EN 18286

Your Guide to the Next Major AI Quality Standard

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Hello and welcome

- In this webinar we will cover:
  - Learn what EN 18286 is being designed to do, how it could support harmonized-standard requirements;
  - The relationships between ISO/IEC 42001, EN 18286 and the EU AI Act
  - How a structured approach to AI quality management could help organizations demonstrate confidence and meet expectations in regulated markets.
- Q+A at the end of the webinar – please add your questions to the chat
- You will get a copy of slides and a recording of the webinar
- Opportunity to ask for a follow up from BSI on the feedback form – available immediately after the webinar concludes.

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Meet our speakers

Hamid Naderi

AI Client Manager

Hamid has expertise in medical engineering, AI systems and medical products, conducting audits against MDR, ISO 13485, ISO/IEC 27001 and ISO/IEC 42001.

Moemmur Shahzad

AI Client Manager

Moemmur has more than eight years’ experience in software, data science and applied machine learning, conducting audits against ISO 9001, ISO/IEC 27001 and ISO/IEC 42001.

Andrea Tirelli

AI GQA Certification Lead

Andrea specializes in AI governance, assurance and conformity assessment, leading the development of AI certification programmes and supporting assessments against ISO/IEC 42001 and ISO/IEC 27001, with expertise in AI standards and regulatory frameworks.

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Our mission

Our goal is the responsible adoption and use of AI for the benefit of society

We have been proactive in our approach to upcoming AI regulations to help AI developers, producers, users, and providers anticipate requirements and seamlessly adopt habits of excellence, without stifling innovation.

Poll 1

How is your organization involved with AI systems?

- We develop or provide AI systems
- We deploy or use AI systems
- We import or distribute AI products
- We advise or assess AI organizations
- We are still exploring AI

Poll 2

Is your organization preparing for the EU AI Act?

- Yes, actively preparing
- Yes, early-stage planning
- Aware, but not started
- Unsure whether it applies
- No current plans

Agenda

1

EU AI ACT and timelines

2

Requirements for High-risk AI system providers?

3

AIA conformity assessment path

4

What is EN 18286?

5

Scope and sturcture of the standard: What is inside, what is outside

6

42K and 18286, differences, similarities: same family, different object.

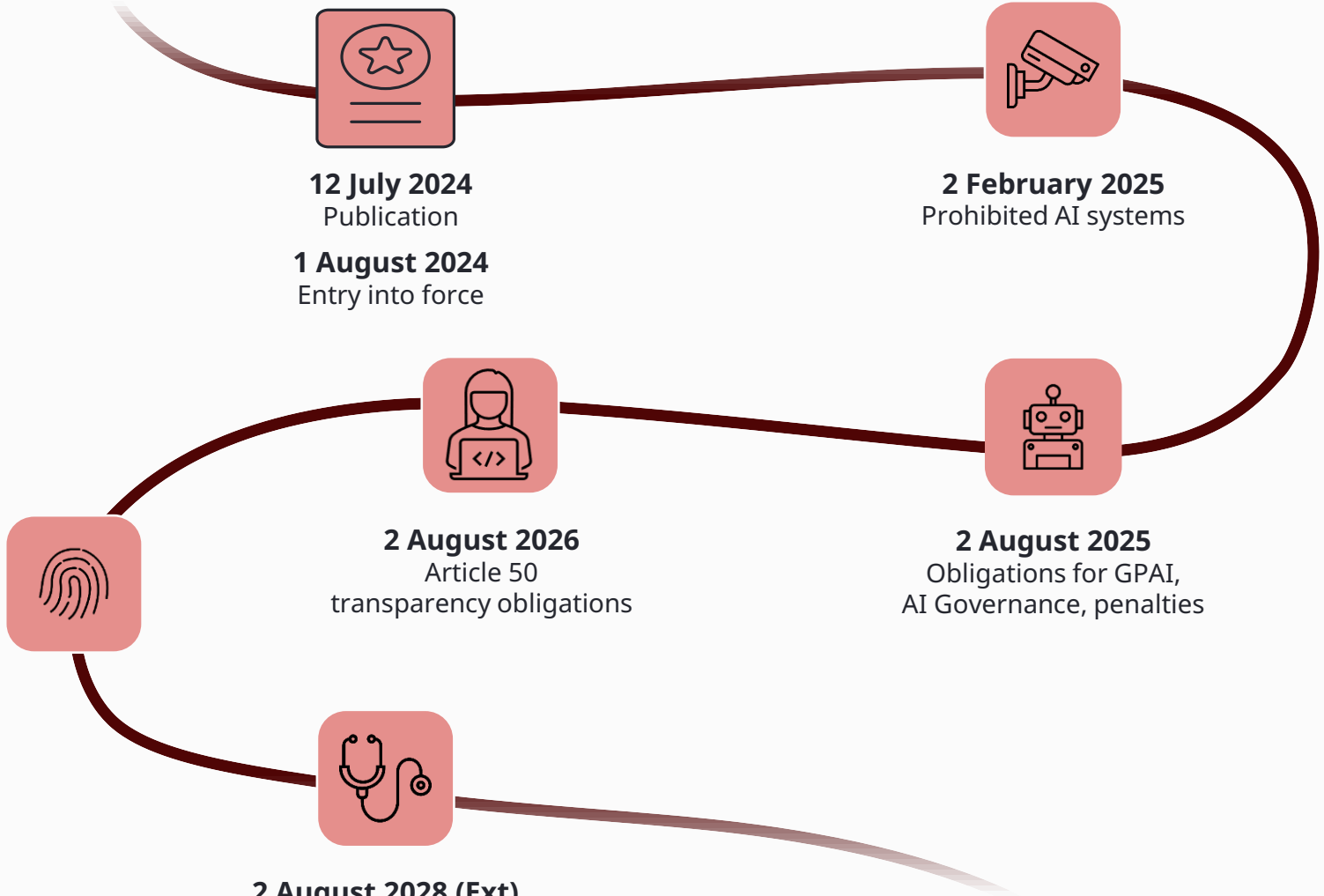
7

Practical next steps

8

BSI Services

The EU AI Act timeline



High-Risk AI Systems and Provider Obligations EU AI Act

High-Risk AI Systems – Article 6

An AI system is considered high-risk when:
- It is itself a regulated product, or
- It is a safety component of a regulated product, and
- That product requires third-party conformity assessment under EU harmonization legislation.

Example:

- AI integrated in **medical devices (MDR)**
  → Already subject to conformity assessment
  → Therefore, classified as **High-Risk AI**

Implication

- High-risk classification triggers **strict regulatory obligations for providers**

Provider Obligations – Article 16

Once classified as high-risk, providers must:

- Maintain **technical documentation**
- Implement **logging and traceability**
- Undergo **conformity assessment procedures**
- Issue **EU Declaration of Conformity**
- Apply **CE marking** where applicable
- Implement **incident handling and corrective actions**

125 bsi

AI Act Conformity Assessment for Annex I AI System

Conformity assessment

Assessment and surveillance of AI QMS

AI Quality Management Systems are mentioned in **Article 17** of the **EU AI Act.**
One potential avenue for presumed conformity is through **EN 18286 certification** which provides a certifiable framework in which AI systems can be developed and deployed as part of an AI assurance ecosystem.

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. 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.

Poll 3

How familiar are you with EN 18286?

- Very familiar, we are already preparing
- Somewhat familiar with its purpose
- I had heard of it
- Not aware before today

What is EN 18286?

What is EN 18286?

Issuing body

CEN-CENELEC JTC 21, WG 2

Mandate

European Commission request M/613

Full title

Artificial intelligence — QMS for EU AI Act regulatory purposes

Regulatory target

EU AI Act Article 17

Primary users

Providers of high-risk AI systems

Status

Not published; not yet cited in the OJEU

Key point: EN 18286 is regulation-born. Its structure follows Article 17 rather than a generic MSS logic

Why a New QMS Standard?

Article 17 requires a provider QMS covering A NUMBER OF statutory elements. Existing standards do not map to that obligation set as written.

Article 17 needs…	ISO 9001 gives…	ISO/IEC 42001 gives…
Compliance strategy incl. conformity assessment	—	—
Design, verification and validation per AI system	Generic product realization	Process-level requirements; controls selectable
Data management systems and procedures	—	Annex A.7 controls (selectable)
Post-market monitoring under Article 72	—	Organizational performance evaluation
Serious incident reporting under Article 73	—	—
Authority / notified body communication	—	—

EN 18286 is the Article 17 map: not a replacement for 42001, but the QMS layer designed for provider AI Act regulatory purposes

Why a New QMS Standard?

A different definition of “quality”

ISO 9000:2015

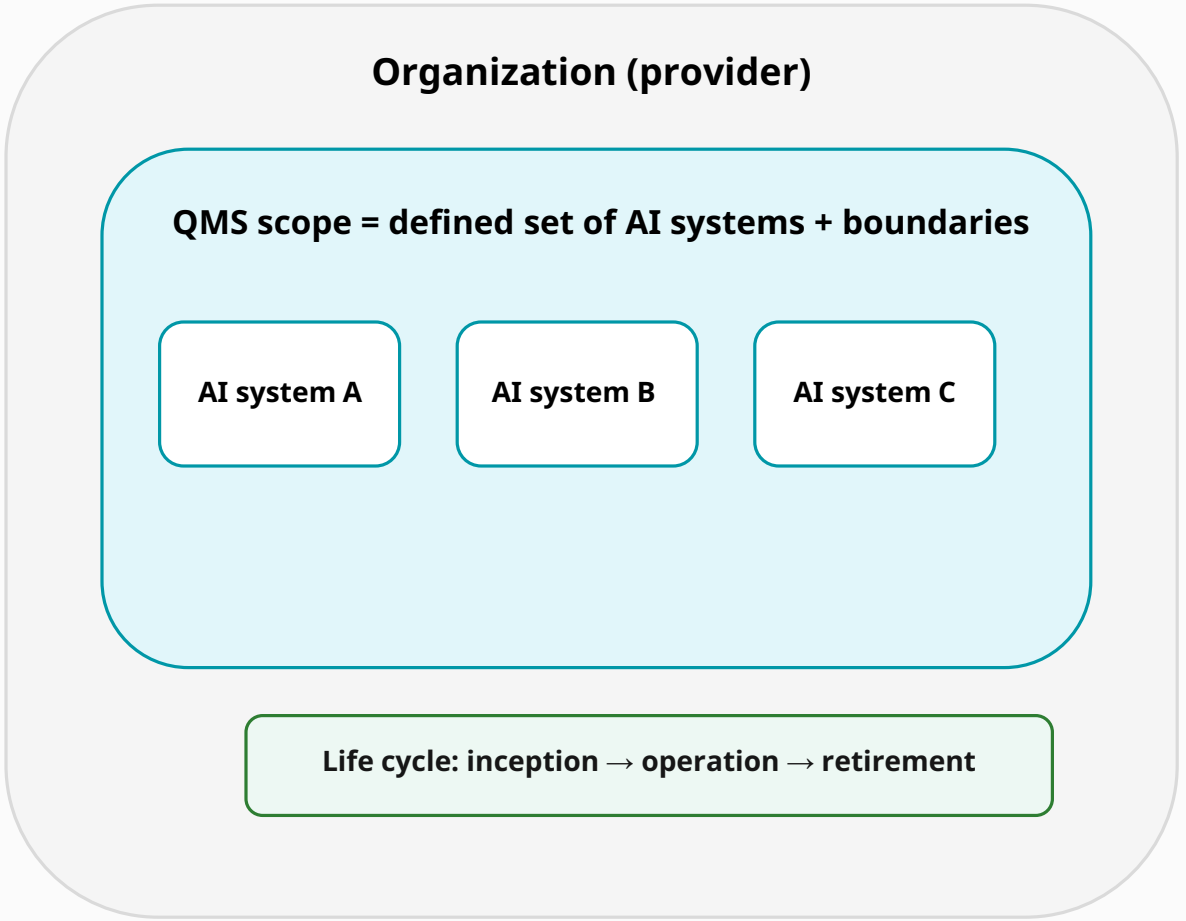
Quality = degree to which inherent characteristics fulfil requirements of customers and interested parties.

EN 18286, 3.1.19

Quality = characteristics that fulfil regulatory requirements, including health, safety and fundamental rights.

Conceptual pivot: in EN 18286, quality means regulatory conformity. The affected person becomes part of the quality equation.

Scope: What’s In



Applies to providers, primarily high-risk AI system providers.

QMS scope is anchored in a set of AI systems, not just the organization.

Covers the entire AI system lifecycle.

Implementation is proportionate to provider size and risk.

Documentation is common to the QMS but evidence is anchored per system.

Scope: What’s Out

NOT

Not a replacement for sector QMS

NOT

Not a product conformity assessment procedure

NOT

Not a risk management system

Perspective	What 18286 does
Organizational	Leadership, roles, competence, documented information
Management system	QMS as the auditable object; evidence for auditors, NBs and authorities
Product / AI system	Per-system requirements, V&V, technical file, PMM, incidents

Structure: Two Layers in One Standard

Organization Management System Layer

Clauses 4, 5, 6, 7 and 10

QMS, management responsibility, planning, support, performance evaluation and improvement.

Nearest relative: ISO/IEC 42001.

Provider Product Life Cycle Layer

Clauses 8 and 9

Product realization, operation and control: risk, lifecycle, design, V&V, data, documentation, PMM and incidents.

Nearest pattern: ISO 13485 / NLF product law.

The AI Act is product-law shaped. A pure organizational MSS cannot carry Article 17 alone

Same Family, Different Object

ISO/IEC 42001 asks

“Does this organization govern its development and use of AI responsibly?”

Object of assurance:
the organization and its AI management system.

EN 18286 asks

“Does this provider’s QMS ensure that each AI system complies with the AI Act throughout its life cycle?”

Object of assurance:
the regulatory conformity of a defined set of AI systems.

Different object. Different criteria. Different beneficiary

What ISO/IEC 42001 Already Covers

EN 18286 area	ISO/IEC 42001 correspondence	Overlap
QMS, interested parties, scope	Clause 4	High (scope logic differs)
Documented information	7.5	High
Management responsibility	Clause 5	High
Planning	Clause 6	High
Support	Clause 7	High
Performance evaluation / improvement	Clauses 9–10	High

A mature AIMS delivers the management chassis of 18286 with limited integration friction.

Own assessment: strongest compatibility in governance; weakest in product-level controls.

What EN 18286 Adds: The Delta

Compliance strategy

4.4

Data management procedures

8.5

Fundamental rights operationalised

3.1.19 / 3.4.8 / 7.2.3

Technical documentation + IFU

8.7

Regulatory communication

7.3.3

Post-market monitoring

9.4

Per-system requirements engineering

8.3.2.1

Serious incident reporting

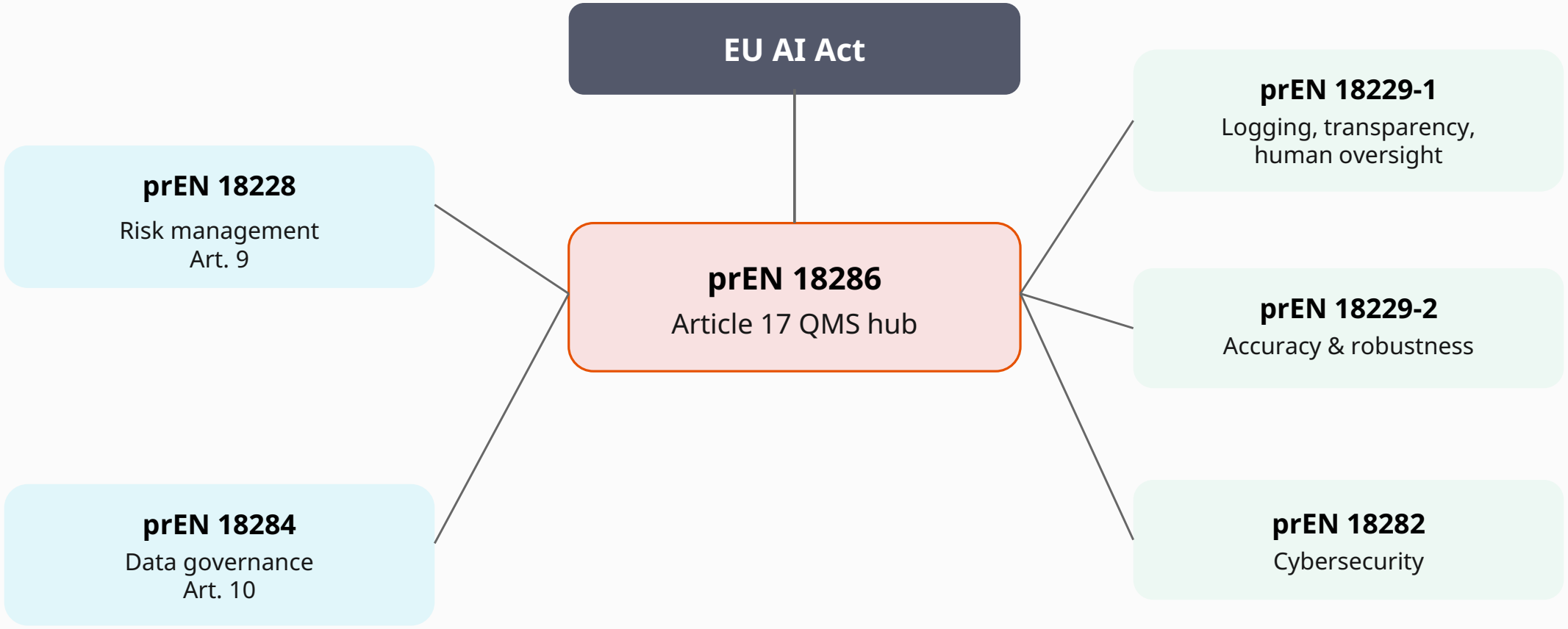
9.5

V&V gates

8.4

The delta is not additional bureaucracy; it is the system-level regulatory evidence layer.

The AI Act Standards Ecosystem



The QMS is where the provider assembles article-specific standards into one documented compliance process strategy.

Non-high-risk Providers: Can You Use This Standard?

The honest answer: yes, as a provider management system tool - no, as a regulatory conformity instrument

Why the question is real - the standard's own tension

Open wording
Scope: "providers that provide AI systems irrespective of size, nature or location"
Introduction 0.1

High-risk anchor
Quality = fulfilment of regulatory requirements; Art. 17 obligates only high-risk providers
3.1.19 / AI Act Art. 17

[FprEN] Conservative reading
"Provider" interpreted as provider of high-risk AI systems
3.2.5 Note 2

Consequence: applied without clear declarations, the certified property — "quality" — collapses toward an empty statement. The value lies in method and disciplines, not conformity to the standard.

Applicability analysis — clause-by-clause

Fully assessable (~47%):
4.2, 4.3, 4.5, 5.1–5.3, 7.1, 7.2, 7.4, 8.4, 8.6, 9.2, 9.3, 10.1, 10.2

With reinterpretation (~37%):
4.1, 6.1, 6.2, 7.3, 8.1, 8.2, 8.3, 8.5, 8.8, 8.9.3, 9.1, 9.5, 9.7
each with the re-anchoring it needs stated inline

Regulatory core (~16%):
the 4.4 complex (4.4.1 a/e, 4.4.2, 4.4.3), 8.7, 8.9.2, 9.4, 9.6
each with the reason it empties

To Wrap It Up

ISO/IEC 42001
"This organization governs AI responsibly"

EN 18286
"Each of these AI systems is managed for EU regulatory conformity across its life cycle"

AI system A · AI system B · AI system C

Different layers. One integrated system. The second layer is where the AI Act lives.

High-risk providers → full standard, presumption-ready at OJEU citation.
Everyone else → compliance engine and lifecycle disciplines on a declared baseline.

Preparing Now: Practical Steps

1

Gap Assessment

Map your existing AIMS against EN 18286 requirements. Identify what you have and what's missing.

2

AI System Inventory

Catalogue all AI systems, classify risk levels per the EU AI Act, and document intended purposes, data sources, and deployment contexts.

3

Lifecycle Controls

Embed Clause 8 & 9 into engineering workflows: design reviews, data validation gates, model testing, Measure / Metric, checkpoints, .

4

Integrated Management System

Implementation and integration of EN 18286 based on organizational needs.

BSI Services

Standards

BSI Trainings

Pre-Certifications

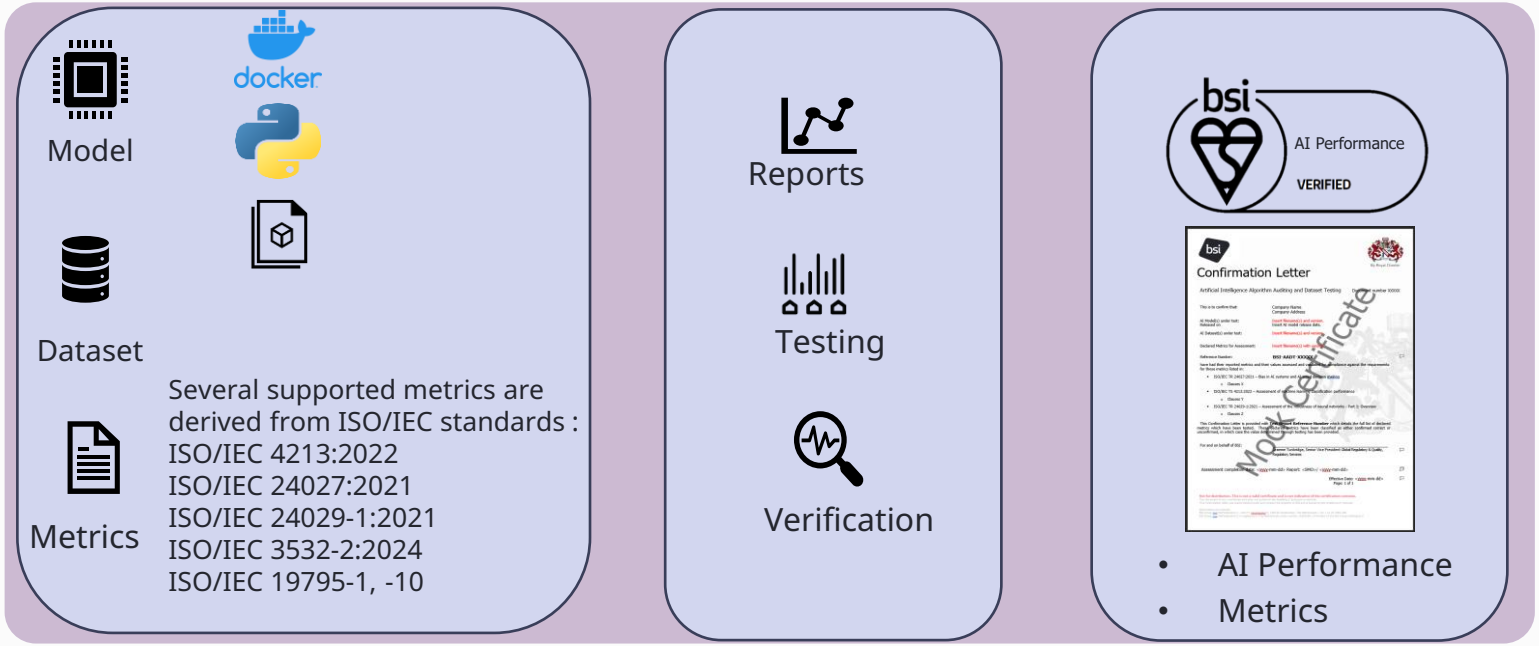
Certification Assessment Service

AI Performance Testing

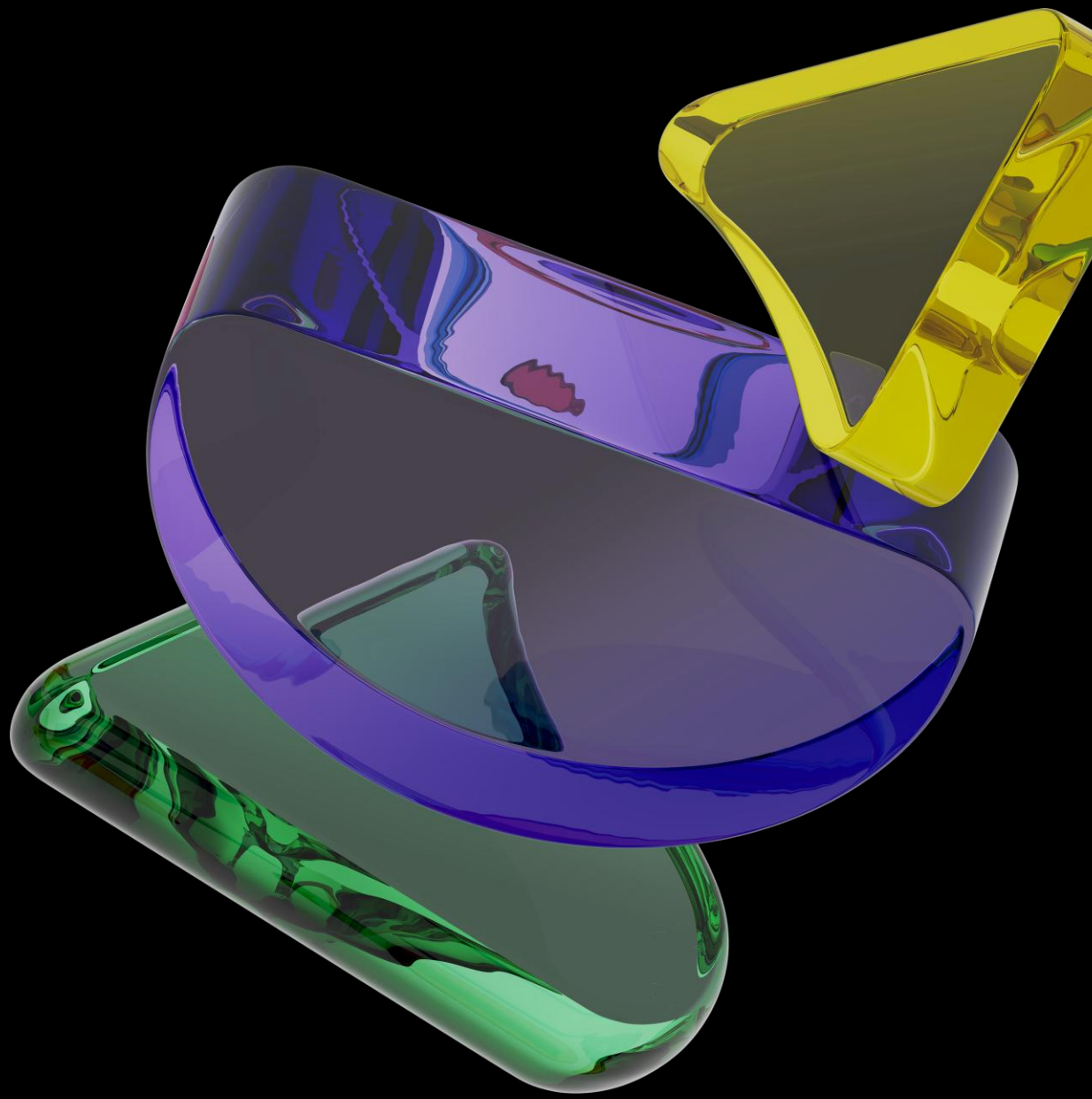
BSI AI Performance

We help enterprises evaluate and verify AI models for fairness, robustness, and regulatory compliance — empowering trustworthy, confident, compliant, and responsible AI deployments

- Based on AIA, any provider or deployer of high-risk AI systems in the EU market will be required to undergo a third-party conformity assessment
- This assessment may involve verifying that datasets and algorithms conform to harmonised state of the art standards
- BSI AI Performance can be complementary to other forms of assessment, such as certification against ISO 42001 (AI management systems)



Thank you



Any questions for our speakers?

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