EU AI Act Explained: Navigating the new legislation with BSI

Agenda

Introduction & Welcome

M. Thirlwell – *Managing Director, AI* & A. Tzavaras – *Head of AI NB*

The AI Act

Sarah Mathew– *Regulatory Lead AI NB*

How BSI supports AI manufacturers

Andrea Sanino – *Senior Product Manager, AI*

Introduction & Welcome

Mark Thirlwell
Managing Director, AI

Aris Tzavaras
Head of AI Notified Body

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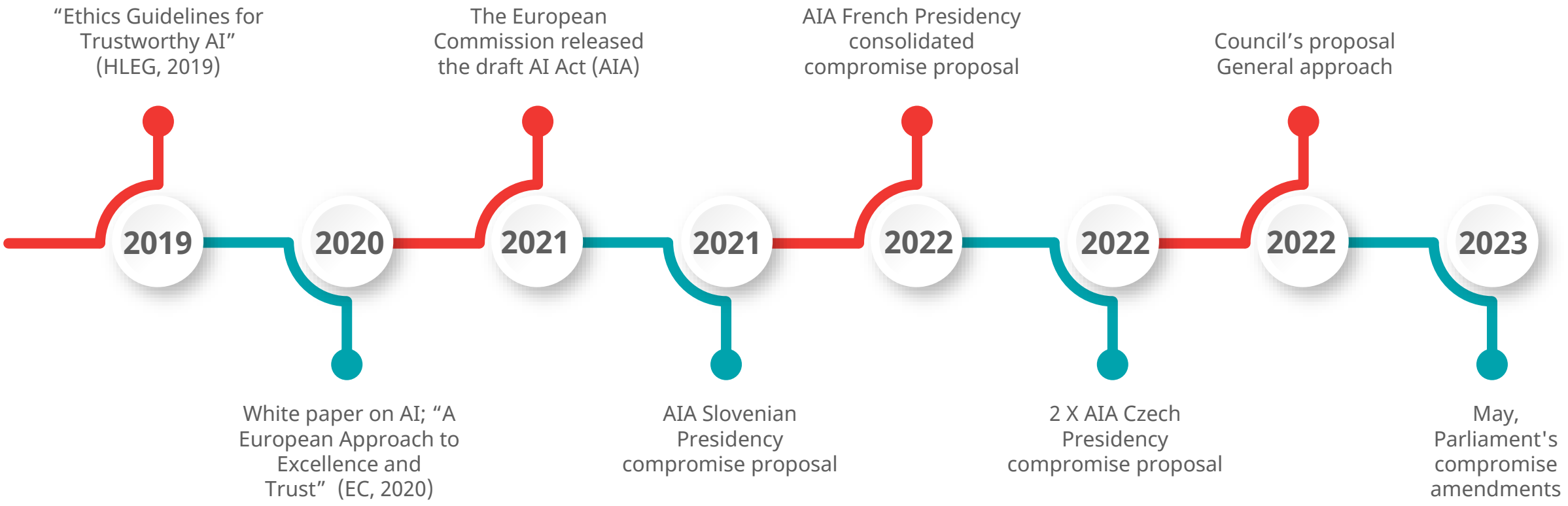
The AI Act

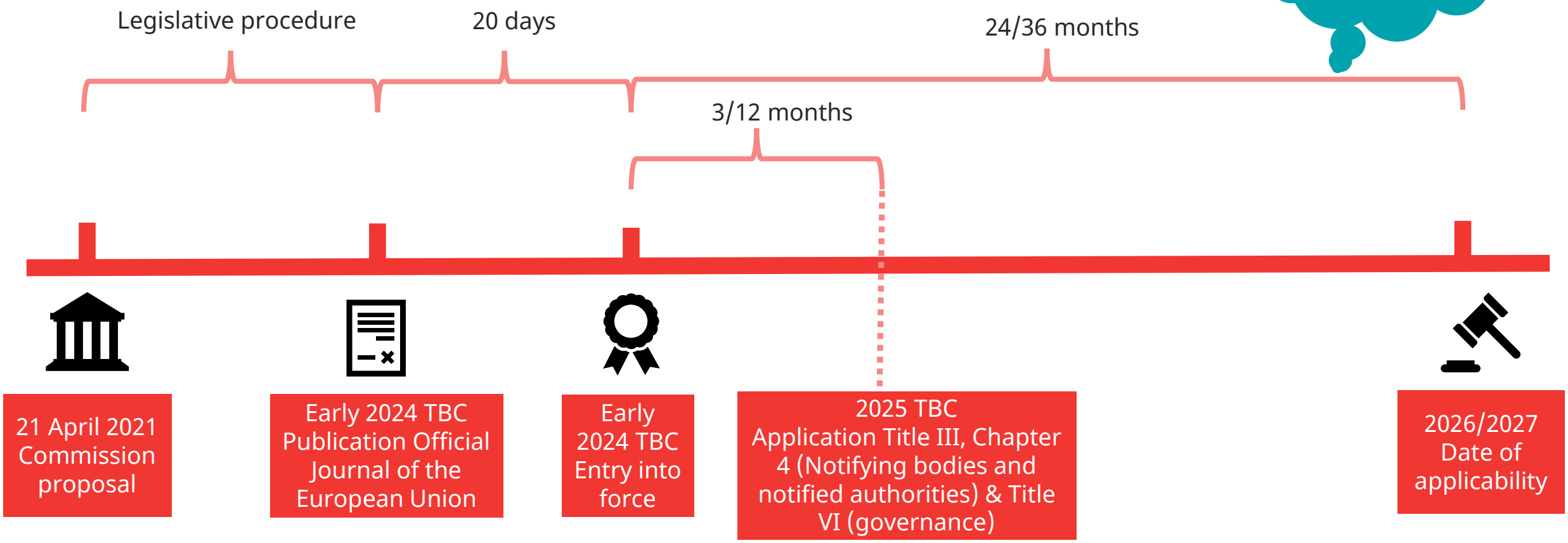
Sarah Mathew
Regulatory Lead AI NB

AIA journey



The AI Act legislative timeline

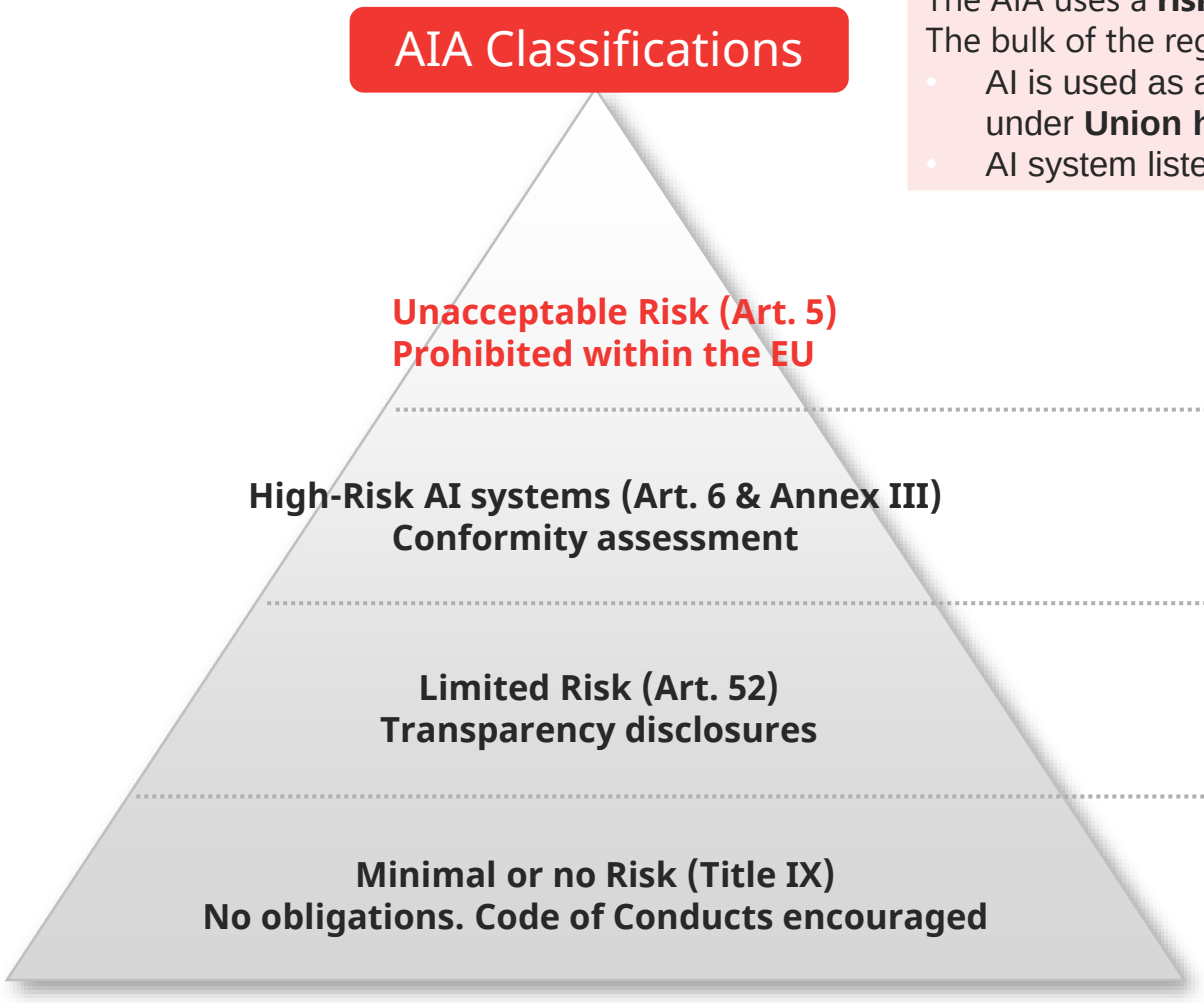
!NOTE!
The Council proposes a 36 months transition period while the Parliament 24 months



A risk-based approach

The AIA uses a **risk-based approach** - requirements get stricter as the risk increases.
The bulk of the regulation pertain to **high-risk AI systems:**

- AI is used as a safety component of a product / AI system is itself a product + covered under **Union harmonisation legislation + 3rd party conformity assessment.**
- AI system listed in Annex III.



Social scoring, risk assessment of persons, facial recognition databases, systems to infer emotions, biometric categorisation systems, real-time and post remote biometric identification, manipulative AI and subliminal techniques.

Biometric systems, critical infrastructure, education, employment, essential services, law enforcement, migration, justice. Additional list to be reviewed annually by the EAIB (art. 84)

Chatbots, Biometric categorisation systems, emotion recognition, deep fake.

AI-enabled videogames, Spam filters, predictive maintenance, process optimisation

AI Conformity Assessment

The AI Act requires providers of high-risk AI systems to conduct a **conformity assessment** before placing them on the EU market.

Annex II:
AI systems under Union harmonisation legislation (e.g., MDR/IVDR)

AI providers should comply with the conformity assessment required under Union harmonisation law **(+)** the requirements set out in Chapter 2, Title III of the AI Act

A **single EU declaration of conformity** may be drawn up in respect of all Union legislations applicable to the high-risk AI system (+) a **single CE marking** will also indicate conformity with other legislation.

As long as the requirements of the AIA are addressed by Union harmonisation law those requirements shall be deemed fulfilled.

Notified bodies which have been notified under those Union harmonisation laws shall be entitled to perform conformity assessments against the requirements of the AI Act

MD/IVD & AI Conformity Assessment

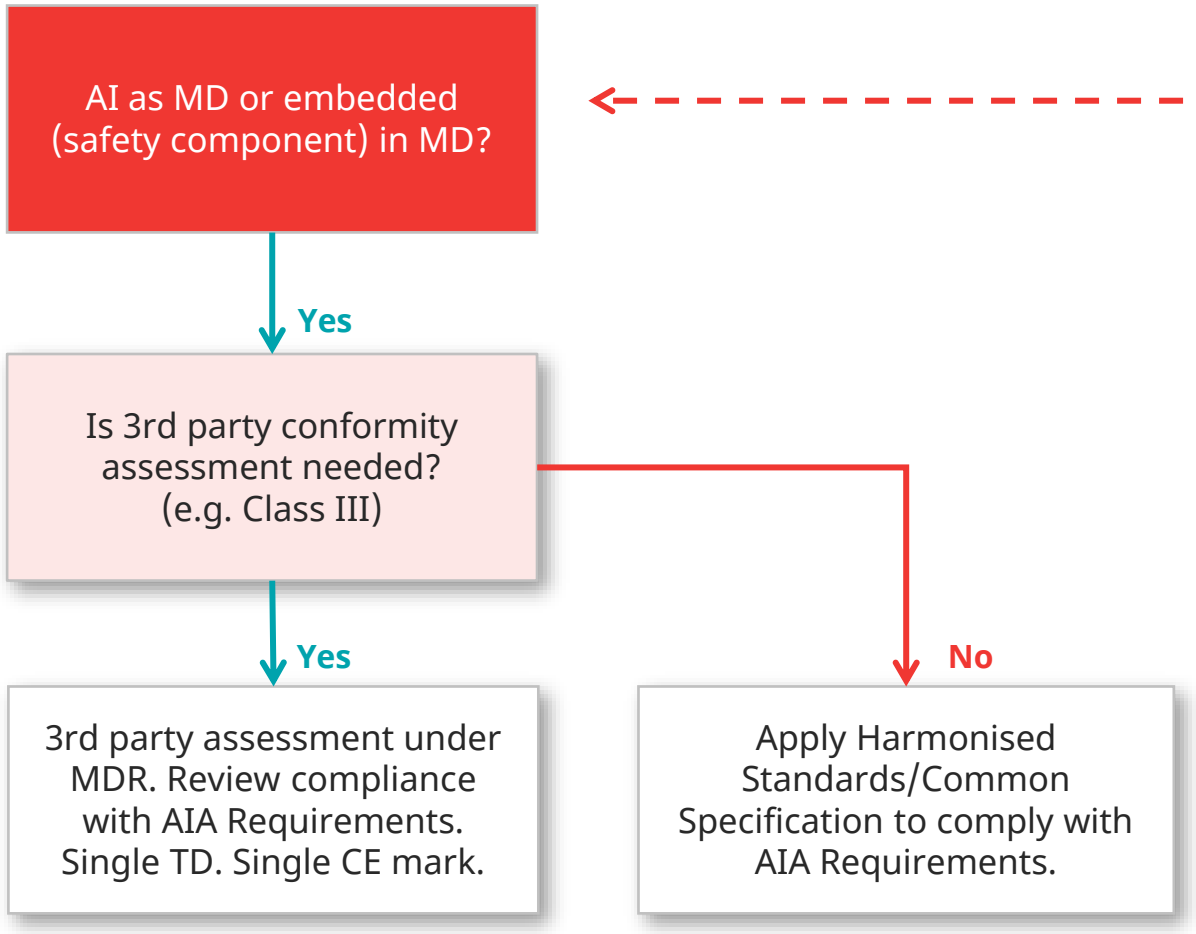
An AI system may apply concurrently to the requirements of the AI Act and the MDR/IVDR because it is a Medical Device/In Vitro Device with an AI component.

High-risk AI systems related to products which are covered by existing Union harmonisation legislation (e.g., MDR, IVDR), the compliance of those AI systems with the requirements of the AI Act should be assessed as part of the conformity assessment already foreseen under that legislation.

A **single conformity assessment** under the MDR/IVDR (*lex generalis*) for the device with an AI component considering the horizontal legislation'S (AI Act) specific requirements (*lex specialis*)

No additional CE marking under the AI Act is required because its conformity assessment requirements are subsumed in the MDR's

MD/IVD & AI Conformity Assessment



AI systems can be:

- used as a stand-alone software system, integrated into a physical product (embedded)
- used to serve the functionality of a physical product without being integrated (non-embedded)
- used as an AI component of a larger system, if the larger system needs the AI component to work, then falls under the AIA.

A **safety component** is a component of a product/system which fulfils a critical safety function. If it fails, it would endanger people's safety and health.

- Where a high-risk AI system that is a safety component of a product which is covered by Union harmonisation law is not placed on the market independently from the product, the manufacturer of the final product should comply with the obligations of the provider in the AIA and notably ensure that the AI system embedded in the final product complies with the requirements of the AIA.

How BSI supports AI providers

Andrea Sanino
Senior Product Manager, AI

BSI: Our Purpose, Mission and Vision

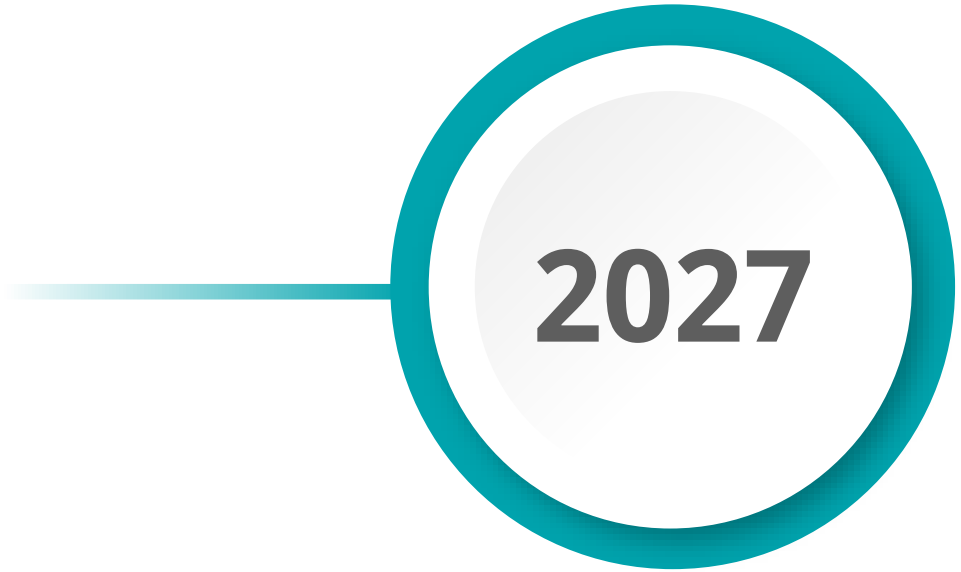
“Inspiring trust for a more resilient world”

Our **missions** is to share knowledge, innovation and best practice to help people and organizations **make excellence a habit.**

Our **vision** is to be the business improvement company that enables organizations **to turn standards of best practice into habits of excellence.**

BSI approach to forthcoming legislation

BSI is promoting a **proactive approach** to the upcoming regulation in order to help AI providers **anticipate requirements** and seamlessly adopt **habits of excellence** without stifling innovation



How BSI is responding to help with the EU AI Act

AI is expected to have a considerable impact on MD/IVD industry with various applications ranging from precision and personalised medicine to medical imaging and patient monitoring.

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How BSI is responding to help with the EU AI Act

MD/IVD AI components review

2023

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.

2027

How BSI is responding to help with the EU AI Act

AI in-depth technical analysis

2023

BSI supports all industries impacted by the AI Act by offering an in-depth technical analysis of AI compliance using standards.

This analysis will focus on many fundamental principles including **fairness, bias and robustness** and will be enhanced by the announced **partnership with Citadel AI**, a provider of AI testing and monitoring tools.

Such complete analysis can support providers **assuring the safety and reliability of AI systems.**

2027

How BSI is responding to help with the EU AI Act

AI regulatory trainings

2023

A full understanding of the rapidly-changing AI regulation panorama **is critical for success.**

BSI is working to provide external audience with **more skills and expertise** to grow opportunities, overcome challenges and deal with uncertainty **during planning, implementation and deployment** of AI systems.

2027

July 2023

ISO/IEC TR 24029-1:2021 - Assessment of the robustness of neural networks

Building trust in AI-enabled devices

Our AI Conformity Assessment offers a **comprehensive solution** to help you establish **trust and credibility** in your AI-enabled devices.

By **partnering** with us, you can **stay ahead** of the emerging AI regulation, allowing you to **reduce your risks** whilst **not stifling innovation.**

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Take home message – Regulatory Aspects

On 21 April 2021, the European Commission proposed the AI Act (AIA), a horizontal regulation that applies to AI systems used in all industries (MD, transport, automation, biometrics, etc.) and that aims to provide legal certainty, promote innovation, and ensure the protection of fundamental rights in the development and use of AI within the European territory.

The AIA is expected to entry into force on early 2024 with a 24/36 months period for applicability.

The AIA classifies devices under 4 classes of risk and requires providers of “High-risk” AI systems to conduct a conformity assessment before placing them on the EU market.

Devices already falling under an existing Union harmonisation legislation (e.g. MDR, IVDR), will need to comply also with the AIA and Notified Bodies will perform a single conformity assessment under both legislations.

Take home message

- BSI is promoting a **proactive approach** to the upcoming regulation by **building significant capability** to be ready for AI system Providers with a range of services.

- In particular, since **the State of the Art (SotA) in AI has evolved** across the last years, the applicable requirements **within MDR/IVDR** related to AI will be assessed by a team of **BSI specialised AI Tech Experts**.

- **BSI supports all industries** impacted by the AI Act by offering an **in-depth technical analysis** of AI compliance and **regulatory trainings**

- This to allow customers to **be Proactively Ready** for the upcoming regulation leveraging BSI to **build Expertise** and **gaining a Competitive Advantage** by committing to AI ethical practices.

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Thank you.