record-Keeping, such as "ISO/IEC 42001 on AI Management Systems" (draft) and "IEEE P7001/D4 – Standard for Transparency of Autonomous Systems" (draft) [23]. In terms of MDs, this requirement might be seen as 'new' under the MDR based on the title of the requirement (see TABLE I). Nevertheless, further analysis should be conducted on a clause level in the AIA and the MDR to identify conflicting scenarios. For instance, some clauses in Record-Keeping might be associated with Post-Marketing Surveillance in the MDR.

D. Conflicting Use of Terminologies

This challenge is related to terms and definitions within different domains. In the MD industry, different disciplines are interconnected, such as AI, Computer Science, and Healthcare. While each field has its terminology, this can lead to concepts with the exact spelling but different meanings or different spelling with the same meaning [38].

The preliminary standardisation work plan [25] includes two foundational standards related to concepts and terminologies. These are "ISO/IEC 22989 – Artificial Intelligence Concepts and Terminology" (published) and "ISO/IEC 23053 – Framework for AI Systems Using Machine Learning" (published). The JRC commented that key terms in these standards might require mapping activities to the AIA and other technical documents [25]. As such, the challenge of the harmonisation of terminologies remains. For example, Design Inputs under the Design Controls, an FDA's guidelines for software design and development process, slightly differ from the terminology used in ISO international standards [39]. Therefore, similar situations may occur with the concepts in harmonised standards, the AIA, and the MDR. Additionally, this situation might challenge the design of a single TD for AI-based SaMD [28].

VI. Conclusions

Once the AIA becomes applicable, AI-based SaMD must comply with both the AIA and the MDR. This paper explores the implications of the AIA in previous work. The challenge associated with the DLC does not directly relate to the AIA, as no methodology is specified. This is not surprising, as the AIA is designed at a high level, and harmonised standards or common specifications are expected to provide more details to facilitate compliance. Three ISO/IEC standards related to the DLC of AI systems are not part of the preliminary standardisation work plan to support the AIA. However, these standards should be analysed to inspect the level of support for the DLC of AI-based SaMD. Moreover, the DLC is associated with TD in the AIA and the MDR. Drawing up a single document might be problematic as conflicting requirements in both documents can occur. Furthermore, the different sets of terminologies in standards, the AIA, and the MDR may impact TD. As such, guidelines are needed for adequate TD of AI-based SaMD, including guidance for documenting pre-defined changes in post-market settings.

Besides interoperability, the requirements in the AIA and the MDR could show duplicated or conflicting clauses for the compliance of AI-based SaMD. The challenges discussed in previous work could be affected by these inconsistent scenarios. Hence, future research work in MDs and AI should consider potential inconsistencies among the MDR, the AIA, and associated standards.

Finally, it is important to note that the AIA will not regulate research (Article 2.6). The AIA regulates products intended to be marketed or put into service in the EU. Hence, the research process is out of scope. Nevertheless, researchers must consider European regulations when there is an intention to commercialise a research project.

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