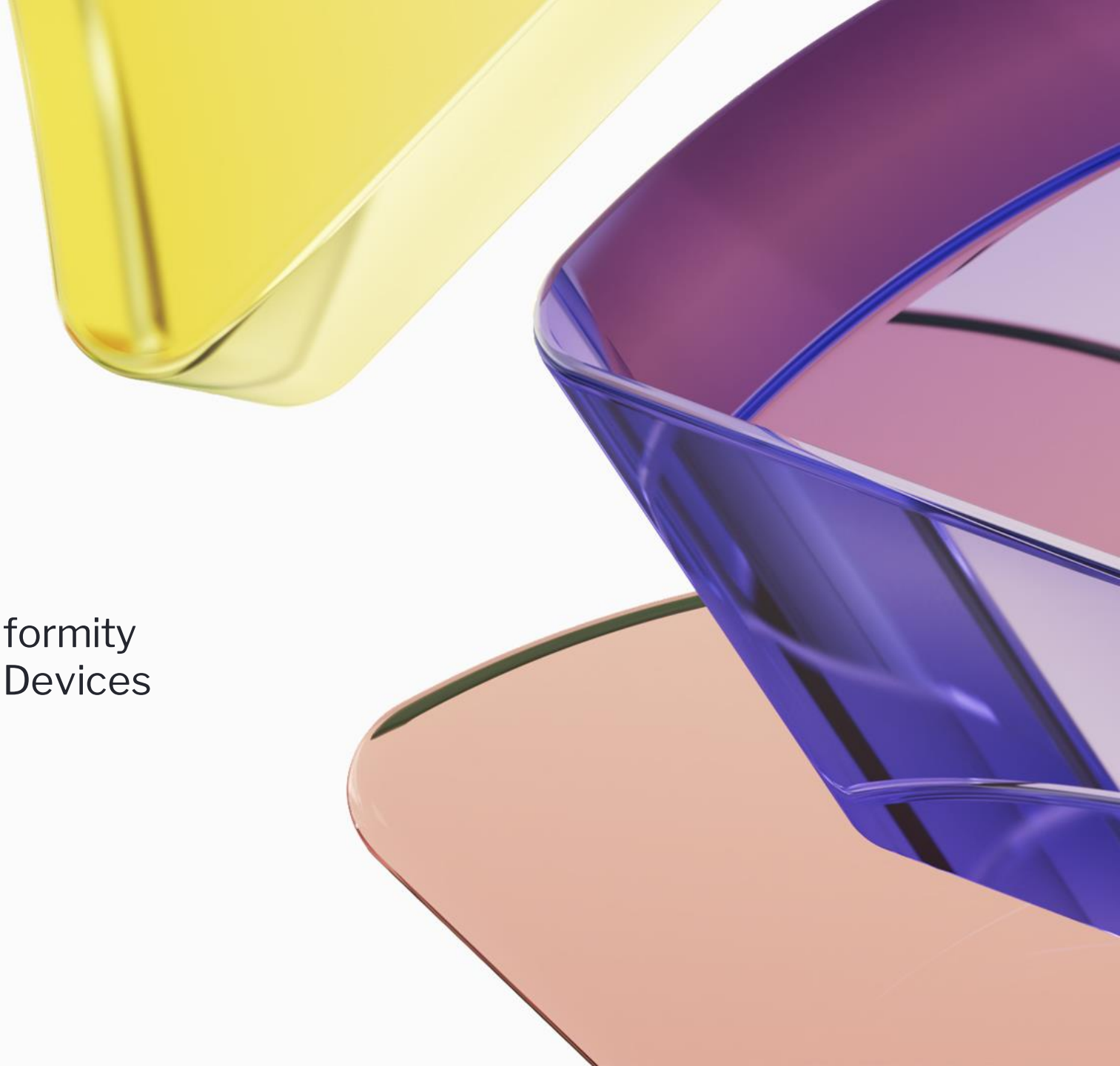


Shaping Trust in AI

Understanding the Challenges of Conformity Assessments for AI-Enabled Medical Devices

MDR & AIA scope

Notified Bodies

Post Market Monitoring Plan

Combined MDR-AIA conformity assessments

Sandboxes

Changes to AIMD

MDR & AIA requirements

Routes to conformity

MDR & AIA scope

When medical devices fall under the AIA?

A device in scope of the MDR that also qualifies as an AI system under the AI Act will need to meet obligations both under the MDR and AI Act.

1

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 **3r-party assessment** under such Union Harmonisation law.

=

High-risk AI system = AIMD

2

Certain applications specified in Annex III are also deemed high-risk. Within the healthcare sector, these include applications related to biometric classification, determining healthcare eligibility, and systems for triaging patients in emergencies.

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and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (OJ L 157, 9.6.2006, p. 24) [as repealed by the Machinery Regulation];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).

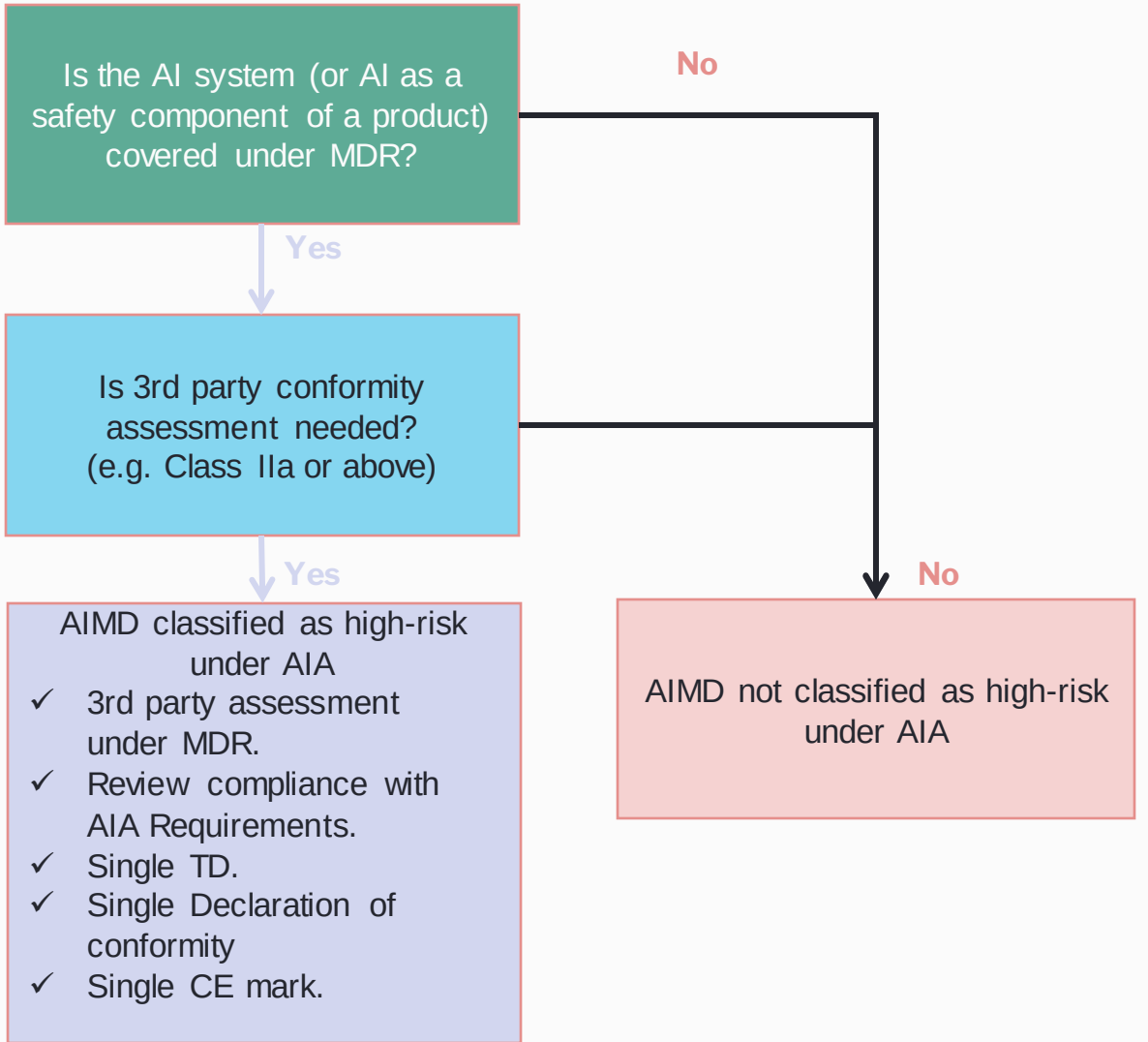
But what is ‘safety component’?

AIA	MDR
• ‘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;	• 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?**

AI competent authority/ Commission needs to clarify the scope of AIMD

When an AIMD system is considered high risk under the AIA?

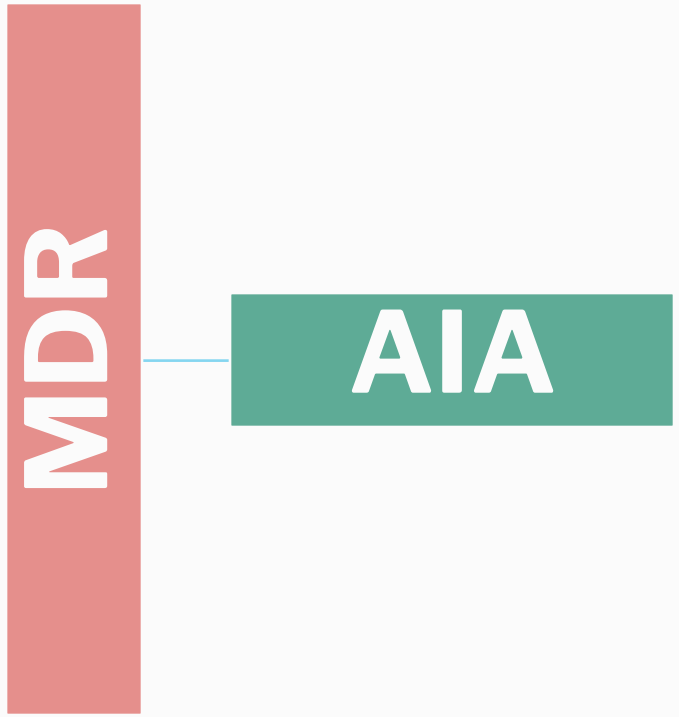
The classification of an AI system as high-risk under the AIA should **not** necessarily mean that the product whose safety component is the AI system, or the AI system itself as a product, is considered 'high-risk' under the MDR.



Vertical VS Horizontal

- MDR falls within the so-called **New Legislative Framework (NLF)** – common EU approach to CE-marking products.
- NLF legal acts are built on the legal concept that whenever a matter is regulated by two rules, **the more specific one should be applied first.** *Lex specialis* wins over *lex generalis.*
- Avoid double-regulatory burden - AIA explanatory memorandum:

*"As regards high-risk AI systems which are safety components of products, this proposal will be **integrated into the existing sectoral safety legislation** to ensure consistency, **avoid duplications** and minimise additional burdens."*



Combined MDR-AIA conformity assessments

MDR & AIA interlink

The AIA calls for a **simultaneous and complementary** application of the AIA with sectorial law.

For high-risk AI systems falling under MDR, the compliance of those AI systems with the AIA requirements should be assessed as part of the **MDR conformity assessment**.

In order to ensure consistency, avoid duplications and minimise additional burdens associated with the cumulative application of the AI Act and MDR:

- AI provider can **integrate** the necessary measures to comply with the AI Act into the procedures and documents already required under MDR.
- The compliance deadline for the AI Act is extended: AIMD with the AI Act within **36 months** following the entry into force of the text.

Combined MDR-AIA conformity assessment

Single Conformity assessment		
Single Technical documentation	Single EU Declaration of conformity	Single CE Mark

MDR & AIA requirements

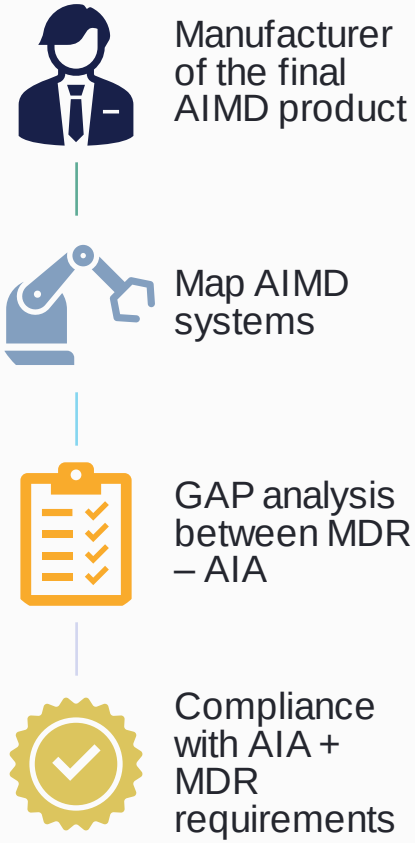
What are the additional requirements set by the AIA on AIMDs?

High risk AI enabled Medical Devices must comply with several obligations. Many of them will sound familiar to anyone pursuing CE Marking under MDR.

AIA - High-risk AI providers obligations	Similar provision in MDR?
Quality management system	✓
Risk management system	✓
Fundamental rights impact assessment	✗
Data and data governance	✗
Documentation keeping	✓
Automatically generated logs	✗
Technical documentation	✓
PMS	✓
Cooperation with competent authorities	✓
Corrective actions & duty of information	✓

AIA - High-risk AI providers obligations	Similar provision in MDR?
EU authorised representative	✓
Conformity assessment	✓
Human oversight	✗
Transparency and provision of information to deployers	✓
Accuracy, robustness and cybersecurity	✓
Sandboxes	✗
Conformity assessment	✓
Accessibility requirements	✗
EU declaration of conformity	✓
EU AI data base registration	✗
CE Mark	✓

What if AIA-MDR requirements overlap?



Blue Guide: *"Where existing legislation contains similar provisions as the Regulation, the corresponding provisions will have to be examined on a one to one basis to* ***determine which is the most specific****."*

AIA Explanatory memorandum: *"With regard to the interplay of requirements, while the* ***safety risks specific to AI systems*** *are meant to be covered by the requirements of this proposal, NLF legislation aims at ensuring the* ***overall safety of the final product*** *and therefore* ***may contain specific requirements*** ***regarding the safe integration of an AI system into the final product****."*

Notified Bodies

AI – MDR Notified Body

- Article 43(3) AIA says that Medical Devices Notified Bodies can control the AI conformity assessment as long as they comply with **art. 33(4) (Independence)** **33(9) (professional integrity)** and **33 (10) (sufficient internal competence of personnel in AI)** and all this should have been assessed when the Notified Body got the designation under the MDR.
- Compared to MDR, Notified Bodies need to meet **additional requirements** for AI conformity assessment:
  - Specialised personnel on AI.
  - Lab facilities to be able to test datasets/models, if not satisfied by manufacturer's evidence.

- All AI-enabled MD when seeking CE Mark will need to apply through an **MDR Notified Body** as this will take control of the combined conformity assessment.

AI Notified Body testing

- 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.

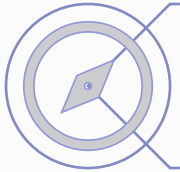
4.5. Notified bodies shall be granted access to the source code of the AI system upon a reasoned request and only when the following cumulative conditions are fulfilled:

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.

Sandboxes

Sandboxes & Testing in real-world conditions



National competent authorities will provide **guidance, direct supervision and support**.

Ensure compliance with **AI Act** but also with other **EU law and sectoral laws - in a single sandboxing project.**

Pre-market phase and/or re-assessment by the provider in case of substantial modification to certified AI systems.

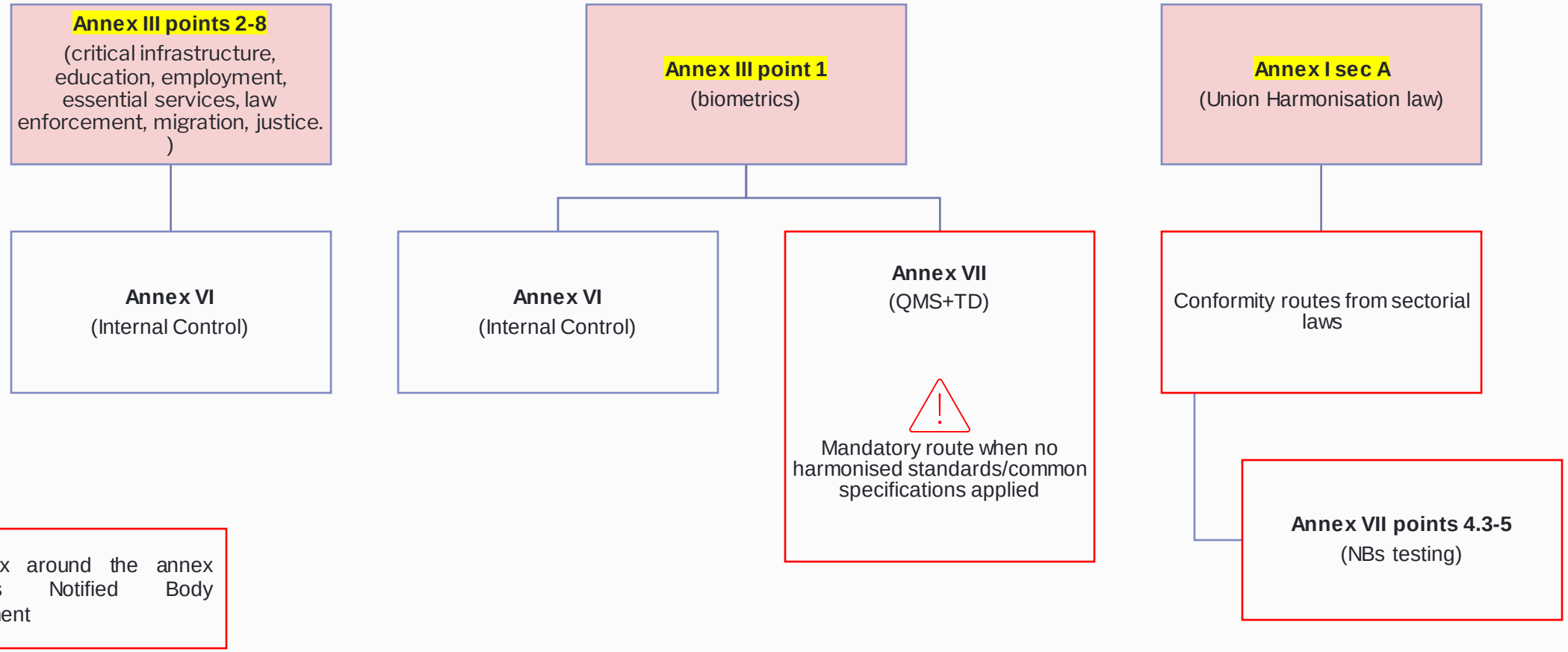
Testing under real conditions possible, but in controlled environment -**Annex II law** provisions on the testing in real world conditions will take precedence.

No derogation from the AI conformity assessment - exit reports and the written proof of participation will be taken positively into account.

Routes to conformity

Which conformity assessment routes are applicable under the AIA?

BSI's interpretation on applicable AIA routes for conformity:



Which conformity routes are applicable under the AIA?

Incompatibility between MDR & AIA routes for conformity.

- No alignment on **routes of conformity between MDR & AIA.**
- Under the MDR, **medical device manufacturers can choose the route for conformity.**
  - If, for example, the manufacturer chooses conformity based on full quality assurance (Annex IX), but the AIA Notified Body calls AI for testing (Type examination)…
    - How to introduce type examination to the conformity assessment when manufacturer has chosen another route of conformity?
    - Does type examination be applied for all types of software, apart from AI? - MDR does not differentiate between Software and AI.

AI competent authority/ Commission needs to clarify how to mix routes of conformity

Post Market Monitoring Plan

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.
- AIMD 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 AIMD, **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.

Changes to AIMD

Changes to approved QMS and AI Systems

Whenever a **change** occurs that may affect the compliance of a high-risk AI system with the AIA (e.g. change of operating system, software architecture) or when the **intended purpose** of the system changes, **the AI system should be considered 'new' and should undergo a new conformity assessment.**

The intended change needs to be assessed by the **Notified Body** which will decide whether a new conformity assessment is needed or if it could be addressed '***by means of a supplement to the EU technical documentation assessment certificate'***.

- **EXCEPTION:** Changes occurring to the algorithm and the performance of AI systems which **continue to 'learn'** after being placed on the market/put into service, provided that those changes were **predetermined and assessed during the conformity assessment.**

Any intended change to the approved QMS will be examined by the Notified Body who will decide if a reassessment is necessary.

Changes to approved QMS and AI Systems

Any distributor, importer, deployer or other third-party that makes a **substantial modification of a high-risk AI system** OR **changes the intended purpose of a non-high risk AI turning it into a high risk one**, it will be considered the provider and will be subject to the AIA providers obligations.

Art. 16 (2) MDR establishing that certain changes should not be considered modifications of a device should still apply to high-risk AIMD. **More specific provisions from sectorial law wins over AIA.**

- NOTE: the MDR manufacturer will be considered AI provider under the AIA if the high-risk AI system that is a safety component of the MD is not placed on the market/put into service independently from the product.

AIMD already in the market before the AIA's entry into force will **not** need to undergo a new conformity assessment unless those systems are subject to **significant changes in their design or intended purpose.**

- Significant changes = Substantial modification