Interplay of Medical Devices and AI

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08 May 2025

Agenda

01 The EU AI Explained

02 AI under the MDR

03 Change Management and Reporting

04 Case Study Change Management

05 Cybersecurity Aspects

06 Post Market Surveillance

07 Challenges in the Certification Process

08 SaMD Team

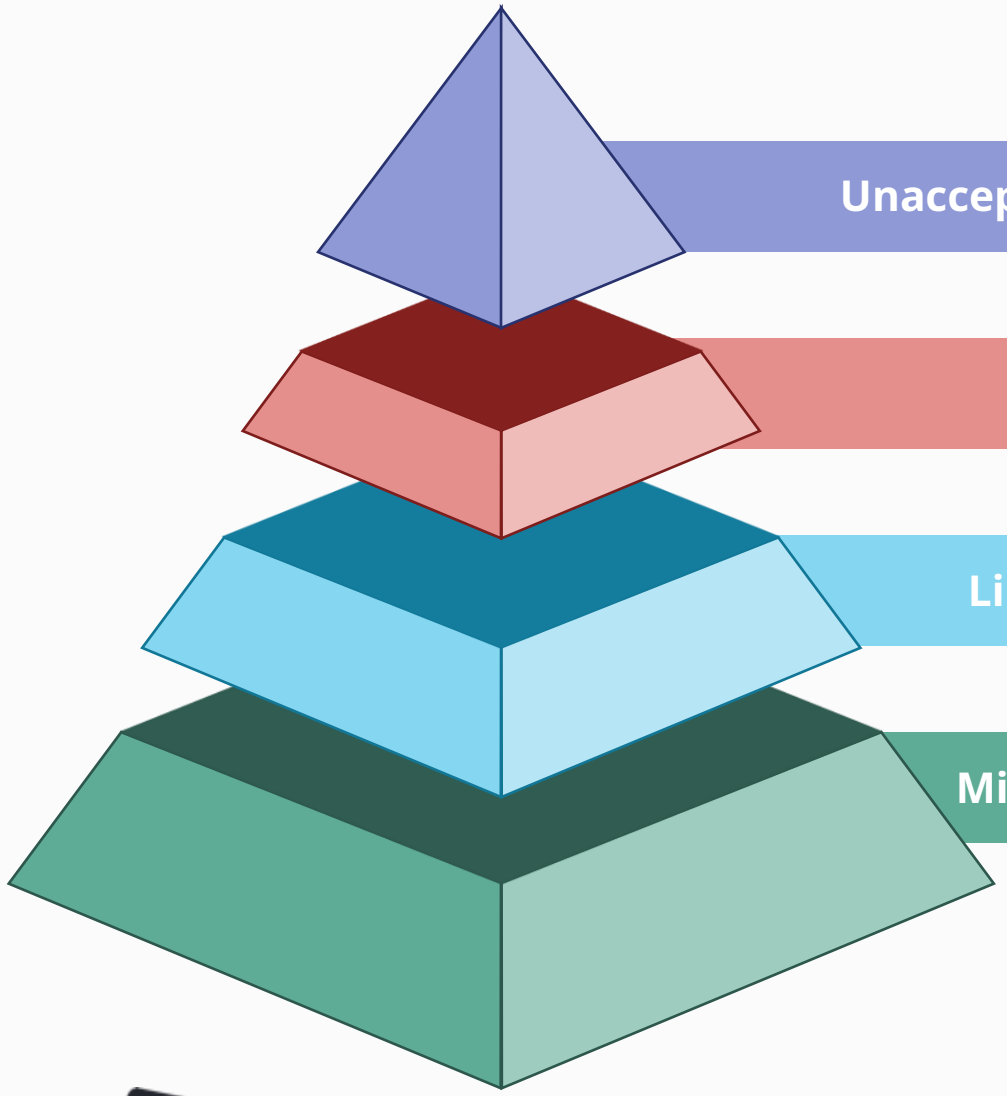
Disclaimer

What is presented today is based on our current knowledge and interpretation of the MDR and the latest available MDCG guidance.

BSI does not consent to the recording of its staff without their express prior consent.

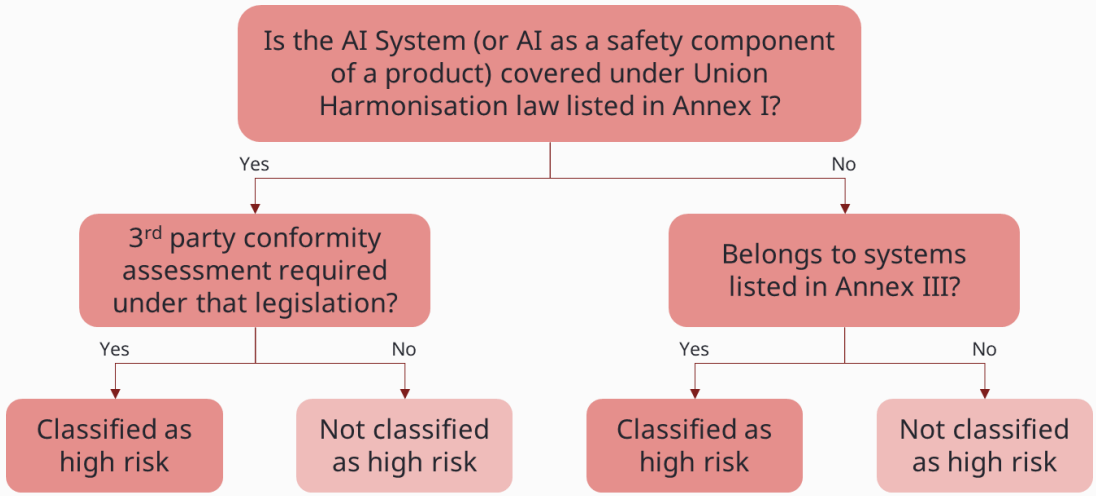
The EU AI Act

What systems fall under the EU AI Act?



Unacceptable	Systems that contravene Eu values because they violate fundamental rights are banned from EU
High	AI applications listed in Annex III or that require third party conformity assessment under any legislation listed in Annex I. Additional obligations are introduced
Limited	AI applications introducing a clear risk of manipulation. Deployers should be informed that an AI is involved
Minimal	Majority of AI applications, no additional obligations are introduced

What systems fall under the EU AI Act?



Annex I: List of Union Harmonisation Legislation

2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51);

10. Regulation (EU) 2016/426 of the European Parliament and of the Council of 9 March 2016 on appliances burning gaseous fuels and repealing Directive 2009/142/EC (OJ L 81, 31.3.2016, p. 99);

11. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1);

12. Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).

Related: Recital 50 and Recital 51

Section B – List of other Union harmonisation legislation

13. Regulation (EC) No 300/2008 of the European Parliament and of the Council of 11 March 2008 on common rules in the field of civil aviation security and repealing Regulation (EC) No 2320/2002 (OJ L 97, 9.4.2008, p. 72);

What high-risk AI providers will need to do?

Conformity assessment

Assessment and surveillance of AI Management System

AI Quality Management Systems are mentioned in **Article 17** of the **EU AI Act.**
One potential avenue for presumed conformity is through **ISO 42001 certification** which provides a certifiable framework in which AI systems can be developed and deployed as part of an AI assurance ecosystem.
The global standard is **applicable to all industries** and specifies the requirements for establishing, implementing, maintaining and continually improving an AIMS.

Technical Documentation review

For **high-risk AI systems** covered by the Union harmonisation legislations listed in Section A of **Annex I**, the provider shall follow the **conformity assessment procedure as required under those legal acts**. EU **AI Act requirements** apply to those high-risk AI systems and **are part of that assessment**. Notifies Bodies which have been notified under both AI Act and those legal acts will control the conformity of the high-risk AI systems with the AI Act requirements.

AI models and datasets verification

In examining the technical documentation, the notified body may require that the provider supply further evidence or carry out further test. Where the notified body is not satisfied with the tests carried out by the provider, **the notified body shall itself directly carry out adequate tests**, as appropriate.

AI under the MDR

AI under MDR

1. MDR

2. Technical Documentation Requirements

3. State of the art

The EU Medical Device Regulation (MDR) (2017/745) replaces the EU Medical Devices Directive, and establishes a regulatory framework for medical devices that **safeguards public health and safety** while supporting the competitiveness of the market.

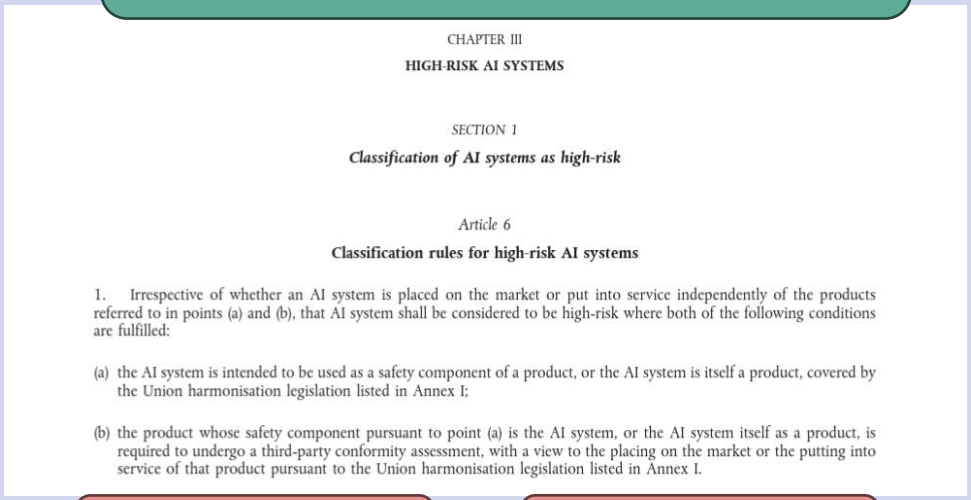
Medical devices are categorized in **different risk classes by their intended use** and risk-specific obligations are introduced for manufacturers.

Compliance with MDR requirements is assessed through a **Conformity Assessment**.

AI under MDR

MDR 2017/745

AI ACT



CHAPTER III

HIGH-RISK AI SYSTEMS

SECTION 1

Classification of AI systems as high-risk

Article 6

Classification rules for high-risk AI systems

1. Irrespective of whether an AI system is placed on the market or put into service independently of the products referred to in points (a) and (b), that AI system shall be considered to be high-risk where both of the following conditions are fulfilled:

(a) the AI system is intended to be used as a safety component of a product, or the AI system is itself a product, covered by the Union harmonisation legislation listed in Annex I;

(b) the product whose safety component pursuant to point (a) is the AI system, or the AI system itself as a product, is required to undergo a third-party conformity assessment, with a view to the placing on the market or the putting into service of that product pursuant to the Union harmonisation legislation listed in Annex I.

Safety Component

AI System

High Risk

→ AI system shall be considered to be **high-risk** where it is used as a **safety component** of a product, or the **AI system is itself a product** and is required to undergo a third party **conformity assessment pursuant to Annex I.**

→ **Conformity assessment** required by a Notified Body under the **MDR** for

Class Im,Is,IIa,IIb and III

Rule 11 for Software

Classification based on MDR Annex VIII Clssification Rules

AI under MDR : What is a ‘safety component’?

AIA

- ‘safety component of a product or system’ means a component of a product or of a system which **fulfils a safety function** for that product or system, or the **failure or malfunctioning** of which endangers the **health and safety** of persons or property;

Article 3(14) of the AI Act

MDR

- No ‘safety component’ definition.
- **‘device deficiency’** means any inadequacy in the identity, quality, durability, reliability, safety or performance of a investigational device, including malfunction, use errors or inadequacy in information supplied by the manufacturer.
- **Does AIA failure of a safety component match the device deficiency?**

Article 2(59) of the MDR

AI under MDR

1. MDR

2. Technical Documentation Requirements

3. State of the art

Article 10
General obligations of manufacturers

Article 52
Conformity assessment procedures

Annex II
Technical documentation

Annex III
Technical Documentation on Post-market Surveillance

Annex IX
Conformity Assessment Based on a Quality Management System and on Assessment of Technical Documentation

AI under MDR

1. MDR

2. Technical Documentation Requirements

3. State of the art

ANNEX I

GENERAL SAFETY AND PERFORMANCE REQUIREMENTS

CHAPTER I

GENERAL REQUIREMENTS

1. Devices shall achieve the performance intended by their manufacturer and shall be designed and manufactured in such a way that, during normal conditions of use, they are suitable for their intended purpose. They shall be safe and effective and shall not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art.

[...]

17.2. For devices that incorporate software or for software that are devices in themselves, the software shall be developed and manufactured in accordance with the state of the art taking into account the principles of development life cycle, risk management, including information security, verification and validation.

MDR and AI during the transition period

Why?

GSPR – 17.2 For devices that incorporate software or for software that are devices in themselves, the software shall be developed and manufactured in accordance with the **state of the art** taking into account the principles of development life cycle, risk management, including information security, verification and validation.

What?

The state of the art in AI has evolved, and continues to do so, with an increasing and more evident associated risk.

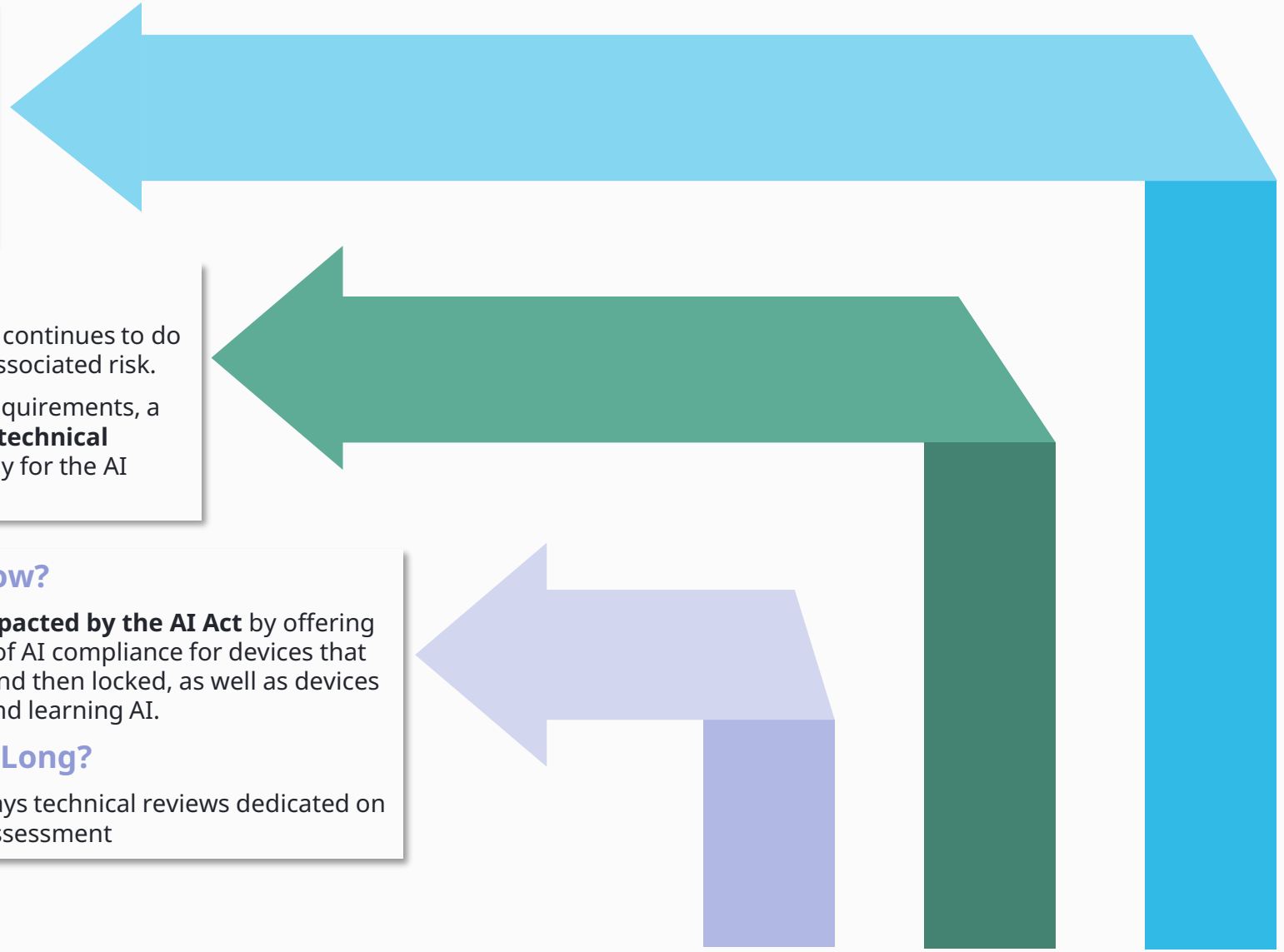
Given this and the applicable MDR/IVDR requirements, a team of **AI experts will undertake a technical documentation assessment** specifically for the AI components of the device.

How?

BSI supports all industries impacted by the AI Act by offering an in-depth technical analysis of AI compliance for devices that were developed/trained on AI and then locked, as well as devices with living and learning AI.

How Long?

AI reviews initial are usually 2-days technical reviews dedicated on the AI assessment



Conformity assessment after transition period

AI notified body assesses the **quality management system and the technical documentation**.

If necessary for the conformity assessment task, the Notified body can have **access to training, validation and testing datasets.**

If in the technical documentation there is no clear evidence that the high-risk AI system is compliant with the AI Act requirements, **the Notified Body can carry out the tests itself.**

Notified bodies can have **access to the source code** of the AI system if needed to check compliance with the AI Act requirements & if the test/audit hasn't been sufficient.

ANNEX VII

CONFORMITY BASED ON ASSESSMENT OF QUALITY MANAGEMENT SYSTEM AND ASSESSMENT OF TECHNICAL DOCUMENTATION

4.3. The technical documentation shall be examined by the notified body. Where relevant and limited to what is necessary to fulfil their tasks, the notified body shall be granted full access to the training, validation, and testing datasets used, including, where appropriate and subject to security safeguards, through application programming interfaces (API) or other relevant technical means and tools enabling remote access.

4.4. In examining the technical documentation, the notified body may require that the provider supplies further evidence or carries out further tests so as to enable a proper assessment of conformity of the AI system with the requirements set out in Title III, Chapter 2. Whenever the notified body is not satisfied with the tests carried out by the provider, the notified body shall directly carry out adequate tests, as appropriate.

4.5. Notified bodies shall be granted access to the source code of the AI system upon a reasoned request and only when the following cumulative conditions are fulfilled:

a) Access to source code is necessary to assess the conformity of the high-risk AI system with the requirements set out in Title III, Chapter 2, and

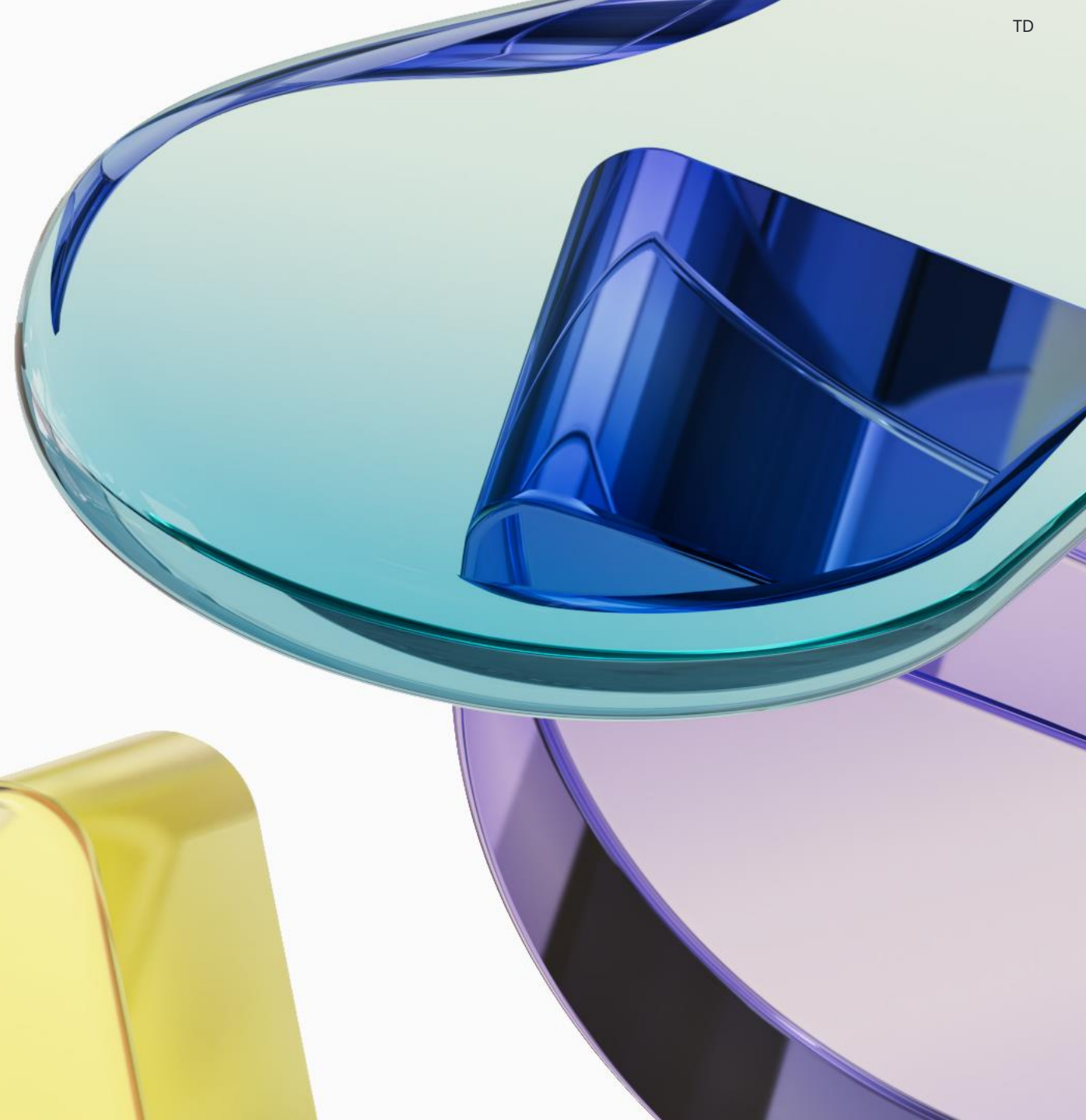
b) testing/auditing procedures and verifications based on the data and documentation provided by the provider have been exhausted or proved insufficient.

MDR and AI

Key points to consider :

- Training & testing datasets need to be clearly described in the technical documentation
- Processes, tools and environments for training, testing and deployment need to be supplied
- Is there a security risk management plan?
- Does the risk assessment cover MD and AI aspects?
- Change management plan
- Model performances
  - bias/fairness
  - robustness
  - concept drift
- Cybersecurity and data poisoning
- Transparency, autonomy, misuse, human oversight, trustworthiness and usability
- Verification and validation protocols and reports

Change Management and Reporting



Changes to approved QMS and AI Systems

Any intended change to the approved quality management system or the list of AI systems covered by the latter shall be brought to the attention of the notified body by the provider.

*The **proposed changes shall be examined by the notified body**, which shall decide whether the modified quality management system continues to satisfy the requirements referred to in point 3.2 or whether a reassessment is necessary.*

The notified body shall notify the provider of its decision. The notification shall contain the conclusions of the examination of the changes and the reasoned assessment decision.

Clause 3.4, Annex VII of the AI Act

*Any change to the AI system that could affect the compliance of the AI system **with the requirements** or its **intended purpose** shall be approved by the notified body which issued the EU technical documentation assessment certificate. The provider shall inform such notified body of its intention to introduce any of the above-mentioned changes or if it becomes otherwise aware of the occurrence of such changes. **The intended changes shall be assessed by the notified body which shall decide whether those changes require a new conformity assessment in accordance with Article 43(4) or whether they could be addressed by means of a supplement to the EU technical documentation assessment certificate**. In the latter case, the notified body shall assess the changes, notify the provider of its decision and, where the changes are approved, issue to the provider a supplement to the EU technical documentation assessment certificate.*

Clause 4.7, Annex VII of the AI Act

Substantial modification – substantial change

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

Chapter I, Article 3 of the AI Act

*Quality system changes should be considered **substantial** if (list is not exhaustive)*

- *The change **affects compliance** of the devices covered by the quality system with the **essential requirements** or the approved type/design*
- *The change **affects the compliance of the quality system** with its own regulatory requirements*

NBOG 2014-3, Section 5.2 / NB-MED/2.5.2/Rec2 Section 2.2

*2.4. The manufacturer in question shall inform the notified body which approved the quality management system of any plan for **substantial changes** to the quality management system, or the device-range covered. The notified body shall assess the changes proposed, determine the need for additional audits and verify whether after those changes the quality management system still meets the requirements referred to in Section 2.2.*

*It shall notify the manufacturer of its decision which shall contain the conclusions of the assessment, and where applicable, conclusions of additional audits. The approval of any **substantial change** to the quality management system or the device-range covered shall take the form of a supplement to the EU quality management system certificate.*

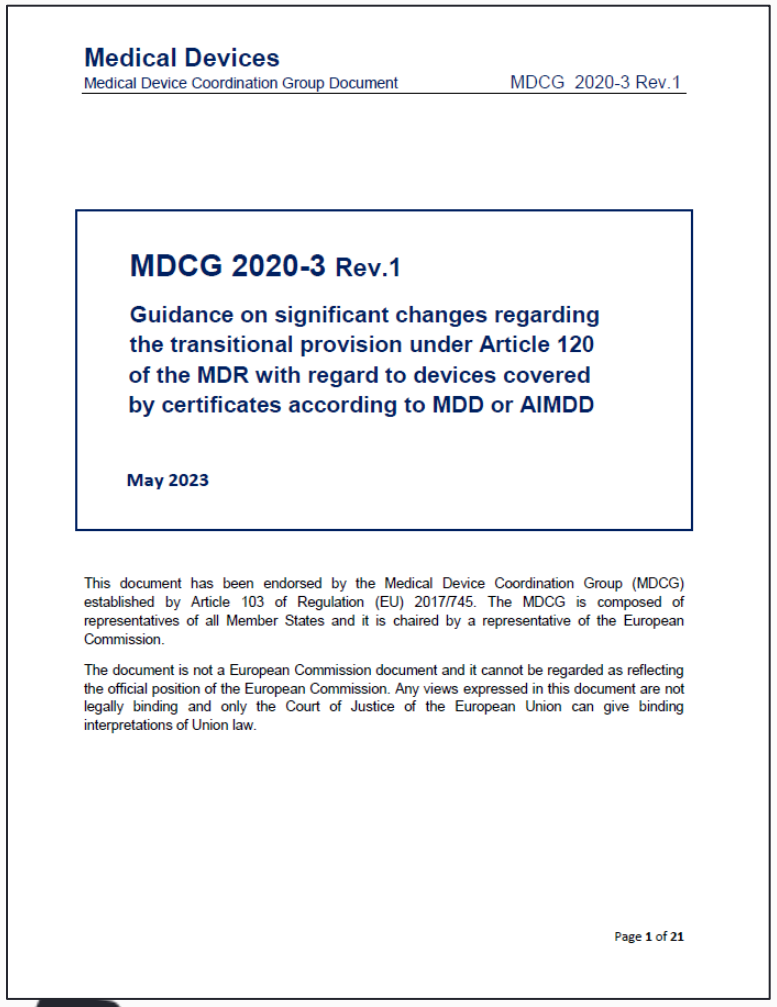
ANNEX IX, CHAPTER I, 2.4 of the MDR

*This guidance document is intended to provide clarification on the changes to a device that should be considered a "**significant change** in design or a significant change in the intended purpose" under MDR Article 120(3). Assessments should be made on a case-by-case basis.*

MDCG 2020-3 Rev1

Notification of Changes

Watch this space



Medical Devices
Medical Device Coordination Group Document MDCG 2020-3 Rev.1

MDCG 2020-3 Rev.1

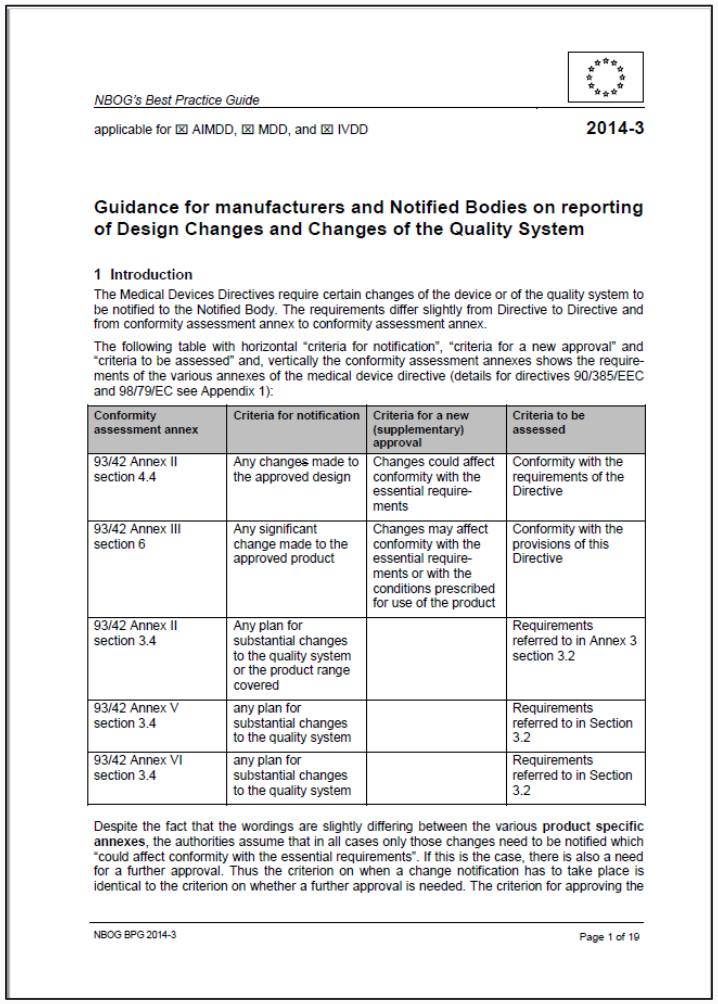
Guidance on significant changes regarding the transitional provision under Article 120 of the MDR with regard to devices covered by certificates according to MDD or AIMDD

May 2023

This document has been endorsed by the Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/745. The MDCG is composed of representatives of all Member States and it is chaired by a representative of the European Commission.

The document is not a European Commission document and it cannot be regarded as reflecting the official position of the European Commission. Any views expressed in this document are not legally binding and only the Court of Justice of the European Union can give binding interpretations of Union law.

Page **1** of **21**



NBOG's Best Practice Guide

applicable for ☒ AIMDD, ☒ MDD, and ☒ IVDD **2014-3**

Guidance for manufacturers and Notified Bodies on reporting of Design Changes and Changes of the Quality System

1 Introduction

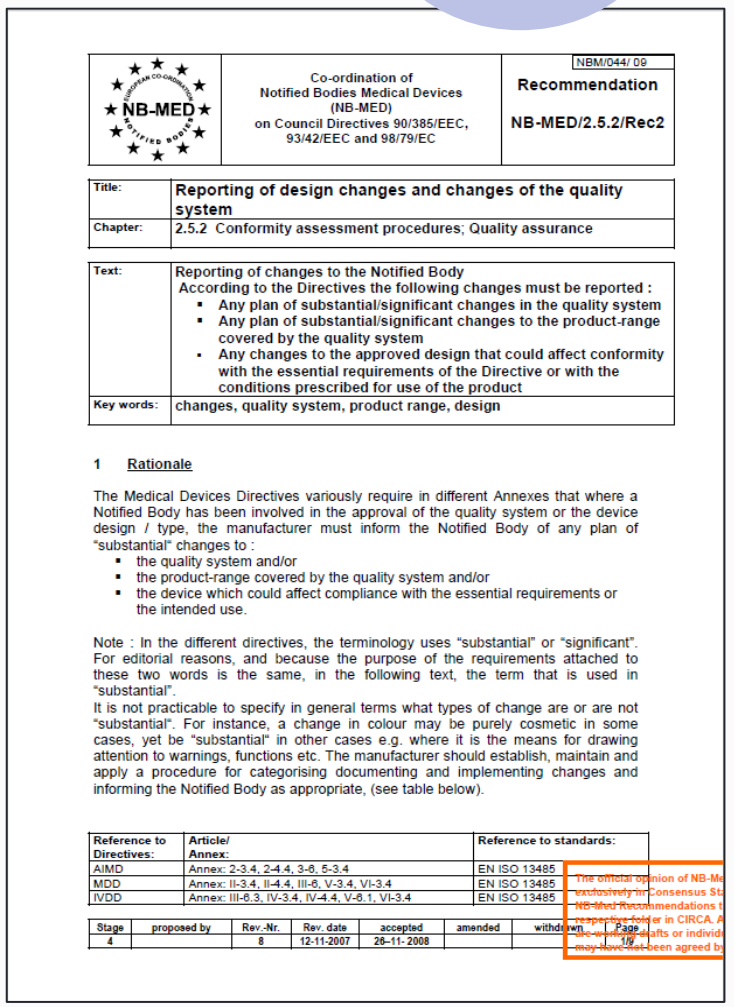
The Medical Devices Directives require certain changes of the device or of the quality system to be notified to the Notified Body. The requirements differ slightly from Directive to Directive and from conformity assessment annex to conformity assessment annex.

The following table with horizontal "criteria for notification", "criteria for a new approval" and "criteria to be assessed" and, vertically the conformity assessment annexes shows the requirements of the various annexes of the medical device directive (details for directives 90/385/EEC and 98/79/EC see Appendix 1):

Conformity assessment annex	Criteria for notification	Criteria for a new (supplementary) approval	Criteria to be assessed
93/42 Annex II section 4.4	Any changes made to the approved design	Changes could affect conformity with the essential requirements	Conformity with the requirements of the Directive
93/42 Annex III section 6	Any significant change made to the approved product	Changes may affect conformity with the essential requirements or with the conditions prescribed for use of the product	Conformity with the provisions of this Directive
93/42 Annex II section 3.4	Any plan for substantial changes to the quality system or the product range covered		Requirements referred to in Annex 3 section 3.2
93/42 Annex V section 3.4	any plan for substantial changes to the quality system		Requirements referred to in Section 3.2
93/42 Annex VI section 3.4	any plan for substantial changes to the quality system		Requirements referred to in Section 3.2

Despite the fact that the wordings are slightly differing between the various **product specific annexes**, the authorities assume that in all cases only those changes need to be notified which "could affect conformity with the essential requirements". If this is the case, there is also a need for a further approval. Thus the criterion on when a change notification has to take place is identical to the criterion on whether a further approval is needed. The criterion for approving the

NBOG BPG 2014-3 Page 1 of 19



NB-MED

Co-ordination of Notified Bodies Medical Devices (NB-MED) on Council Directives 90/385/EEC, 93/42/EEC and 98/79/EC

NBM/044/ 09

Recommendation

NB-MED/2.5.2/Rec2

Title:	**Reporting of design changes and changes of the quality system**
Chapter:	**2.5.2 Conformity assessment procedures; Quality assurance**

Text:	**Reporting of changes to the Notified Body** **According to the Directives the following changes must be reported :** ▪ **Any plan of substantial/significant changes in the quality system** ▪ **Any plan of substantial/significant changes to the product-range covered by the quality system** ▪ **Any changes to the approved design that could affect conformity with the essential requirements of the Directive or with the conditions prescribed for use of the product**
Key words:	**changes, quality system, product range, design**

1 Rationale

The Medical Devices Directives variously require in different Annexes that where a Notified Body has been involved in the approval of the quality system or the device design / type, the manufacturer must inform the Notified Body of any plan of "substantial" changes to :

- the quality system and/or
- the product-range covered by the quality system and/or
- the device which could affect compliance with the essential requirements or the intended use.

Note : In the different directives, the terminology uses "substantial" or "significant". For editorial reasons, and because the purpose of the requirements attached to these two words is the same, in the following text, the term that is used in "substantial".
It is not practicable to specify in general terms what types of change are or are not "substantial". For instance, a change in colour may be purely cosmetic in some cases, yet be "substantial" in other cases e.g. where it is the means for drawing attention to warnings, functions etc. The manufacturer should establish, maintain and apply a procedure for categorising documenting and implementing changes and informing the Notified Body as appropriate, (see table below).

Reference to Directives:	Article/ Annex:	Reference to standards:
AIMD	Annex: 2-3.4, 2-4.4, 3-6, 5-3.4	EN ISO 13485
MDD	Annex: II-3.4, II-4.4, III-6, V-3.4, VI-3.4	EN ISO 13485
IVDD	Annex: III-6.3, IV-3.4, IV-4.4, V-6.1, VI-3.4	EN ISO 13485

Stage	proposed by	Rev.-Nr.	Rev. date	accepted	amended	withdrawn	Page
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The official opinion of NB-Me… exclusively in Consensus St… NB-Med Recommendations t… respective folder in CIRCA. A… are working drafts or individ… may have not been agreed by…

Case Study

Case 1 – Change management plan

- **Device**: SaMD that uses AI-based deep learning for segmentation and aids in diagnosing, reviewing, and analysing CT scans
- **Class**: IIa
- **Intended Purpose**: support CT interpretation by providing information on abnormal areas suspicious of intracranial hemorrhage and to visualize vasculatures by removing skeletal density.
- **Change Management Plan** to include not only re-training of the model but also changes to the neural network architecture
- **Acceptance criteria** to deploy a re-trained model: performance criteria should be equal or superior to those of the original model

Questions:

- Is the change management plan acceptable?
- Are the acceptance criteria adequate?

Case 1 – Change management plan

- **Modifications to the model architecture are classified as a substantial change** according to NBOG 2014-3, and therefore, changes to the current model architecture are not permitted. Should any modifications to the model architecture occur, need to resubmit for new CE certificate.

- **Acceptance criteria** to deploy a re-trained model should take into the account not only performances, but all benchmarks involved in approving the original models (**robustness, cybersecurity, absence of unwanted biases, revisit all AI lifecycle steps**)

Post Market Surveillance

Post-Market-Monitoring System

- Providers of high-risk AI systems must establish and document an appropriate **post-market monitoring system** **based on a post-market monitoring plan** to continuously check compliance with AIA regulatory requirements.

- Medical Device Health Software with Artificial Intelligence providers can integrate the **extra AIA PMS** requirements into the already existing **PMS under the MDR**.
  - They need to use the **AI PMS template** that the Commission will issue.
  - A single PMS if achieves an equivalent level of protection.

- For AIMD, the **market surveillance authority** will be the same as under the MDR.

- AIA enforcement procedures will not apply for MD with Artificial Intelligence, **MDR procedures takes preference.**

Extra PMS requirements under the AIA:

Actively and systematically collect, document and analyse relevant data gathered from deployers or other sources, on the **AI high-risk performance throughout their lifetime.**

Evaluate the continuous compliance of the AI system with the **AIA requirements** (Chapter 2, Title III).

Analysis of interaction with other AI systems. Excluding sensitive operational data of deployers which are law enforcement authorities.

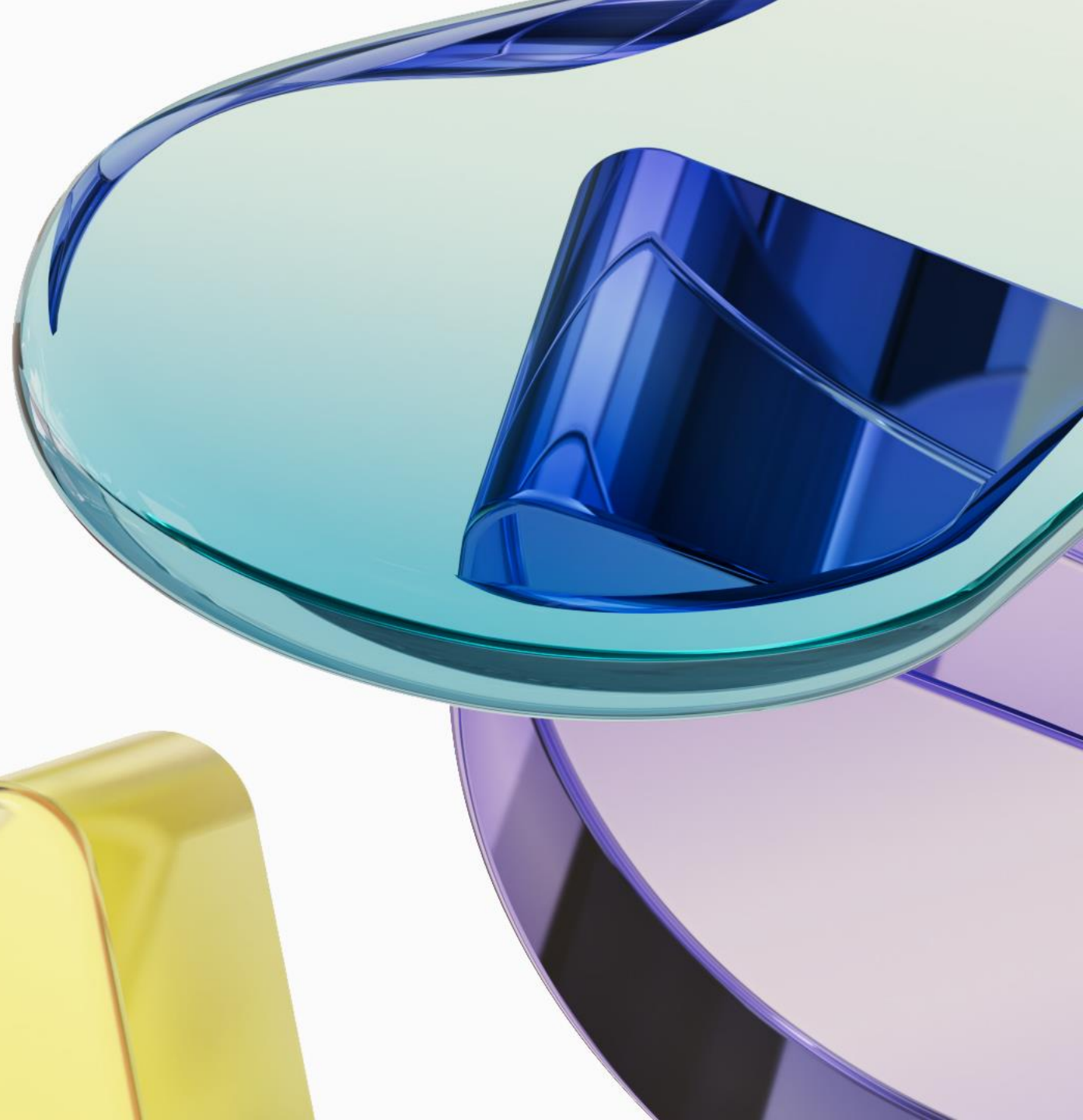
Challenges in the AI certification process

Challenges in the AI certification process

Key points:

- Lack of transparency in AI models (explainability, Back-box models like deep learning models)
- insufficient data validation : incomplete data sources, bias and quality control of datasets used for training and validation
- Risk management (lack of relevant documents related to AI e/.g: lack of a robust risk management plan to address failure during deployment)
- Generalization of AI model, mostly of the clinical performance of the AI model. Not sufficient evidence provided to support clinical claims.
- Bias and fairness has not been fully validated
- Weak / lacking processes for algorithm life cycle management

Introduction to the SaMD Team



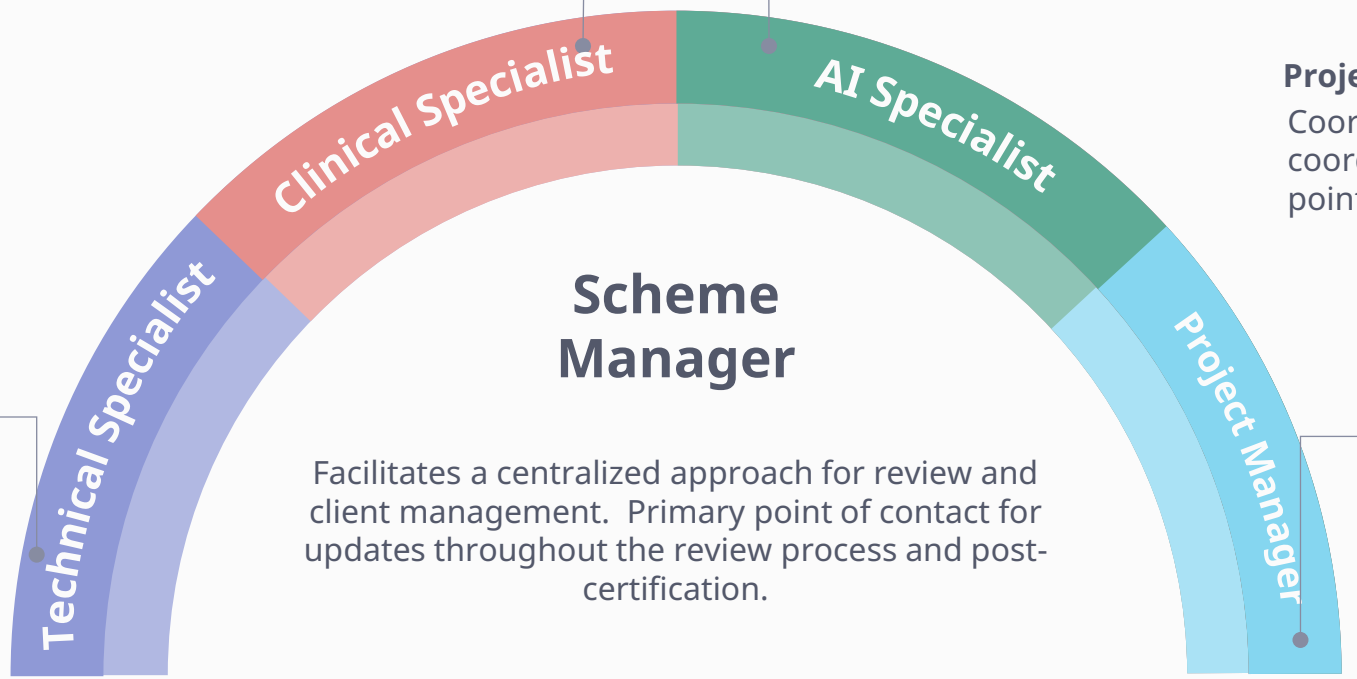
SaMD Review Team

Clinical Assessment
Focused on clinical documentation & assessment

Specialty Tech Assessments
Applicable only for devices that contain artificial intelligence or other specialty aspects

Primary Reviewer
Focused on technical documentation and assessment

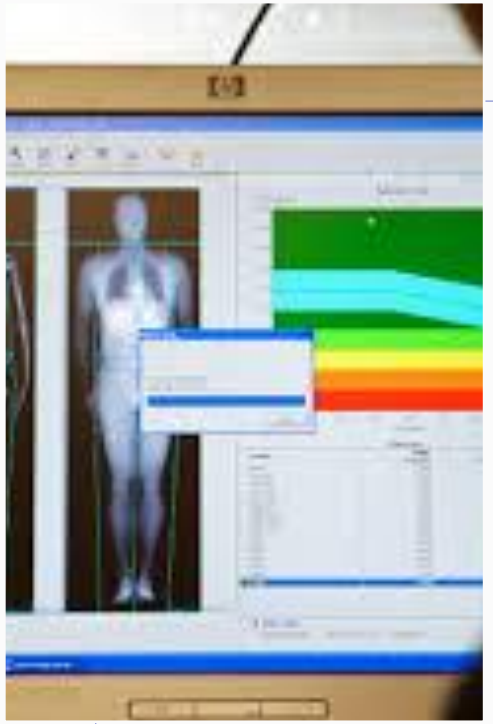
Project Manager
Coordinates scheduling of reviews and coordination of resources. Additional point of contact for review status.



The EU AI Act Meets the MDR

Inma Pérez Ruiz – AI Regulatory lead, BSI

Differentiating Software Roles in Medical Devices



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'* [1].

[1] *Article 2(1), Medical Device Regulation (EU) 2017/745.*

Differentiating Software Roles in Medical Devices

- **Medical Devices Software (MDSW)**[1] '(…) *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(…)*'

  ≋ Software as a Medical Device (SaMD)[2]

- **Software driving or influencing the use of a device**[3] *'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 (…).'*

  - Software that is considered a part/component or an accessory to a MD.
  - Art. 2 (2) MDR: an **accessory** is any instrument, including software, that supports additional functionalities to a MD .

  ≋ Software in a Medical Device (SiMD)[4]

[1] *MDCG, "Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR," 2019.*
[2] *IMDRF Guidance, 'Software as a Medical Device (SaMD): Key definitions', 2013.*
[3] *MDCG 2019-11.*
[4] *IMDRF Guidance.*

Does your software contain AI?

Article 3 (1) AI Act *"a **machine-based system** designed to operate with **varying levels of autonomy**, 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**".*

EUROPEAN COMMISSION

Brussels, 6.2.2025
C(2025) 924 final

ANNEX

ANNEX

to the

Communication to the Commission

Approval of the content of the draft Communication from the Commission - Commission Guidelines on the defintion of an artificial intelligence system established by Regulation (EU) 2024/1689 (AI Act)

Understanding the scope

AI systems can either

1) be used on a stand-alone basis, **outside** of existing product safety laws like the MDR, 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)**

For an AI system to be evaluated within the scope of the MDR, **it must be associated with a medical device product**, as described in the second option.

Are all medical devices considered high-risk under the AIA?

NO!

AI used as a **safety component** of a product OR the **AI system is itself a product**

+

Covered under Union Harmonisation law (Annex I)

+

Subject to **3rd party assessment** under such Union Harmonisation law

=

High-risk AI system = AI-enabled medical device

Risk classification under the AIA does not change the risk classification under the MDR.

Annex I - Union Harmonisation Legislation

ANNEX I

List of Union harmonisation legislation

Section A. List of Union harmonisation legislation based on the New Legislative Framework

1. Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (OJ L 157, 9.6.2006, p. 24) [as repealed by the Machinery Regulation];
2. Directive 2009/48/EC of the European Parliament and of the Council of 18 June 2009 on the safety of toys (OJ L 170, 30.6.2009, p. 1);
3. Directive 2013/53/EU of the European Parliament and of the Council of 20 November 2013 on recreational craft and personal watercraft and repealing Directive 94/25/EC (OJ L 354, 28.12.2013, p. 90);
4. Directive 2014/33/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to lifts and safety components for lifts (OJ L 96, 29.3.2014, p. 251);
5. Directive 2014/34/EU of the European Parliament and of the Council of 26 February 2014 on the harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres (OJ L 96, 29.3.2014, p. 309);
6. Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC (OJ L 153, 22.5.2014, p. 62);
7. Directive 2014/68/EU of the European Parliament and of the Council of 15 May 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment (OJ L 189, 27.6.2014, p. 164);
8. Regulation (EU) 2016/424 of the European Parliament and of the Council of 9 March 2016 on cableway installations and repealing Directive 2000/9/EC (OJ L 81, 31.3.2016, p. 1);
9. Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC (OJ L 81, 31.3.2016, p. 51);
10. Regulation (EU) 2016/426 of the European Parliament and of the Council of 9 March 2016 on appliances burning gaseous fuels and repealing Directive 2009/142/EC (OJ L 81, 31.3.2016, p. 99);
11. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1);
12. Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).

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Are all medical devices considered high-risk under the AIA?

…AI used as a **safety component** of a product OR the **AI system is itself a product…**

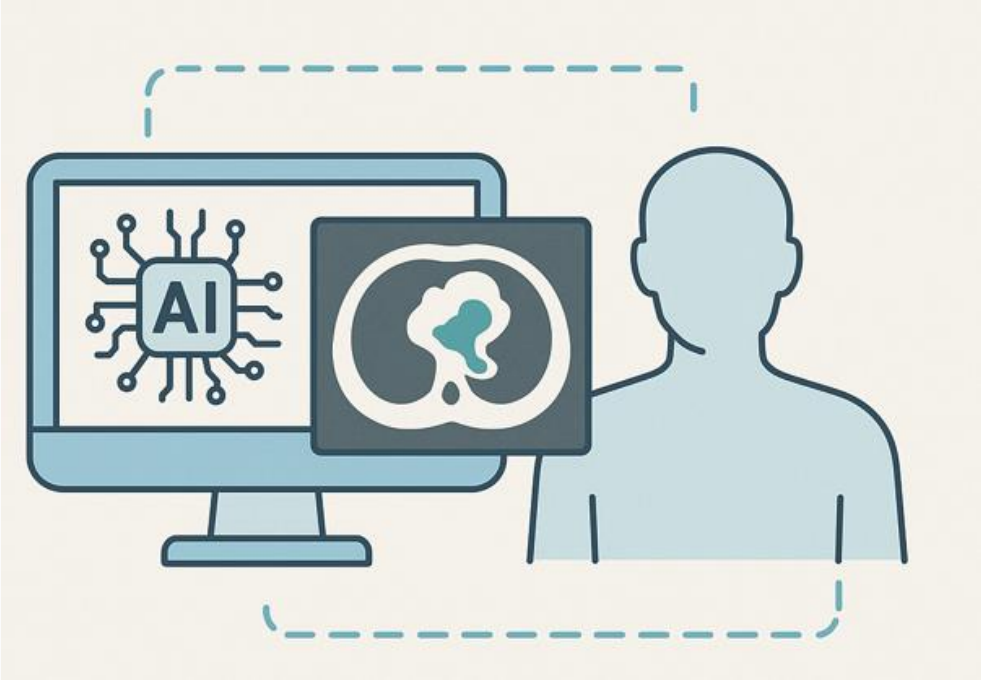
Example:

Software for automated CT image segmentation aimed at the early diagnosis of specific cancer types.

The MDSW qualifies as *'itself a product'* when the AI software functions independently of any other device and has its own intended medical purpose.

Here, the AI functions as the core medical device with a direct diagnostic purpose.

High Risk under the AIA if MDR Class IIa or higher.



Are all medical devices considered high-risk under the AIA?

…AI used as a **safety component** of a product OR the **AI system is itself a product…**

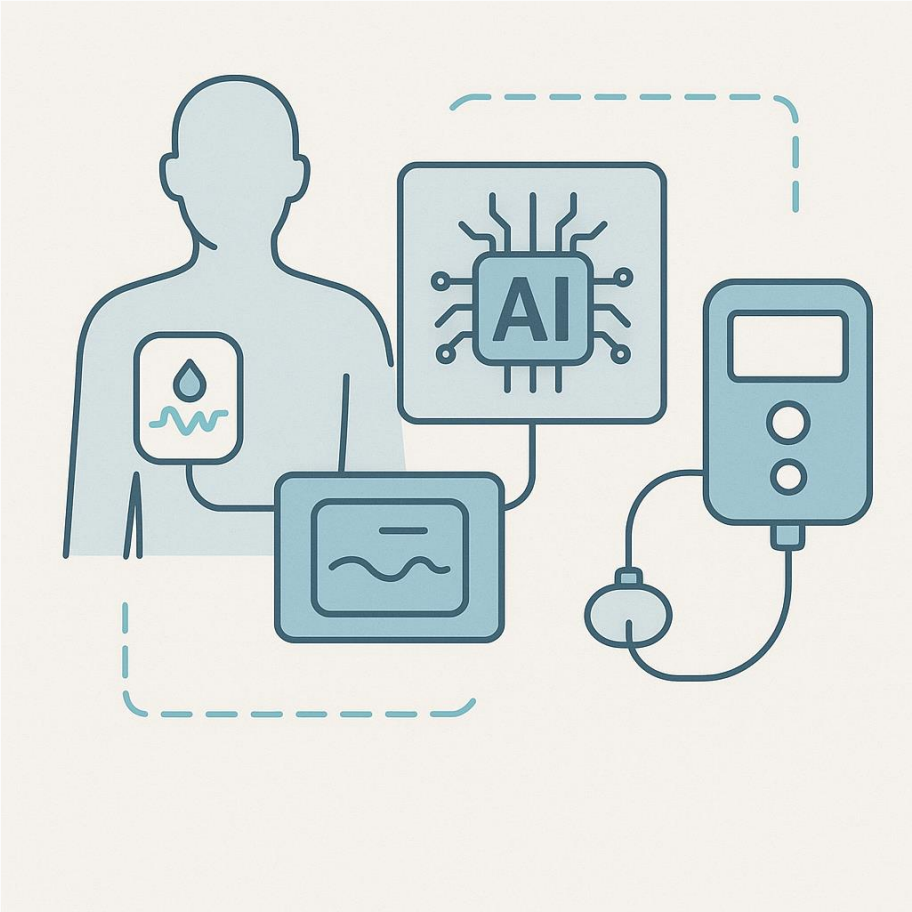
Example:

Insulin pump system with a glucose monitoring software, where an AI-based algorithm predicts blood sugar trends using continuous glucose monitoring data.

The MDSW drives or influences a (hardware) medical device and acts as a safety enhancing component with a medical purpose.

The AI component plays a safety role by adjusting insulin delivery to prevent adverse glycemic events.

High Risk under the AIA if MDR Class IIa or higher.



Are all medical devices considered high-risk under the AIA?

…AI used as a **safety component** of a product OR the **AI system is itself a product…**

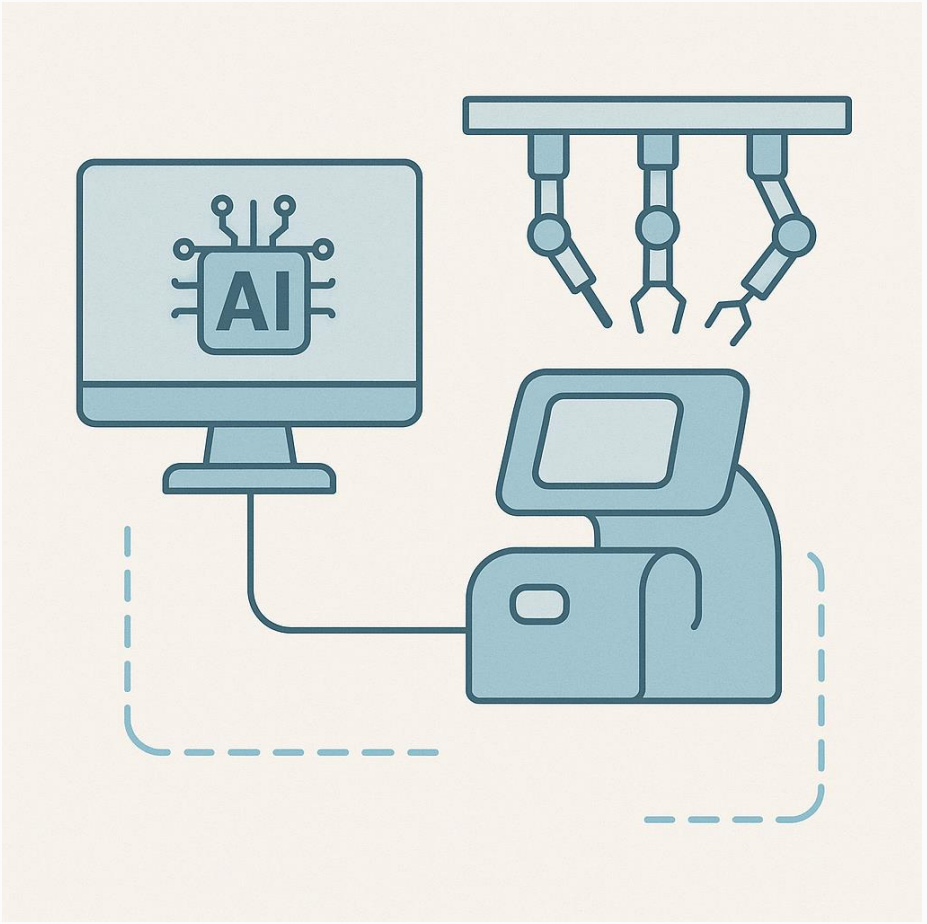
Example:

AI monitoring system that oversees hardware performance in a surgical robot.

AI-software driving or influencing the use of a medical device, where the AI component ensures the operational safety of the system but does not directly serve a medical purpose.

The AI component enhances the system's reliability and safety but does not contribute directly to medical decision-making or treatment.

High Risk under the AIA if MDR Class IIa or higher.



MDR-AIA future Commission Guidelines

Article 96

Guidelines from the Commission on the implementation of this Regulation

(e) detailed information on the relationship of this Regulation with the Union harmonisation legislation listed in Annex I, as well as with other relevant Union law, including as regards consistency in their enforcement;

What are the implementation dates (Art. 113 (c))?

12 July 2024
Publication
1 August 2024
Entry into force

2 February 2025
Prohibited AI systems

2 August 2025
Obligations for GPAI, AI Governance, plus penalties

2 August 2026
All rules of the AI Act, plus obligations for high-risk systems (Annex III)

2 August 2027
Obligations for high-risk systems (Annex I)

What happens with legacy devices (Art.111(2))?

- The date of application of obligations for “Annex I high-risk AI systems” is **2 August 2027**, meaning:
  - If the AI-enabled MD has been placed on the market/put into service **before 2 August 2027:**
    - If the AI system is subject to **significant changes** in its design or intended purpose **on or after 2 August 2027, AIA’s obligations apply**.
    - If the AI system is subject to significant changes in its design or intended purpose **before 2 August 2027: AIA obligations do not yet apply.**
  - If the AI-enabled MD is placed on the market/put into service **on or after 2 August 2027, then AIA’s obligations apply**.

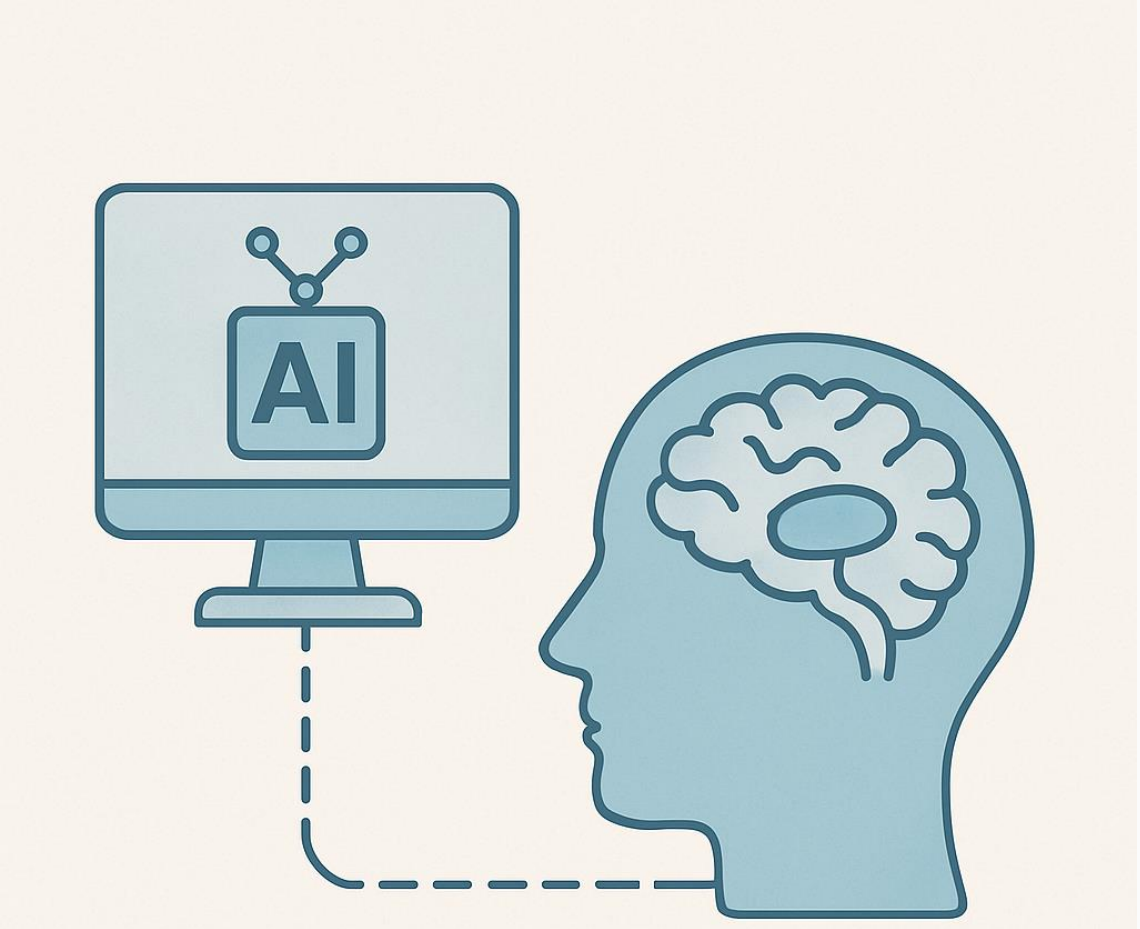
Case Study

The following example is used for illustrative purposes. Any resemblance to any organisation or product is purely coincidental.

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.



Radiopic Limited Power

- **MDR classification?**
    - It would be considered Class III medical devices due to Rule 8 since it is an active implantable device.

Radiopic Limited Power

- **Is this AI?**
  - Yes. It uses machine learning techniques, performs inference by processing brain signals to generate stimulation, operates autonomously without continuous human input and influences the physical environment (the brain).
  - Even though it's a static system it still falls within scope. The guidelines explicitly include static models, noting that the ability to learn (adaptiveness) after deployment is not a mandatory requirement for being considered an AI system.

Radiopic Limited Power

- **Is this high Risk under AIA?**
  - Yes:
    - MDSW drives or influences a (hardware) medical device. The AI component is embedded into the medical device functionality.
    - AI component is a *"safety component"*, as the failure/malfunctioning of which might endanger the health of the patient.
    - MDR Class III products are required to undergo a 3rd party conformity assessment.

Radiopic Limited Power

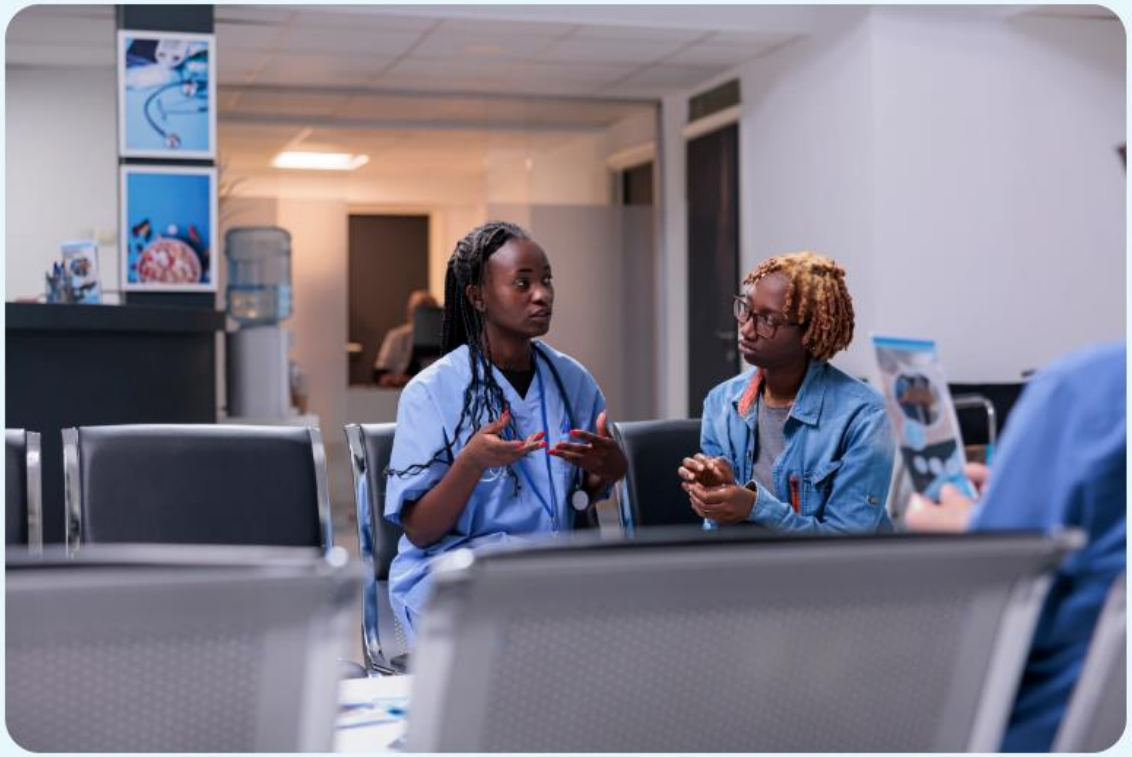
- **When is MDR & AIA aplicable ?**
  - If placed on the market/put into service after 2nd August 2027 → MDR & AIA applicable.
  - If placed on the market/put into service before 2nd August 2027 → Only MDR applicable.
    - BUT if significant changes after 2nd August 2027 → AIA & MDR applicable.

Whitepaper

Discover essential insights with our 'EU AI Act meets MDR' whitepaper

Stay informed and competitive with our latest whitepaper on the EU Artificial Intelligence Act. Understand your role in compliance with this Act, and how it interplays with the EU Medical Devices Regulation.

Our expert whitepaper, "The EU AI Act meets MDR - Everything AI-enabled medical device manufacturers need to know", is authored by Regulatory Leads and the Head of AI Notified Body at BSI.



Download Whitepaper

Thank you

Q&A