Analysis of the Classification of Medical Device Software in the AI Act Proposal

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Abstract

The Artificial Intelligence Act (AIA) proposal by the European Commission (EC) is considered the first legal attempt to harmonize rules for AI systems. The proposal is designed to regulate AI systems in different European economic sectors, including Medical Devices (MD). This paper aims to examine the classification of AI systems in the AIA and their alignment with the Medical Device Regulation (MDR). The analysis focuses on Software as a Medical Device (SaMD) and Software in a Medical Device (SiMD), excluding general-purpose AI systems and machinery products (i.e., driven systems and safety components), as investigation in the Machinery Directive legislation is required. The strategy is to identify the classification conditions for AI systems by mapping key terms and definitions related to Article 6 in the AIA. Then, these conditions are translated into propositions suitable for the MD domain and presented in a flow chart for discussion. The primary source of information for the analysis is the MDR and the AIA, considering the latest revisited version of the proposal (Presidency compromise text, document 11124/22). We conclude this paper by discussing the classification pathway for SaMD and SiMD according to the AIA and additional discussion on terminology-related concerns and suggestions.

Keywords

Artificial Intelligence Act Proposal, Medical Device Regulation, Medical Device Software, AI System Classification

1 Introduction

1.1 The Medical Device Regulation

The Medical Device Regulation (MDR) aims to ensure the safety of concerned patients and to enhance the quality of Medical Devices[2] (MD) in the European Union (EU) without ignoring innovative and creative technologies [1, 2]. Since the MDR focuses on MDs, it is domain-specific rather than generic. The main objective of the new regulation is to strengthen protection against risks posed by MDs and to update regulations to account for new technologies. The MDR replaces the previous EU Medical Device Directive (MDD) to modernize the EU legal framework system to address the market's current needs and new technologies [3]. The MDR has more focus on device safety as compared to the MDD. The MDR provides general guidelines and regulations that must be followed before putting MDs into the market, regardless of the technology used for developing MDs. Thus, regulations provided by the MDR apply to all medical devices irrespective of the technology perceived. The classification rules for MDs follow a *risk-based approach*, considering the vulnerability of the human body and the potential risk associated with the device (MDR, recital 59) [4, 5]. The classification of MDs is divided into four

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[2] The use of the term *device* is implemented in this paper as a synonym of *medical device.*

classes: I, IIa, IIb, and III (MDR, Article 51). For manufacturers to identify the appropriate Class of a device, 22 rules must be considered, divided into invasive, non-invasive, and active devices and other special rules (MDR, Annex VIII). Once the Class of an MD is identified, the manufacturer must follow the applicable obligations and safety and performance requirements [4]. The European Medicines Agency (EMA), a decentralized agency of the EU, associated a level of risk to the classes where Class I has the lowest risk and Class III the highest (see Figure 1) [6, 7].

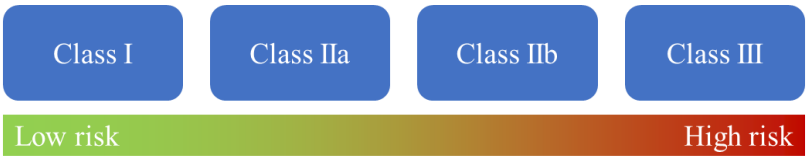


Figure 1. MD classes and their association to a risk level [6], where Class I is associated with low risk and Class III with the highest risk.

1.2 The Artificial Intelligence Act Proposal

The Artificial Intelligence Act (AIA) is a proposed European law on Artificial Intelligence (AI) – the first law on AI by a significant regulator anywhere [8]. The AIA is predicted to be a *Global Standard* in the future, as it focuses on determining to what extent AI has a positive rather than negative effect on everyone's life. The legal framework proposed is generic, attempting to provide generalized obligations, procedures, and requirements that could be adopted across disciplines to ensure AI applications are safer, more robust, and more ethical in the European market. As the name suggests, the AIA focuses on regulations essential for applying AI to applications and systems; therefore, it is technology specific. The proposal applies to all products that either contain a component that uses AI, or an AI system is considered a product itself [8]. Based on the *Subject Matter* (Article 1), most of the obligations and requirements proposed are aimed at regulating AI systems. The proposal is divided into four main sections: prohibited practices, obligations and requirements for high-risk AI systems, additional transparency obligations for specific practices, and rules for monitoring purposes [9]. The AIA also includes classification rules for high-risk AI systems, further discussed in Section 3.1. An *Explanatory Memorandum* (EM) is attached at the beginning of the AIA, a document that explains the proposal and used by National Parliaments to examine the AIA. The EM introduces the background, reasons, and context of the proposal and, within subsection 5.2.2, the classification of AI systems. Although, the EM will not be part of the Act once enacted [10].

1.3 What is a Medical Device?

The MDR defines the term *Medical Device* (MD) as a single or combination of articles intended for medical purposes, for which those purposes are formulated by medical action (e.g., diagnosis, prevention, and monitoring) and medical states (e.g., disease, disability, and physiological state) [11]. Within this definition, *software* is included as an article. In general, the implementation of software in the MD domain is divided into two categories: Software as a Medical Device (SaMD) and Software in a Medical Device (SiMD). SaMD is software for medical purposes which may *not necessarily be part* of the hardware [12]. This term is not used in the MDR, although the definition of an MD indicates that software is considered an MD if its intended use is for medical purposes [11, 12]. In other cases, *software* could also be utilized as an accessory and combined with other articles. An *accessory* is embedded into an MD to support its performance, which is also known as SiMD [12]. The task of an *accessory* is to drive or influence the performance of a device, but as a stand-alone component does not perform medical actions [4, 11, 12]. According to Recital 12 in the MDR, accessories could also be regulated under the Machinery Directive (MDI). This depends on the definition stated in Article 2.a (MDI), which is referred to as *machinery*, an assembly that contains connected components, including driven systems. In Europe, the Medical Device Coordination Group, a group of representatives of

Member States dealing with issues and guidelines related to MDs, SaMD is referred to as Medical Device Software (MDSW) [4, 12].

This paper aims to understand the different classifications that an MD may have under the AIA. This is essential to understand the classification of MDs in the AIA proposal and inspect for inconsistency between both documents, the MDR and the AIA. Hence, the research question of this paper is to answer: *What is the classification scope for MDs in the AIA?* Note that this analysis should not be taken as legal guidance but as a necessary exercise to better understand the future of MDs under the AIA proposal. The rest of the paper is divided as follows: in Section 2, we define the scope and describe the strategy for the analysis of the classification of MDSW in the AIA; in Section 3, we performed the analysis by understanding in more detail the classification rules in the AIA, initial mapping of the classification in the AIA and the MDR, and building a flow chart based on propositions and conclusion for further discussion; in Section 4, we discuss the pathway of the classification of MDs shown in the flow chart and other concerns observed in terms of terminology; and finally, in Section 5 we present our conclusions and directions for future work.

2 Methodology

In this section, we explain the strategy carried out for the examination of the classification of MDs adopting AI techniques according to the AIA. This process was performed by understanding and mapping terms and definitions from the rules established in the proposal. The scope of our analysis focuses on SaMD, with the assumption that most of the MDs adopting AI will be stand-alone software solutions [13]. To slightly expand the scope, we include SiMD but exclude devices considered *machinery products*[3], as this requires further analysis of an additional legal document, the MDI. Additionally, the latest revisited version of the proposal includes new provisions for general-purpose AI systems in response to recent emergent technologies such as ChatGPT [14]. This is also out of the scope of this analysis. Additional provisions regarding obligations and requirements for general-purpose AI systems were introduced in the new Title IA. The primary data sources for this analysis are two legal documents: the MDR and the AIA[4]. We consider the latest revised version available[5]. In the rest of this paper, we will refer to three main sections from each legal document as follows: *recitals*, which introduce reasons for the *enacting terms* and are located after the word *'whereas:*'; *articles*, which are the normative part of an Act (enacting terms); and, *annexes*, which contain rules or technical data and are generally mentioned in articles [15]. Other official EU sources, such as posts, articles, and reports, and the *Explanatory Memorandum* (EM) attached to the proposal are excluded from the analysis as a measure to avoid prejudice.

We analyzed by mapping terms and definitions, finding relevant conditions, and building propositions in a *logical reasoning* approach to reduce subjectivity. First, we performed an exercise to understand the classification rules stated in the AIA. Based on that process, and as a starting point, we generated an initial graph showing the relationship between the AIA and the MDR. Afterward, we identified relevant conditions from the classification of AI systems in the AIA and expanded them based on related recitals, articles, definitions, and annexes. Then, these conditions were translated into *propositions* in terms of MDs using logical reasoning symbols, and subsequently, these propositions were combined using *logic connectives*, depending on a conclusion. Propositions are statements with *true* and *false* values, whereas logic connectives, e.g., AND/OR Boolean operators, connect propositions associated with a conclusion. We refer to the conjunction of the propositions and connectives with their respective conclusions as implications, equivalent to "if… then…" [16, 17]. At the end of the analysis, we deliver a flow chart based on these implications as an outcome of the analysis process, representing the classification processes of MDs. By building propositions and a flow chart, we expect to cover relevant rules and pathways of the classification of MDs under the AIA for greater discernment. The symbols and elements used in Section 3.3 (Building Propositions and the Flow) with their corresponding meaning are shown in Table 1.

[3] For instance, driven systems and safety components.
[4] Available in https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52021PC0206.
[5] Presidency Compromise text on the AI Act (document 11124/22). Available in https://data.consilium.europa.eu/doc/document/ST-11124-2022-INIT/en/pdf.

Table 1
Symbols and corresponding meaning used in Section 3.

Propositions and Logic Connectives [16, 17]	Flow Chart Elements [18, 19]
$s(p)$ shall be read as $p\ is\ s$.	represents a *state* of the activity.
$s \wedge p$ shall be read as $s\ and\ p$.	represents a *transition* to another element.
$s \vee p$ shall be read as $s\ or\ p$.	represents a *decision.*
$\neg s$ shall be read as $not\ s$.	represents a *note*.
$p \in l$ shall be read as $p\ belongs\ to\ l$.	represents *end* of flow.
	represents an *exception*.
	represents *parallel state* of activities.

3 Analysis

3.1 Understanding the Classification of AI Systems

This section will examine the classification rules for AI systems based on the AIA proposal. The AIA proposes a clearly defined *risk-based approach* to specify rules for AI systems due to the potential generation of *"... risks and cause harm to the public interest and rights that are protected by Union law ..."* (AIA, recital 14) [9]. This arrangement of rules proposes the classifications for AI systems, which are associated with risks and threats to fundamental rights and values. The AIA directly introduces *high-risk* as a classification for those AI systems with a specific modality, i.e., stand-alone solutions and safety components, and purpose, i.e., products within the NLF (Annex II) and other use cases (Annex III) [20]. Once providers comply with legal obligations and requirements set out in Title III, high-risk AI systems are permitted in the Union Market (AIA, Article 6) [9, 21]. Besides high-risk AI systems, it is possible to identify[6] three other AI system classifications: (1) unacceptable, (2) non-high, and (3) deceiving[7] risk [9]. We explain these in turn. First, the *unacceptable risk* classification is identified in the list of prohibited practices in the AIA (Article 5). When the intended use of an AI system falls under one or more of these descriptions of practices, the AI system is banned from the market because of unacceptable risks associated with fundamental rights and the European Union's interest (AIA, recital 14). Examples of unacceptable risk AI systems could be subliminal manipulation (e.g., toys with voice assistance encouraging dangerous activities), social scoring, and real-time biometric identification systems [21, 22]. It is important to note that, according to Recital 27, high-risk AI systems must not pose an unacceptable risk to place on the Union market or put into service. Secondly, the proposal also refers to *non-high-risk* AI systems as those that voluntarily apply a code of conduct based on the requirements set out in Chapter 2 of Title III (AIA, Article 69) and optional requirements associated with sustainability, accessibility, and diversity (AIA, Recital 81) [9]. Using the prefix "*non-*" in the non-high-risk classification suggests that high- and non-high-risk AI systems do not overlap[8], although this is not clarified in the AIA. Lastly, *deceiving-risk* classification is identified in Article 52, segregation of AI systems that are associated with impersonation and deception risks and subjected to transparency obligations [9, 21, 23]. According to Recital 70, deceiving-risk AI systems could overlap with high-risk classification (without predisposition to the obligations in Title III) or non-high-risk classifications, suggesting an AI system is not deceiving on its own [9]. The overlapping behaviour of the AI system classification is illustrated in Figure 2, and the summary of the classification of AI systems is shown in Table 2, in which we introduce definitions for each classification formulated based on the rules in the AIA.

[6] By means that the AIA does not directly state that unacceptable, deceiving, and non-high-risk AI systems are classifications. But we are considering them as these rules segregate AI systems and differentiate them from the high-risk once. Hence, applicable obligations and requirements will depend on the classification assigned to the AI system.
[7] Other sources refer to this as *limited* risk. But, as these AI systems are associated to impersonation and deception risks, we consider using the term *deceiving* to refer to both types of risks.
[8] When referring to *overlapping behavior*, we refer to characteristics of two objects, e.g., high- and non-high-risk AI system, that could be similar or commonly happen together.

Table 2
Definition of Classification of AI Systems, based on rules in the AIA proposal.

Risk Classification	Definition	Examples	In the AIA
Unacceptable	AI systems perceived as a potential threat to people's fundamental rights and EU values, which are associated with significant potential for *manipulation*, exploitation, and social control. Consequently, these are banned from the market. This classification does not overlap with any of the other classifications.	Subliminal techniques, exploitation of the vulnerability of specific groups.	Recital 15 and Article 5.
Deceiving	AI systems associated with *impersonation* and *deception* risks must comply with specific transparency obligations (Article 52).	Chatbots	Recital 70 and Article 53.
High	AI systems are products themself or safety components and belong to the NFL (Annex II) or specific use cases (Annex III). These must comply with obligations and requirements set out in Title II. Although some high-risk AI systems may be considered deceiving, additional transparency obligations must be applied.	Medical Devices and Machinery Systems.	Recital 27 and Article 6.
Non-High	AI systems that are free of use and voluntarily follow legal requirements from Chapter 2 of Title III. Some Non-High systems may be considered deceiving; hence transparency obligations must be considered.	Accessories for Medical Devices (excluding machinery devices)	Recital 81 and Article 69.

Figure 2. Graphical representation of the classifications of AI systems. Deceiving is the only risk classification that overlaps with high- and non-high risk.

In the following subsection, we examined the relationship between the MDR and AIA, including a graphical representation of the classification and its association with the MDR.

3.2 Initial Mapping Process

In this section, we present the first steps to analyze the classification of AI Systems under the AIA and their association with the MDR. This is to understand the relationship between the legal document and the proposal in a general approach. Based on Section 1.1 (The Medical Device Regulation) and Section 3.1 (Understanding the Classification of AI Systems), we created an initial representation of the classification of devices in the AIA and the MDR, shown in Figure 3. The direction of this graph starts from the AIA (at the top) to the MDR (at the bottom), as the former refers to MDs in Annex II, section a, but the MDR does not mention the AIA (yet). When analyzing this graph, our first presumption is

that *all* MDs adopting AI might belong to the high-risk classification under the AIA. This is visible by following the orange line drawn in Figure 3, which covers all device classes. This is particularly concerning, as Class I devices adopting AI techniques, considered devices with the lowest risk associated (see Figure 1), might be subject to additional regulatory procedures. Although, we shall see that a deeper analysis of the classification rules reveals some further distinctions to be recognized. For the following subsection, we will focus mainly on Article 6 (Classification rules for high-risk AI systems) to verify whether MDs belong to this classification by default.

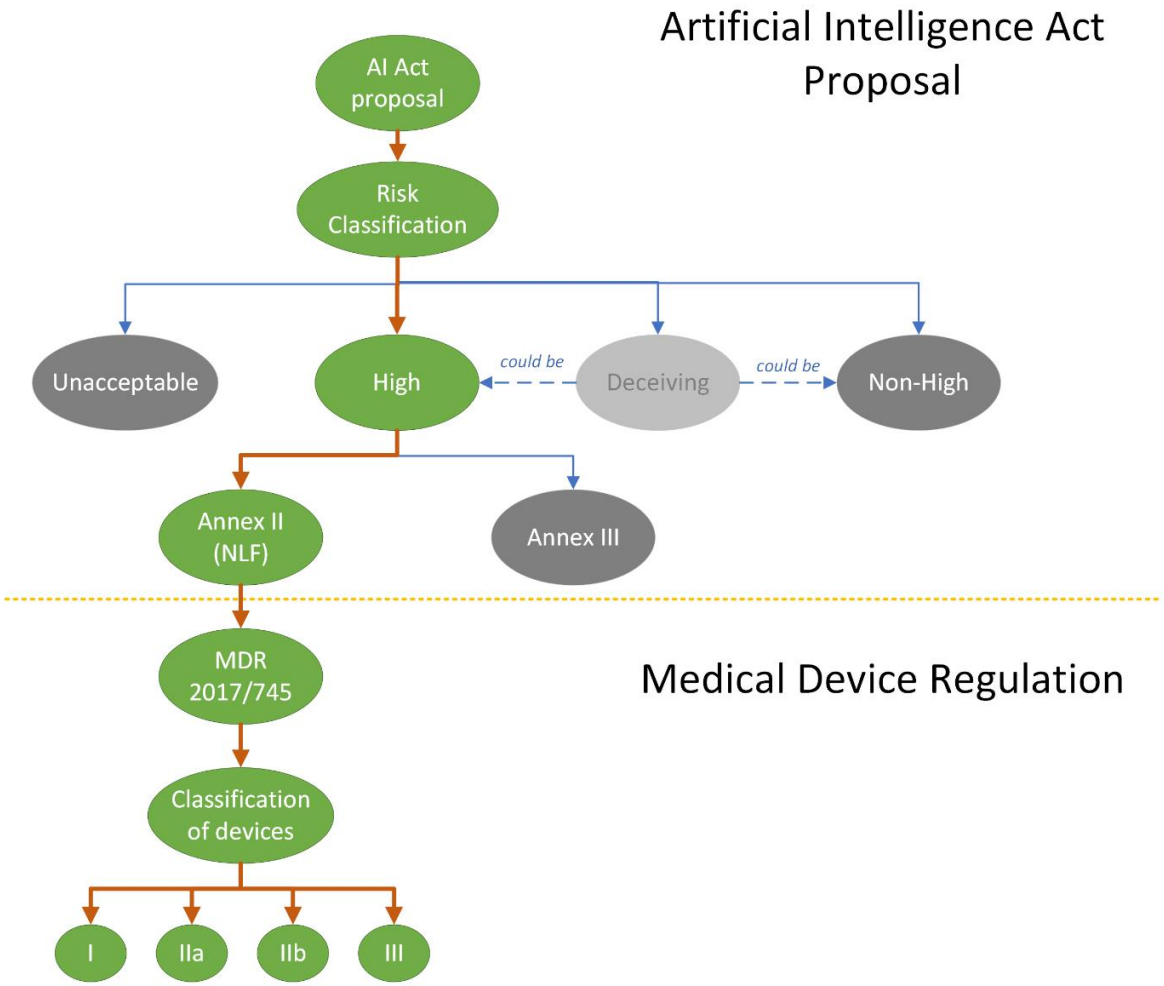


Figure 3. Initial Mapping of the AIA and the MDR. The orange line shows the connection between the AIA to the MDR, covering the four possible classes for devices.

3.3 Building Propositions and the Flow Chart

We next perform a more comprehensive analysis of the classification of AI systems and their association with MDs incorporating AI techniques. The following step describes a more extensive analysis by (1) building general conditions from the classification rules of AI systems, (2) formulating these conditions into propositions in an MD perspective, (3) building implications with a combination of propositions, and (4) building a flow chart based on the implications. As already examined in Figure 3, it seems that MDs adopting AI techniques are classified as *high-risk* under the AIA, regardless of the Class assigned to the device. Although, we assume that MDs might fall into other classifications depending on the conditions.

The first step in this broader analysis is identifying relevant conditions in the AIA for classifying AI systems. The starting point of this process was Article 6 (AIA), which contains the rule classifications for high-risk systems for safety components or stand-alone products. We identified other conditions

related to Article 6 by mapping key recitals, definitions, and annexes. The mapping process also considered other recitals and articles mentioned in Table 2. This mapping process is illustrated in Figure 4, in which the dashed lines that connect sections are referred to as *edges* and enumerated for easy reference. Green edges and areas correspond to the classification of high-risk AI systems. Edges and orange areas are associated with Article 6, so the edges started from this article to other relevant sections. Pink edges and areas in other recitals and articles are related to Article 6, so the dashed lines started from these to Article 6. This process derived four conditions, shown in Table 3, which are used as the basis to analyze the route classification of SaMD and SiMD in the AIA.

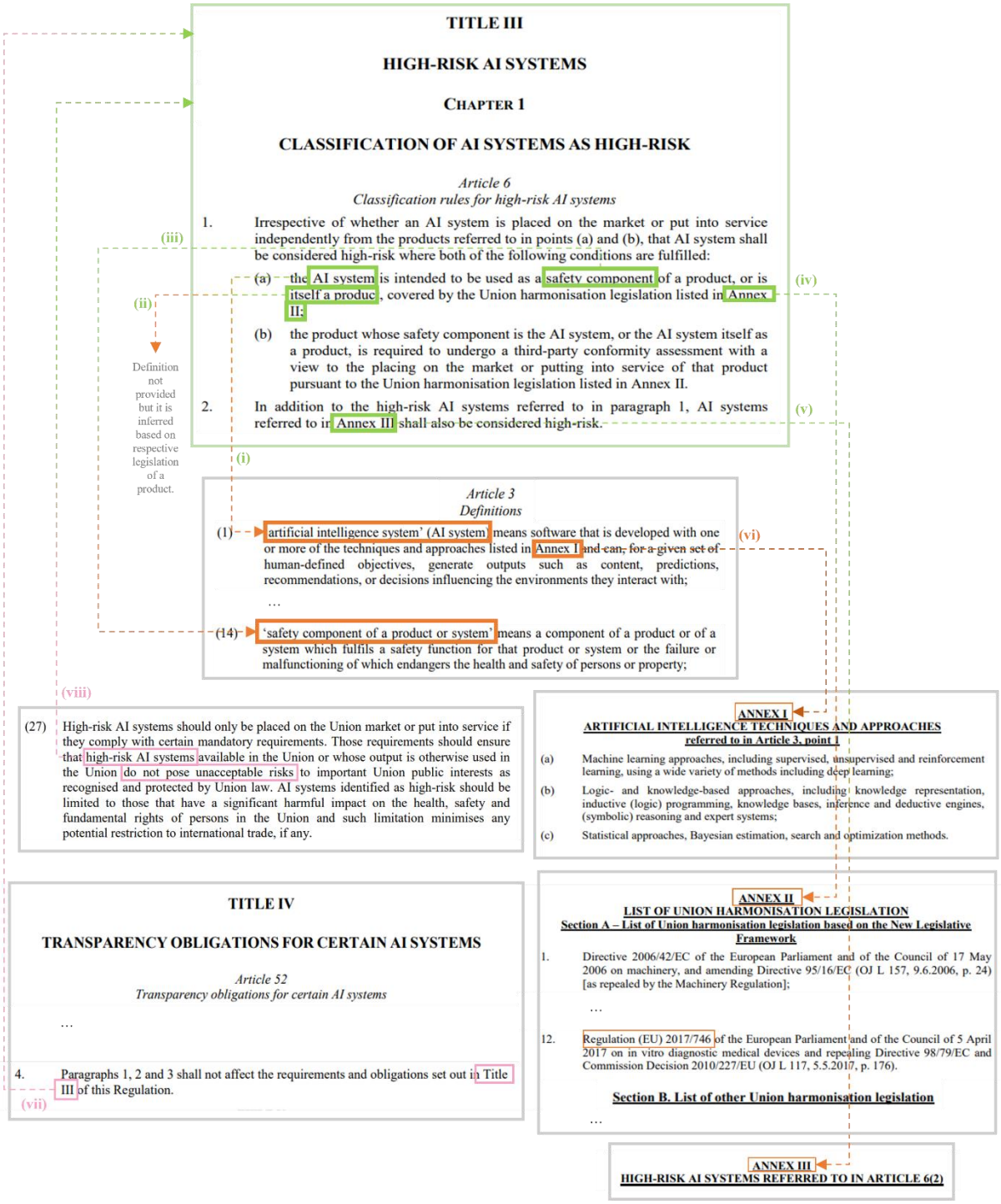


Figure 4. Illustration of the mapping process to identify conditions for the classification of AI systems. Other recitals, articles, and annexes mentioned in Table 2 were also considered.

Table 3
Conditions identified for the classification of AI systems in the AIA. This includes the relevant edge illustrated in Figure 4 to other relevant definitions, articles, and annexes.

	Conditions	In the AIA	Related Edge
1	*Product* integrates as an *AI system*, that uses the approaches and methods: (a) Machine Learning, including statistical approaches. (b) Logic- and knowledge-based.	Upon the definition of AI systems introduced in Article 2.1.	See (i), also subsequent connection (vi).
2	Intended use for an AI system belongs to *prohibited practices*.	As per Article 5 and Recital 27.	See (viii)
3	The AI system is: (a) a product itself or, (b) a safety component of a product;	As per Article 6.	For 3(a), see (ii); and 3(b), (iii).
4	AI system listed in: (a) the Annex II (NLF legislation); or, (b) Annex III (specific use cases);	As per Article 6.	For 4(a) see (iv); and 4(b), (v).

The conditions in Table 3 were translated into a suitable form for an MD to formulate propositions and conclusions, shown in Table 4. Although to perform this process, we altered the direction of the analysis from the MDR to the AIA to prioritize MDs. First, we must ensure that the *product* performs *medical purposes* [24], regardless of the article, technology, or method utilized by the manufacturer (proposition a). Then, as an MD could be as simple as a sticking plaster, it is considered that an MD must contain *software*[9] (proposition b). Such software should contain an AI system using specific methods and approaches indicated in the definition of AI (proposition c); otherwise, the device is out of the scope of the AIA. Next, the intended use of AI systems embedded into MDs must not fall into unacceptable risk (proposition d); otherwise, the AI system will be banned from the European Union. Then, deceiving practices were considered in proposition e, which are applicable for high- or non-high-risk. Lastly, even though the term *product itself* is not defined in the AIA and the MDR, we assume this term refers to devices that perform a medical purpose and are intended to be placed on the market or put into service. Therefore, regarding software, SaMD is identified as a *product itself* (proposition f). If an MD contains an AI system, but the latter does not perform medical purposes (accessory), this is not regulated under the AIA, and the AI system is classified as a *non-high-risk* system.

Table 4
Propositions and conclusions based on conditions in Table 3 and build in a suitable form for MDs.

Propositions	(a) Product (p) is an MD (m). (b) m contains software (s). (c) s contains *AI system* (a). (d) a belongs to prohibited practices (pp). (e) a belongs to deceiving practices (dp). (f) a performs medical purposes (mp).
Conclusions	C1 m under the scope of the AIA. C2 a is *unacceptable risk* (u). C3 m is a *high-risk* system (r). C4 a is a *non-high-risk* system (n)

[9] The definition of *software* is in accordance with the ISO/IEC/IEEE 24765:2017 as a "[…] combination of statements in a programming language […] that enable computer hardware to perform computational or control functions […]".

We connected the propositions with logic connectives and associated them with a specific conclusion, shown in Table 5. Overall, when any proposition in implication (1) is *false*, the MD is out of the scope of the AIA, i.e., the AIA is not applicable for compliance. The implication number (1) is critical to establishing an initial decision on whether the device might be considered under the AIA, which is preconditioned by the definition of an AI system (Article 2.1). Once this implication is true, the pathway to determine what classification in the AIA the device begins by assessing unacceptable practices. We establish implication (2) as predominant among implications (3) and (4). This is because there is no relevance whether the AI system (device itself or an AI accessory) is classified as high- or non-high-risk; this will be banned from the European Union market if its intended purpose falls into unacceptable risks. When implication (2) is *false*, the following implications determine whether the device is high- (implication 3) or non-high-risk (implication 4) and deceiving risks if applicable. When it is determined that an MD falls under the scope of the AIA, obligations, and requirements shall be considered alongside the MDR (Article 43). It is important to note that the *safety components of a product* (condition 3.b, Table 3) are not considered for this analysis, as this is related to devices considered *machinery* and requires further analysis of the MDI. A graphical representation of these implications is shown in Figure 5, which is further discussed in Section 4.1 (Classification of devices in the AIA). The color code in the flow chart represents the following: items in yellow are the designed propositions, orange elements are conclusions, and the blue ones are additional information related. Some items included an identification (ID) code for easy referencing when discussing the diagram. The syntaxis of this code is the prefix $FC\{N\}$ where FC stands for flow chart and $\{N\}$ is a positive integer number.

Table 5
Implications formulated from propositions and conclusions presented in Table 4.

	Implications	Conditions Table 3	Propositions Table 4	Comments
1	$M: m(p)$ $S: s(m)$ $A: a(s)$ $C1: m \in aia$ $if\ M \wedge S \wedge A\ is\ true,$ $then\ C1\ is\ true$	(1) and (4.a)	(a), (b), and (c)	Root implication. MDs under the scope of the AIA. If this condition is *false*, other conditions are not relevant. In other words, whether AI is embedded in MDs is not under the definition of AI systems per the AIA. Hence it is out of the scope of the proposal.
2	$U: a \in pp$ $C2: u(a)$ $if\ C1 \wedge \neg U\ is\ false,$ $then\ C2\ is\ false$	(2)	(d)	Predominant implication. Other classifications are irrelevant if an AI system embedded in an MD fall into prohibited practices. This should be taken as a predominant classification.
3	$M: mp(a)$ $D: a \in dp$ $C3: r(m)$ $if\ C2 \wedge (M \vee (M \wedge D))$ $is\ true\ then\ C3\ is\ true$	(3.a) and (4.a)	(e) and (f)	The MD is part of the list in Annex II from the AIA, and the device is a *product itself* (SaMD). If this is false, we are dealing with SiMD, e.g., AI systems, as an accessory. If *deceiving* practices are identified, additional transparency obligations must be considered.
4	$C4: n(m)$ $if\ C2 \wedge (\neg M \vee (\neg M \wedge D))$ $is\ true\ then\ C4\ is\ true$	(3.a) and (4.a)	(e) and (f)	The MD is listed in Annex II but does not perform medical purposes. Hence it is an accessory. Other than machinery devices, SiMD is categorized as a non-high-risk system. If *deceiving* practices are identified, transparency obligations must be considered.

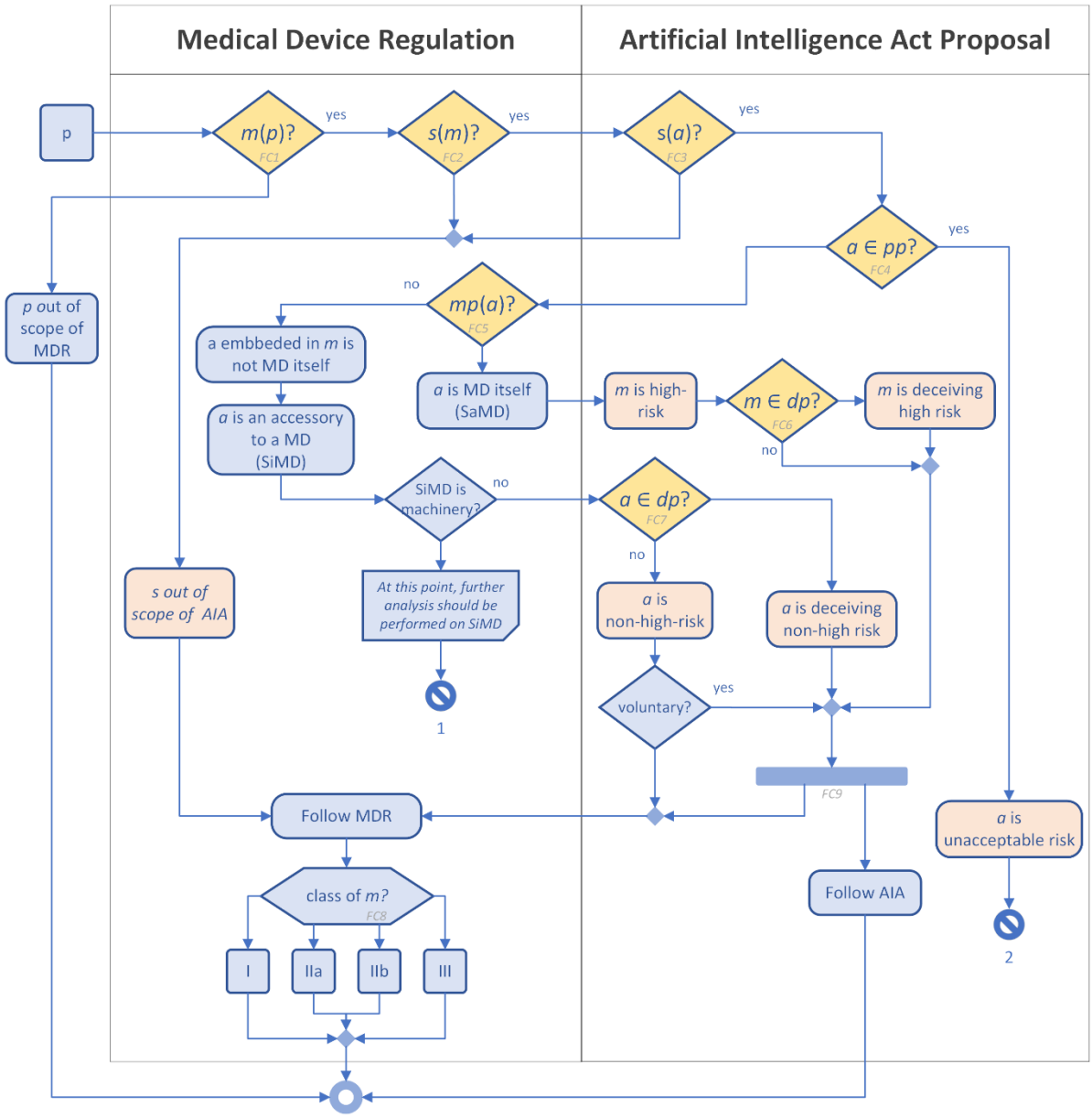


Figure 5. Flow Chart for the classification of SaMD and SiMD (excluding machinery) under the AIA.

4 Discussion

This section discusses the flow chart designed in Section 3 (Analysis) around SaMD and SiMD, excluding machinery devices and general-purpose AI Systems. Additional observations and suggestions are discussed concerning terminology used in the AIA proposal.

4.1 Classification of devices in the AIA

In this subsection, some points will be discussed about the flow chart crafted (Figure 5) in terms of SaMD and SiMD (excluding machinery devices):

- The initial graph presented (Figure 3) suggested that MDs fall into the high-risk classification in the AIA. The flow chart delivered in our analysis showed that MDs might fall into other classifications and not just into high-risk.

- The proper classification of the MDs depends on whether the device contains software and whether such software has one or more specific AI methods and approaches. Hence, this could be applicable for MDs that contain software: SaMD and SiMD.
- SaMD adopting specific AI techniques for medical purposes may fall into three categories: high risk, high and deceiving risk, or unacceptable risk. SiMD with specific AI techniques may fall into three categories: non-high risk, non-high and deceiving risk, or unacceptable risk. Notice that in the flow chart, SaMD and SiMD classified as *unacceptable risk* are not directly represented as it is irrelevant if the device is a SaMD or SiMD. The AI system will be banned from the European market (see exception 2 in the flow chart). However, the following statements are understood.
- On the one hand, when an AI system is classified as *unacceptable-risk*, and this is a device itself, i.e., SaMD, the *device* could be classified as unacceptable, as the AI system is the device itself. Conversely, MDs embedding an AI system to support the performance of the device, i.e., SiMD, the AI accessory, is classified as unacceptable, not the device. The classification of SaMD and SiMD is illustrated in Figure 6.
- Note that SiMD may be classified as high-risk when the device is considered machinery, or the AI system is used as a safety component. Machinery products fall under different legislation, the MDI. However, further analysis is required (see exception 1 in the flow chart).
- An MD will contemplate two classifications separately: one classification in the MDR and another one for the AIA. This is also understood as the fact that the device does not inherit the classification of the AI system. This statement is in according with Recital 31, which states, "*The classification of an AI system as high-risk pursuant to this Regulation should not necessarily mean that the product [device]… is considered 'high-risk' under … the relevant … legislation that applies to the product [device]*". This also means that it is irrelevant to the position of the block of device classes in the flow chart (see FC8), as these two classifications from the AIA and MDR are independent. Although, we suggest locating this block of device classes after assessing unacceptable risks to avoid re-designing tasks.
- Obligations and requirements shall be considered alongside the MDR when an MD falls in the scope of the AIA (see FC9). This depends on the classification assigned to the MD in the AIA. For SaMD, obligations and requirements in Chapter 2 of Title III must be considered additional to the MDR. For SiMD classified as non-high risk, the manufacturer determines whether to apply codes of conduct (Article 69) based on the requirements set out in Chapter 2 of Title III in the AIA.

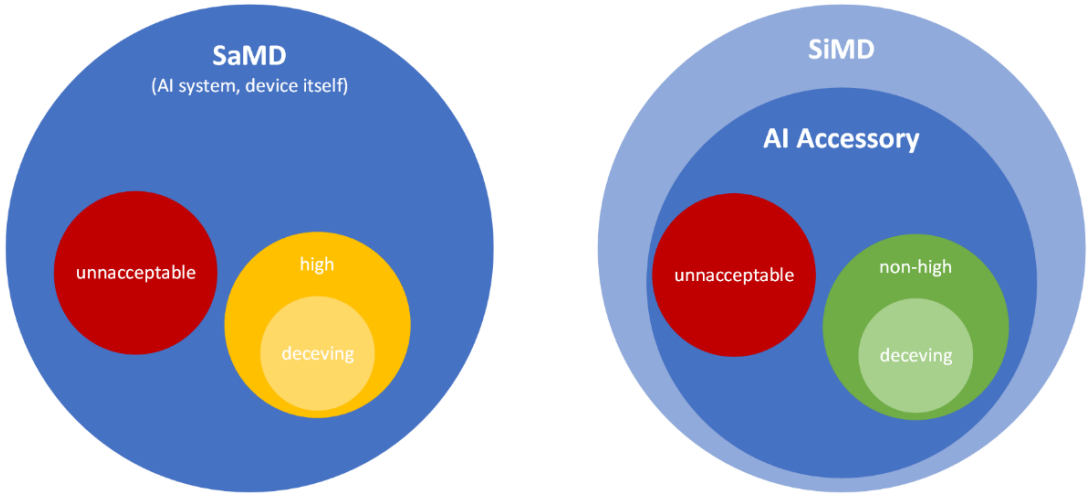


Figure 6. Classification of SaMD and SiMD (excluding machinery products) in the AIA proposal.

4.1.1 Example of Classification of SaMD in the AIA

To illustrate the discussion in Section 4.1, we will introduce a simple example from a high-level perspective based on a real-world mobile app that is considered an MD. Notice that for this scenario, we will use the term *provider* to refer to a manufacturer that develops an AI system (or has an AI system developed by a third party) for medical purposes and markets the device (Article 3.2 in the AIA and Article 2.30 in the MDR). Let us assume this mobile app is intended for *symptoms checker* purposes and is considered a Class I SaMD and CE marked accordingly. For this example, to identify the classification of the device in the AIA proposal, the principal features to consider are the assessment tool (AI Chatbot) and Machine Learning methods used to identify symptoms and possible conditions. The following could be evaluated[10] from a high-level perspective based on the flow chart and IDs presented in Figure 5:

- FC3. The symptoms checker on the mobile app contains AI techniques and approaches. These AI techniques and approaches are part of the branch of Machine Learning, which is listed in the definition of AI system in the AIA. Based on this, the symptoms checker should be considered an AI system under the AIA.
- FC4. The intended use of the device does not seem to fall into unacceptable practices. In general terms, this app does not perform real-time biometric surveillance, does not use subliminal manipulation of behavior beyond someone's consciousness, does not exploit the vulnerability of a specific group, or does not perform social scoring on natural people.
- FC5. As the symptoms checker is intended for the diagnosis/triage of symptoms based on the inputs of a user, this symptoms checker tool is an MD. Hence, it is classified as a *high-risk* AI system.
- FC6. Additionally, this app contains an AI-enabled chatbot that is used during the assessment of symptoms. This is also classified as *deceiving* due to the chatbot as impersonation and deceptive risks.
- Conclusion. The *symptoms checker* mobile app falls within the scope of the AIA, and it is classified as high- and deceiving-risk. Hence obligations and regulatory requirements from the AIA must be considered.

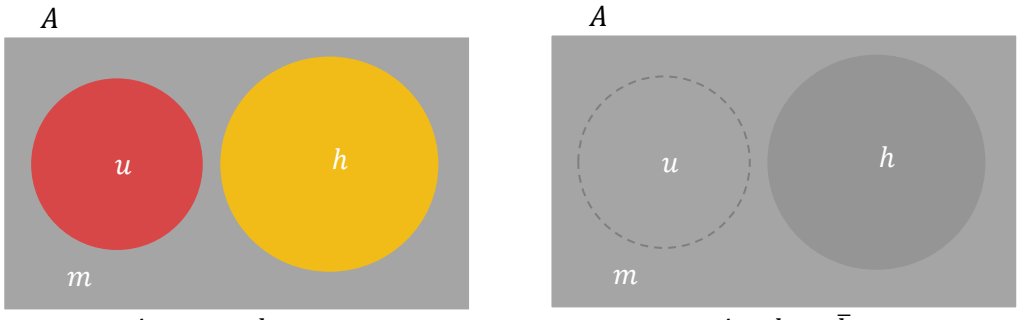
This mobile app example is classified as a high- and deceiving-risk AI system, and this classification is independent of the Class I assigned in the MDR. This means that the provider of this SaMD example must comply with (1) obligations and requirements set out in the MDR for Class I devices and (2) obligations and requirements in the AIA due to its condition of being a *high-risk* AI system, and on top of that, additional transparency obligations due to the chatbot.

4.2 The Use of the Term Non-High-Risk

The term *non-high* risk was utilized on several occasions in the AIA proposal. Even though we used this term during our analysis, we must bring up the following observation. It was also found that the term *non-high risk* has related expressions used as synonyms, such as "*not high-risk*" and "*other than high-risk*." It is assumed that the AIA introduces the term *non-high risk* to refer to any AI system that is *less* than high-risk. Although, by interpreting the term in a logical analysis, this term might bring confusion. Let us represent the risk classification for AI systems (A) in a Venn Diagram to illustrate this misleading term. For this exercise, the ideal representation of high-risk (h) and unacceptable-risk (u) AI systems are by pairwise mutually exclusive sets. The rest of the universe of A will be represented as m (see Figure 7, left side). Please, note that deceiving-risk AI systems are not represented in the Venn Diagram, as this classification overlaps with high- or non-high-risk; hence, there is no case in which an AI system is deceiving on its own (AIA, recital 70). When referring to the negation of h, this is referred to as $\neg h$, translated as "*not high-risk*" or *non-high-risk*. Hence, when referring to *non-high-*

[10] FC1, FC2, and FC8 propositions were already covered with the pre-conditions of the example. Hence, it is not necessary to evaluate these propositions for this scenario.

risk ($\bar{h}$) AI systems, this could be understood as the set $\bar{h}$: $\{u, m\}$, represented in a light gray color in Figure 7 (see right side). This implies that $\bar{h}$ are any AI systems different than a high-risk that may cover unacceptable risk AI systems different than high-risk. We suggest introducing a definition in Article 3 to state the definition of non-high-risk AI systems or using a different term, such as minimal risk.



$A = u \cup h \cup m$

$A = h \cup \bar{h}$

where $\bar{h} = u \cup m$

Figure 7. Venn Diagram to illustrate possible misleading use of the term non-high-risk as a classification of AI systems.

4.3 Inconsistency Use of Classification Terms

It was observed that other sources report slightly different classifications besides unacceptable and high risk. We will discuss two pieces of information: the *Explanatory Memorandum* attached to the AIA and the *Regulatory Framework Proposal on Artificial Intelligence*. The AIA has a document attached called *Explanatory Memorandum* (EM). This piece clearly explains EC proposed acts, and national Parliaments use this document for examination [10]. The EM in the AIA introduces the background, reasons, and context of the proposed Act, and within subsection 5.2.2, the AI systems levels of unacceptable, high, and *low or minimal* risk. In another post [21], the legal framework was broadly described and introduced the AI system classification levels unacceptable, high, *limited*, and *minimal or no* risk. This post represents the classification as a risk-level pyramid, as shown in Figure 8. Based on the previous two materials mentioned, the following observations are formulated:

- These sources frame the risk levels slightly differently, specifically for AI system classifications other than unacceptable and high risk. The EM introduces *low or minimal*, whereas [21] *minimal to no* risk. Additionally, [21] introduces another risk classification named *limited*. Hence, it is necessary to harmonize the risk classification of AI systems and introduce a proper definition.
- Representing the AI classifications in a pyramid approach might not be appropriate. According to the short description in [21], *limited*-risk AI systems are subject to transparency obligations. As previously mentioned in Section 3.1 (Understanding the Classification of AI Systems), Recital 70 described the overlapping behavior of these with high-risk and minimal AI systems[11]. In such cases, the representation of the classifications in a hierarchical graph is limited to displaying overlapping of *limited* risk with the *high*- and *minimal*-risk classifications.
- It is unclear whether the AIA will consider AI systems low-risk or associated with an absence of risk. As previously mentioned, various sources frame the risk classification slightly differently, especially those less than high-risk. The AIA does not clarify an absence of risk but implicitly defines no obligations to systems *other than high-risk* AI systems, which may suggest low-risk conditions for some AI systems.

[11] Assuming minimal risk is "equivalent" to *non-high-risk* AI systems.

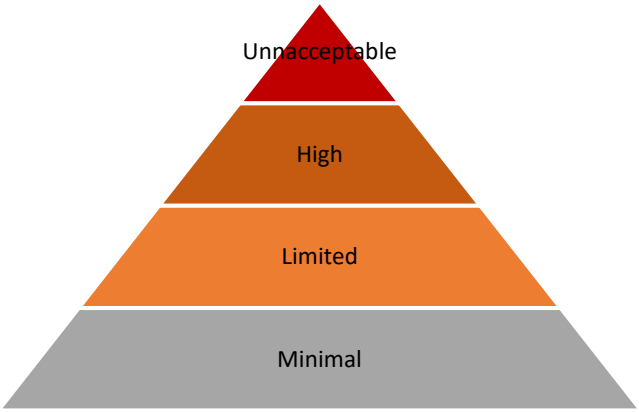


Figure 8. The risk-level pyramid illustrates the four AI system classifications [21]. This pyramid does not communicate the overlapping of *limited* in the *high* and *minimal* classifications.

4.4 Other Concerns

- The AIA established that some practices related to real-time biometric identification for law enforcement could be allowed upon authorization. Article 5.2 states, *"[…] real-time biometric identification systems […] shall comply with necessary and proportionate safeguards and conditions in relation to the use, in particular as regards the temporal, geographic and personal limitations […]*", but it is not clarified whether these systems would be subject to regulatory requirements such as those set out in Chapter 2 of Title III. This might represent a regulatory gap in the proposed legal framework.
- The term *product* and *final product* has also been used in some sections of the AIA. It is not clear if *product* and *final product* refers to the same artefact. For *final product* it is interpreted that this term is used to describe the products from other NLF legislations; therefore, the word *manufacturer* has been used alongside the term *product*. If these terms refer to the same artefact, we suggest fixing a single term for harmonization.
- The terms *stand-alone* and *component of a product* have been used in the EM and in the AIA. Although, these are not defined in the proposal. It is not clear if *stand-alone* is a synonym of *a product itself*, and if the terms *component* and *safety component* refer to the same artefact. We suggest using a single term to harmonize terminologies in the document.
- The classification of MDs which fall under the AIA is expected to adhere to the guidelines and procedures mentioned in the proposal. However, the AIA is based on a risk-based approach, and the AIA does not define the term *risk* explicitly. Therefore, it would be helpful to have the provision of the term *risk* defined explicitly rather than referencing from other memorandums and articles, as the term *risk* may have different intensities of use for each domain. This will ensure that there are no loopholes in the proposal, and this will help the AI community to move rapidly towards safe and trustworthy AI systems, as well as responsible AI, and this will serve the MD domain immensely.
- Pronouns are used in Article 24.3, which impairs objectivity. This Article says: "… *Where the legal act listed […] enable the manufacturer of the product to opt out from a third-party conformity assessment […] that manufacturer may make use of that option only if he has also applied harmonized standards or […] common specifications […] covering the requirements set out in Chapter 2 of this Title [III]"*. From the previous sentences, the term *manufacturer* is referred to as *man*, using the pronoun *he*. It is recommended to rephrase such sentences as the regulation should sound more general.

5 Conclusion

This work discusses the classification of AI systems in the AIA proposal and its alignment with MDs. The outcome of the analysis was a flow chart used to support the understanding of the classification scope for MDs under the AIA. This work is limited to examining SaMD and SiMD, excluding machinery products and general-purpose AI systems. Despite the initial examination suggesting that all MDs would be classified as high-risk in the AIA, our analysis indicates otherwise. SaMD could fall into high-risk, high- and deceiving-risk, and unacceptable-risk classifications in the AIA. Although, there is no scenario in which SaMD is classified as non-high risk. SiMD could be classified as non-high-risk, non-high- and deceiving-risk, and unacceptable risk in the AIA. However, SiMD might be classified as high-risk if the device is considered a machinery product, but further analysis of the MDI is required. Notably, an MD does not inherit the risk associated with the classification in the AIA, which would result in the Class assigned in the MDR remaining unchanged. For instance, if a device Class I (associated with low risk) is classified as high-risk in the AIA, the classification in the MDR remains unchanged. Consequently, manufacturers should take both classifications separately, considering applicable requirements and obligations in the AIA and the MDR. Additional terminology-related concerns were also observed. First, the term non-high-risk could be misleading, as unacceptable AI systems could also be interpreted as non-high-risk systems. This is important to consider for better control of the term; hence we suggest defining it or using a different term, such as minimal risk. Second, other sources report slightly different classification terms, which may lead to confusion regarding the MDR and AIA. This issue may also lead to uncertainty about whether the AIA considers AI systems entirely risk-free or that they pose minimal or low risks. Finally, terms such as stand-alone and risk are not defined in the AIA, which may limit the interpretations of the proposed legislation. For future work, exploring the requirements set out in Chapter 2 of Title III in the AIA and comparing them with the safety and performance requirements in the MDR will be interesting. Additionally, a similar analysis presented in this paper could be explored but in alignment with the U.S. Food and Drug Administration initiatives for the adoption of AI in MDs.

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