IHE EUROPE EXPERIENCE DAYS 3-4 JUNE 2024

The EU AI Act

Understanding the challenges to AI-enabled Medical Device conformity assessments

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AI Act & MDR Interplay

The AI Act regulation is written in a horizontal manner, yet the AI Act is still a product legislation.

The AI Act is complementary – adds an additional layer to the MDR – addresses specific risks of AI.

AI Act & MDR Interplay

The New Legislative Framework

- AI Act & 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.

- Avoid double-regulatory burden - 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."*

Scope of the MDR & AI: risk classification

A device in scope of the MDR that also qualifies as a high-risk AI system under the AI Act will need to meet obligations both under the MDR and AI Act. **But when is it considered high-risk?**

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 **3rd-party assessment** under such Union Harmonisation law

=

High-risk AI medical device system

2

Certain stand-alone applications specified in Annex III are also deemed high-risk but are not under the MDR scope.
Within the healthcare sector, these include applications related to biometric classification, determining healthcare eligibility, and systems for triaging patients in emergencies

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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.

Scope of the MDR & AI

But what is ‘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;

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?

The Commission will issue Guidelines clarifying the scope.

What are the additional requirements set by the AIA?

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

AIA - High-risk AI providers obligations	Similar provision in MDR?
EU Authorised representative	✓
Human oversight	X
Transparency and provision of information to deployers	X
Accuracy, robustness and cybersecurity	✓
PMS	✓
Accessibility requirements	X
EU declaration of conformity	✓
EU AI database registration	X
CE Mark	✓

*Transition period of **36 months** following the entry into force.*

What if AIA-MDR requirements overlap?

- The Medical device manufacturer can integrate the necessary measures to comply with the AI Act into the procedures and documents already required under MDR
  - Gap analysis between MDR - AIA requirements

- To avoid duplications, the AI Act allows a single conformity assessment under the MDR
  - Single Technical documentation
  - Single EU declaration of Conformity
  - Single CE Mark

The Commission will issue Guidelines clarifying the scope.

Small and medium-sized enterprises

- Simplified technical documentation form (Simplified Annex IV).
  Notified bodies will accept this form
- "Simplified" quality management system

The Commission will develop Guidelines

- Reduction of fees in third-party conformity assessment processes
- Priority access to AI regulatory sandboxes + free of charge
- Member states shall establish dedicated communication channels for advice and queries on the AIA

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 environments - Annex I 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

Notified Bodies

- 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 their 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 Medical Devices 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 training and trained models of the AI system if needed to check compliance with the AI Act requirements & if other ways to verify this has been exhausted.

ANNEX VII

Conformity based on an assessment of the quality management system and an assessment of the technical documentation

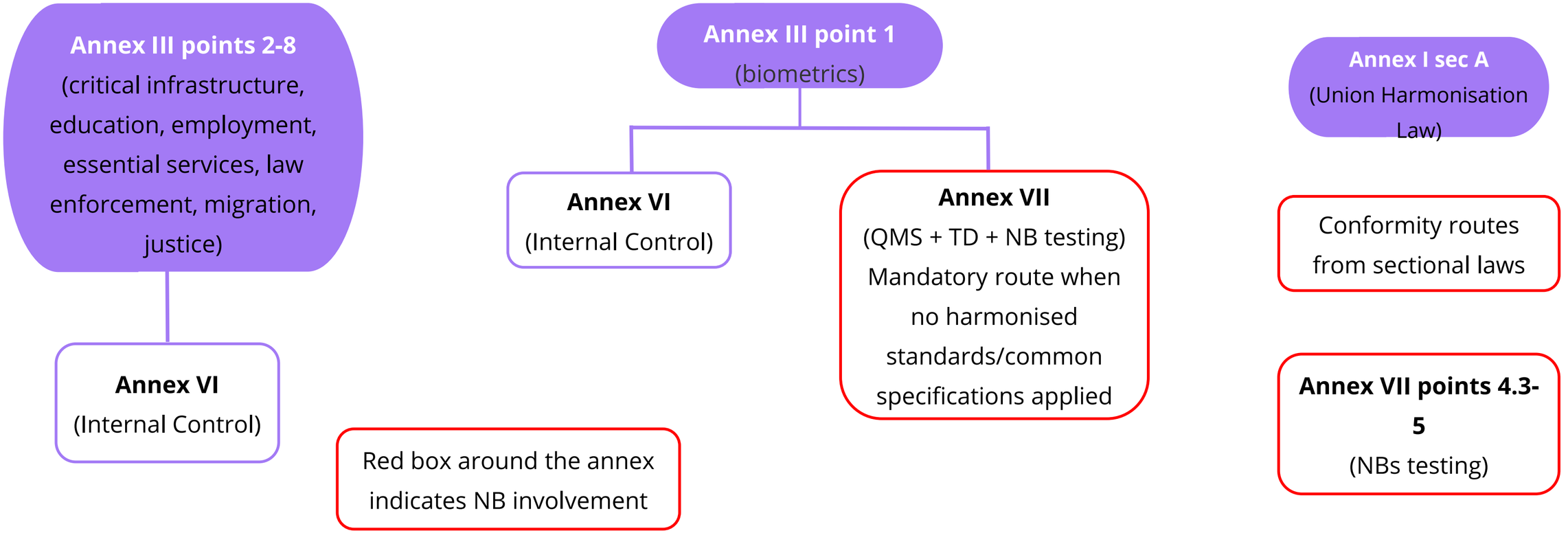
4.3. The technical documentation shall be examined by the notified body. ***Where relevant and limited to what is necessary to fulfil its tasks***, the notified body shall be granted full access to the training, ***validation***, and testing data sets used, ***including, where appropriate and subject to security safeguards,*** through 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 supply further evidence or carry out further tests so as to enable a proper assessment of the conformity of the AI system with the requirements set out in Chapter III, Section 2. 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.

4.5. Where necessary to assess the conformity of the high-risk AI system with the requirements set out in Chapter III, Section 2, ***after all other reasonable means to verify conformity have been exhausted and have proven to be insufficient,*** and upon a reasoned request, the notified body shall also be granted access to the ***training and trained models*** of the AI system, ***including its relevant parameters***. ***Such access shall be subject to existing Union law on the protection of intellectual property and trade secrets.***

Which conformity assessment routes are applicable under the AIA?

Hardian'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 their route for conformity.

- If, for example, the manufacturer chooses conformity based on full quality assurance (Annex IX), but the AIA NB calls for AI testing (Type examination)
  - How to introduce type examination to the conformity assessment when manufacturer has chosen another route of conformity?

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

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.
- High-risk AI-enabled medical device 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 achieved an equivalent level of protection
- The market surveillance authority will be the same as under the MDR
- AIA enforcement procedures will not apply, MDR procedures take preference.

Extra PMS requirements under the AIA

Actively and systematically collect, document and analyse relevant data gathered from deployers or other sources, on the **performance of AI high-risk system 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 AI Systems

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

The intended change to the TD needs to be assessed by the NB 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.

Changes to 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 system 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 AI-enabled medical devices.

More specific provisions from sectorial law wins over AIA.

AI already in the market before the AIA's general date of application will **not** need to undergo a new conformity assessment unless those systems are subject to **significant changes in their design or intended purpose**

NOTE: the MDR manufacturer will be considered an AI provider under the AIA if the high-risk AI system that is a safety component of the medical device is not placed on the market/put into service independently from the product (i.e. embedded)

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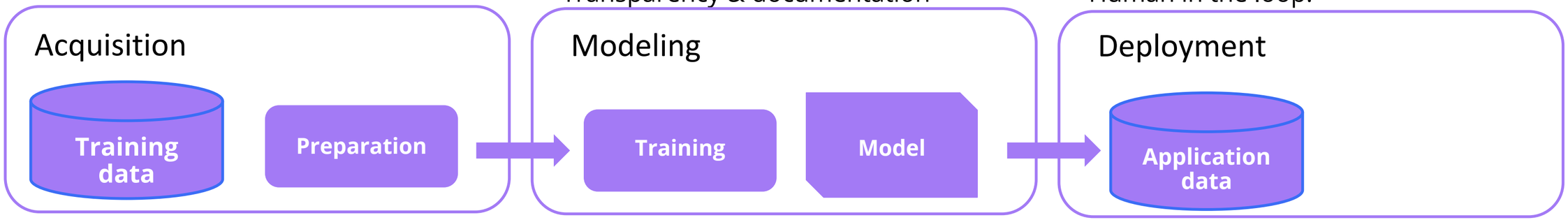
Art. 11-13 AEOI:

Transparency & documentation

Art. 14 AIA:

Human in the loop.



Art. 10 AIA: Training data:

- Correctness
- Representativeness
- Minimizing bias

Art. 15 AIA: Performance:

- Accuracy
- Robustness
- IT security

Risk management and Quality Management

Penalties for Non-Compliance

In cases of non-compliance, the Act grants the authority to recall an AI system completely.

Breach Under the Act	Potential Fine Under the Act
Breach of prohibition on unacceptable risk AI systems or **data governance provisions for high-risk AI systems**	Up to the higher of **EUR 35 million or 7%** of the total worldwide annual turnover
Non-compliance with any other requirement under the Act	Up to the higher of **EUR 15 million or 3%** of the total worldwide annual turnover
Supplying incorrect, incomplete, or misleading information to notified bodies and national authorities	Up to the higher of **EUR 7.5 million or 1%** of the total worldwide annual turnover

Recital 178 AI Act:

*"Providers of high-risk AI systems are encouraged to **start to comply**, on a **voluntary basis**, with the relevant obligations of this Regulation already **during the transitional period.**"*

Timeline

Transition period

6 months

Prohibitions

It is now ILLEGAL to use AI for any ‘unacceptable risk’ use case.

12 months

Deployment

Obligations on providers of general purpose AI models go into effect.
Appointment of member state competent authorities.

18 months

Post-market Monitoring

Commission implementing act on post-market monitoring.

Listed high risk

Obligations on high-risk AI systems specifically listed in Annex III.
Regulatory sandboxes to be operational.
Member states to have implemented rules on penalties, including administrative fines.

Future harmonised ISO standards →

Timeline

Medical device manufacturers have 36 months to comply

36 months

Unlisted High risk AI

Obligations for high-risk AI systems that are not prescribed in Annex III but are intended to be used as a safety component of a product, or the AI is itself a product, and the product is required to undergo a third-party conformity assessment under existing specific EU laws, for example toys, radio equipment, **medical devices, in vitro diagnostic medical devices**, civil aviation security and agricultural vehicles

Questions

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