



The EU AI Act in Focus: Making Sense of Conformity Assessments

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Nemko has created Trust since 1933

In our increasingly digital world, trust in digital systems, services, and transactions is paramount. Some of the critical elements of digital trust include Security, Privacy, Reliability, Transparency, Compliance, User Experience, and Ethical Use of Technology.

Nemko Digital offers digital trust solutions, complementing Nemko's existing services, to extend its commitment to its customers and support them into the digital realm.

Physical Trust



Nemko made the physical world a safer place since 1933

VS.

Digital Trust



Nemko augmented its proposition by Providing Trust in a Digital World



With you today

Bas Overtoom

Senior AI Trust Expert



- **Experienced AI & Data Executive:** Over a decade of consultancy experience, driving AI and data transformations for top global organizations.
- **Responsible AI Advocate:** Passionate about responsible AI to address business, social, and environmental challenges.
- **Global Business Expertise:** Strong international background, including seven years in Asia, fostering cross-cultural collaboration.
- **AI Trust & Business Development:** Leads global business development at Nemko Digital, promoting AI Trust worldwide.
- **VC Advisor for AI Scale-Ups:** Supports AI startups within a prominent Dutch VC fund to achieve global growth.

Monica Fernandez

Head of AI Assurance



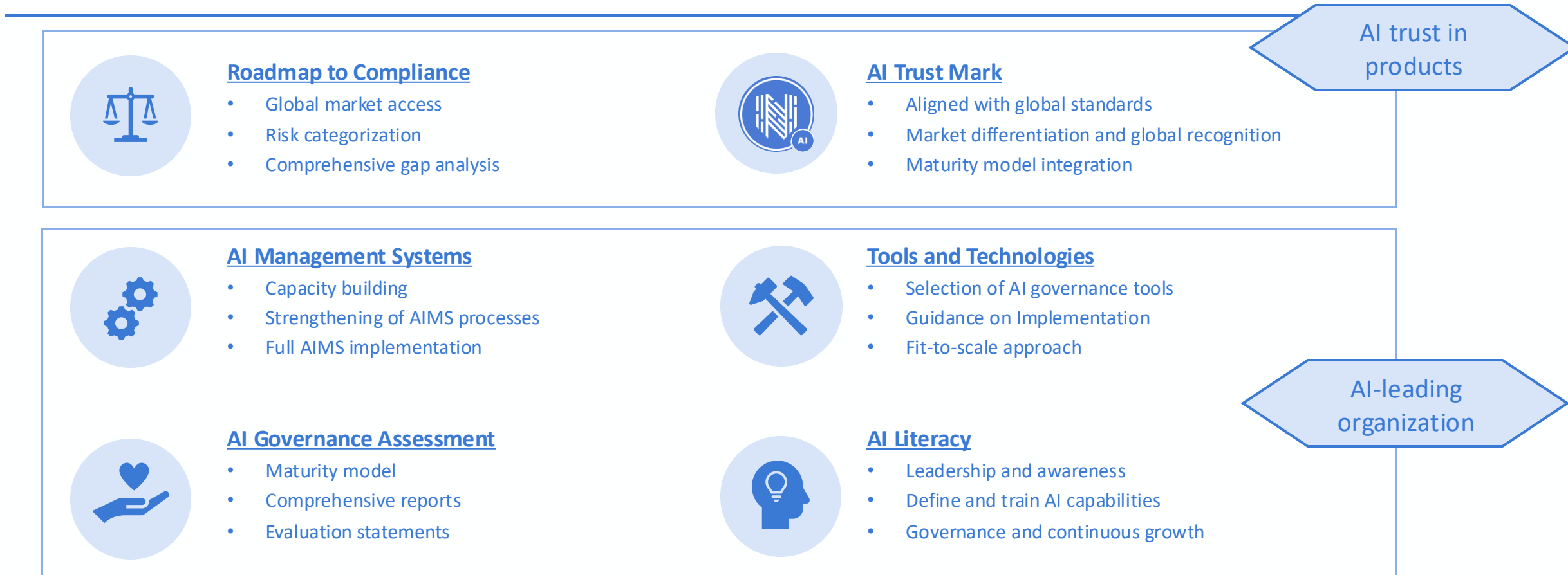
- **Trustworthy AI Advocate:** Actively engaged in research, education, and policy to advance AI fairness and mitigate bias.
- **Ethical AI Researcher:** Explored ethical, legal, and social challenges of AI fairness before joining Nemko Digital.
- **Strong Academic Background:** Holds a master's in AI from Radboud University and a bachelor's in Neuroscience from the University of Edinburgh.
- **AI Trust & Strategy:** Helps shape Nemko Digital's AI Trust offerings, ensuring fairness, safety, and effectiveness.
- **Strategic AI Leadership:** Developing AI Trust vision, roadmap, and services.



Key Interests from Customers

Nemko Digital leverages over 90 years of compliance expertise to offer end-to-end governance, risk assessment, and assurance services tailored to evolving AI regulations and standards in alignments with product legislation.

Key interests



EU AI Act

A unified regulatory and legal framework for all sectors and types of artificial intelligence.

EU ACT has come in to force in Europe



- Regulatory Framework for whole EU
- Risk-Based Approach to AI Regulation
- Clear compliance and transparency Requirements
- High Penalties for Non-Compliance
- Innovation Safeguards
- Global Impact on AI Governance
- Adopted in 2024, Full Enforcement in 2026



Understanding the EU AI Act in a page

	Provider	Deployer	Importer	Distributor	Obligations
Prohibited AI	Y	Y	Y	Y	Prohibited
High Risk AI	Y	Y	Y	Y	Must undergo a conformity assessment
Limited Risk AI	Y	Y	N	N	Must adhere to transparency requirements
Low Risk AI	N/A	N/A	N/A	N/A	No obligations – Subject to codes of conduct
GPAI	Y	N	N	N	Subject to GPAI-specific requirements



How is an AI System defined by the EU AI Act? (Article 3)

Definition

A machine-based system

One that is designed to operate with varying levels of autonomy

May exhibit adaptiveness after deployment

Infers from the input it receives, how to generate outputs such as predictions, content, recommendations or decisions that can influence physical or virtual environments

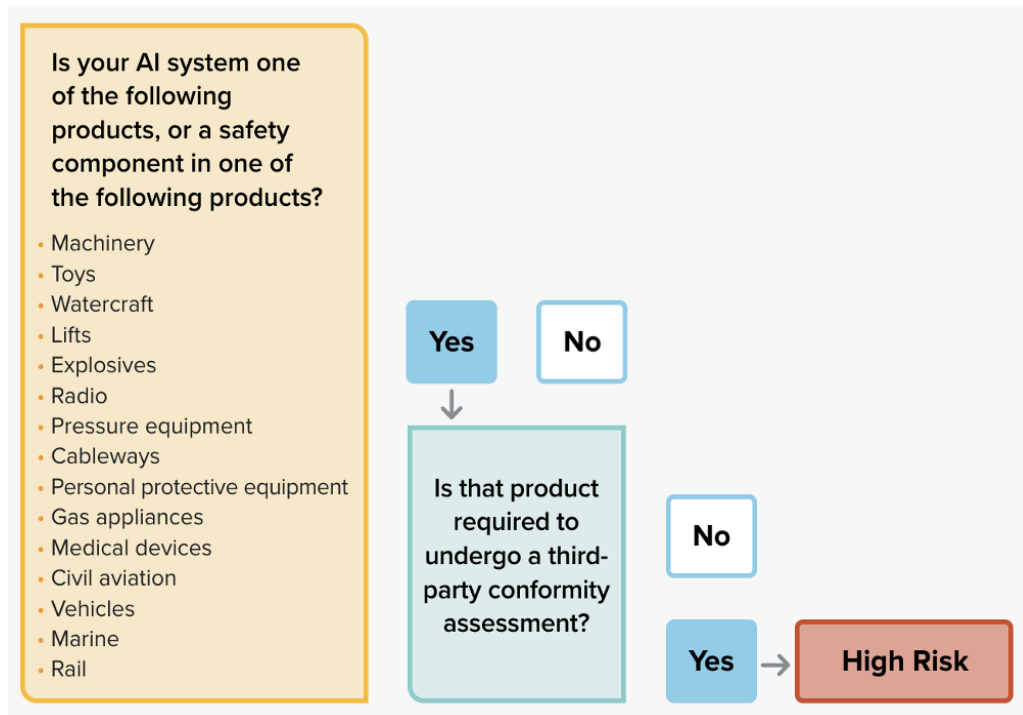
Very broad definition **covering a wide range of AI systems** including:

- Stand-alone AI software systems
- Systems integrated into a physical product
- Systems used to serve a physical product without being integrated into the product (e.g., serving as a safety component of the product)
- AI component of a larger software system



What is considered high risk? Two categories.

1) AI systems that are a product or safety component in a product covered under EU's New Legislative Framework (Annex I) that are required to have a conformity assessment.



OR

2) AI systems falling into specific use cases (Annex III) - needs to be registered into an EU database.

- Management and operation of critical infrastructure
- Education and vocational training
- Employment, worker management and access to self-employment
- Access to and enjoyment of essential private services and public services and benefits
- Law enforcement
- Migration, asylum and border control management
- Assistance in legal interpretation and application of the law.

Our question to you!

Are you aware of the risk category your AI systems fall under in the EU AI Act?



Conformity Assessments

CE Marking for High-Risk AI Systems in EU AI Act:

Very 1st CE marking in the context of AI

Before the CE marking can be affixed, the high-risk AI system must undergo a successful **conformity assessment** to determine whether the system complies with the essential requirements.

Digital CE marking

High risk AI systems provided digitally only if it can be easily accessed via the interface from which the AI system is accessed or via an easily accessible machine-readable code or other electronic means.

Physical CE marking

High risk AI systems embedded in a product. Can be complemented by a digital CE marking.

Article 48 of EU AI Act

Obligation for providers to affix CE marking to show:

1. Complies with provisions of act
2. Allows the AI system to move freely within internal market

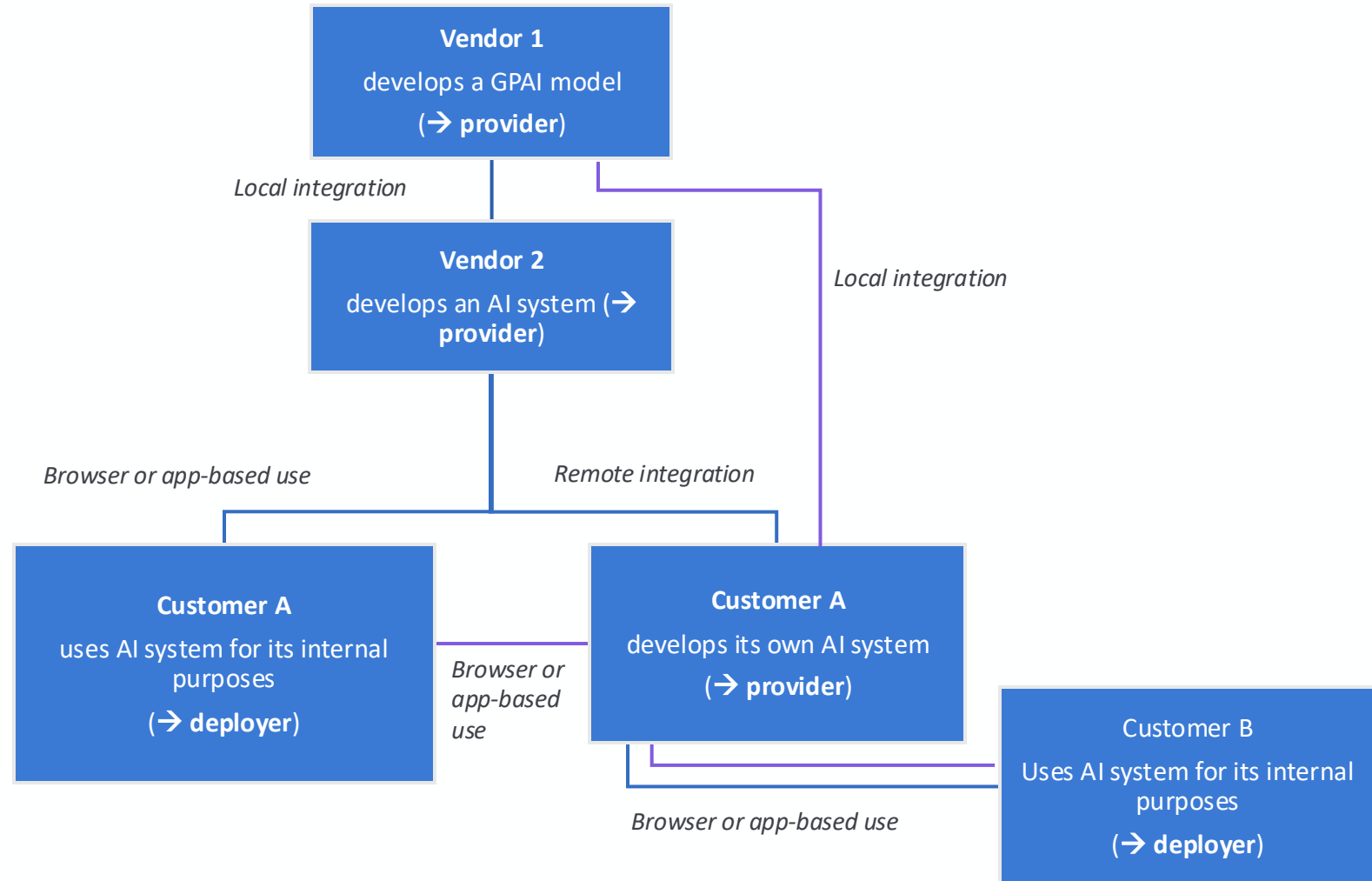


Who needs to conduct a conformity assessment? Depends on role.

Entity	Conformity Assessment is required when....
Provider	They place on the market or put into service a high-risk AI system.
Distributors, Importers, Deployers or Other 3 rd parties	<ul style="list-style-type: none">• They put their name or trademark on a high-risk AI system already placed on the market or put into service• They make a substantial modification to a high-risk AI system in such a way that it remains a high-risk AI system• They modify the intended purpose of an AI system that has not been classified as high-risk in such a way that the AI system becomes high-risk.
Product Manufacturers	In the case of high-risk AI systems that are safety components of products covered by the EU harmonization legislation, the system is placed on the market or put into service under the name or trademark of the product manufacturer.

*A new Conformity Assessment must be carried out if any changes to the AI system are implemented that could affect its compliance or if the purpose of the AI system changes.

Role complexity when procuring and using third party GPAI



Two types of conformity assessments

1. INTERNAL CONTROL: Self assessment w/o notified body if you can show that you adhere to harmonized EU safety standards (typically done by the provider)

- Verify that the established QMS for the high-risk AI system is in compliance with the requirements of Article 17 of the EU AI Act.
- Requirements include **regulatory compliance, technical specifications, quality controls and testing, data management, risk management, monitoring, reporting**, etc.
- Examine the information contained in the technical documentation to assess the compliance of the AI system with the relevant essential requirements for high-risk AI systems (Chapter III, Section 2 of the AI Act)
- Verify that the AI system's design and development process and post-market monitoring are consistent with the technical documentation (Article 72)
- **Prepare a Declaration of Conformity**
- **Maintain it for 10 years** (after the AI System has been placed on the market or put into service).
- **Affix the CE mark to the product** indicating that it can be used throughout the EU.



Two types of conformity assessments

2. NOTIFIED BODY ASSESSMENT: Quality management system assessment and technical documentation if you cannot show or rely on EU harmonized safety standards

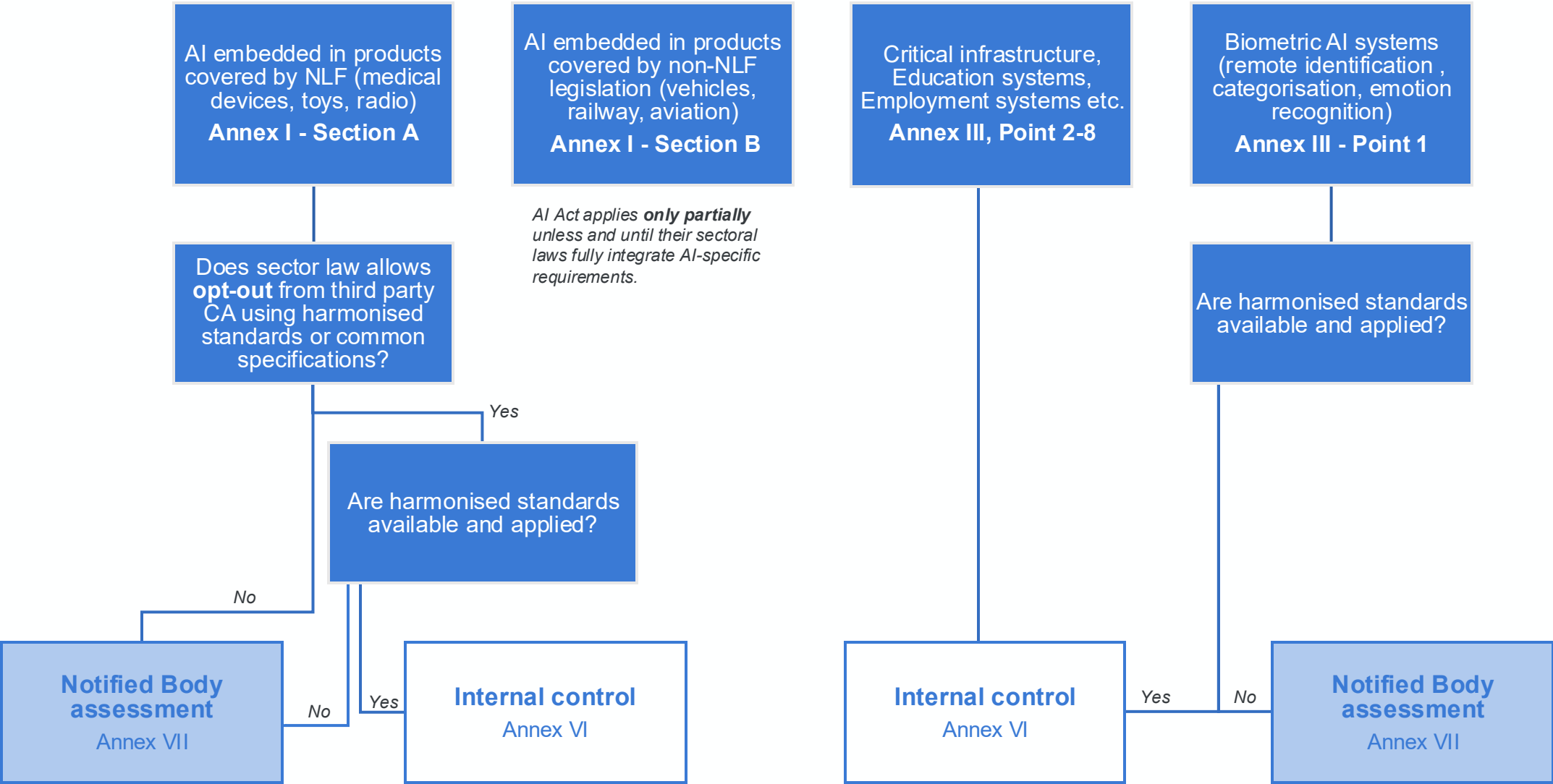
- Performs conformity assessment activities including testing, certification, and inspection.
- Everything in the internal assessment

The Notified Body

- Shall be granted full access to the training, validation and testing data sets. In certain circumstances, the notified body may request access to the training and trained models of the AI system.
- Can access to the premises where the design, development and testing of the AI systems is taking place.
- Can carry out periodic audits to make sure QMS is maintained.
- Can carry out addition tests of the AI systems for which an EU technical documentation assessment certificate was issued.



Conformity assessment routes

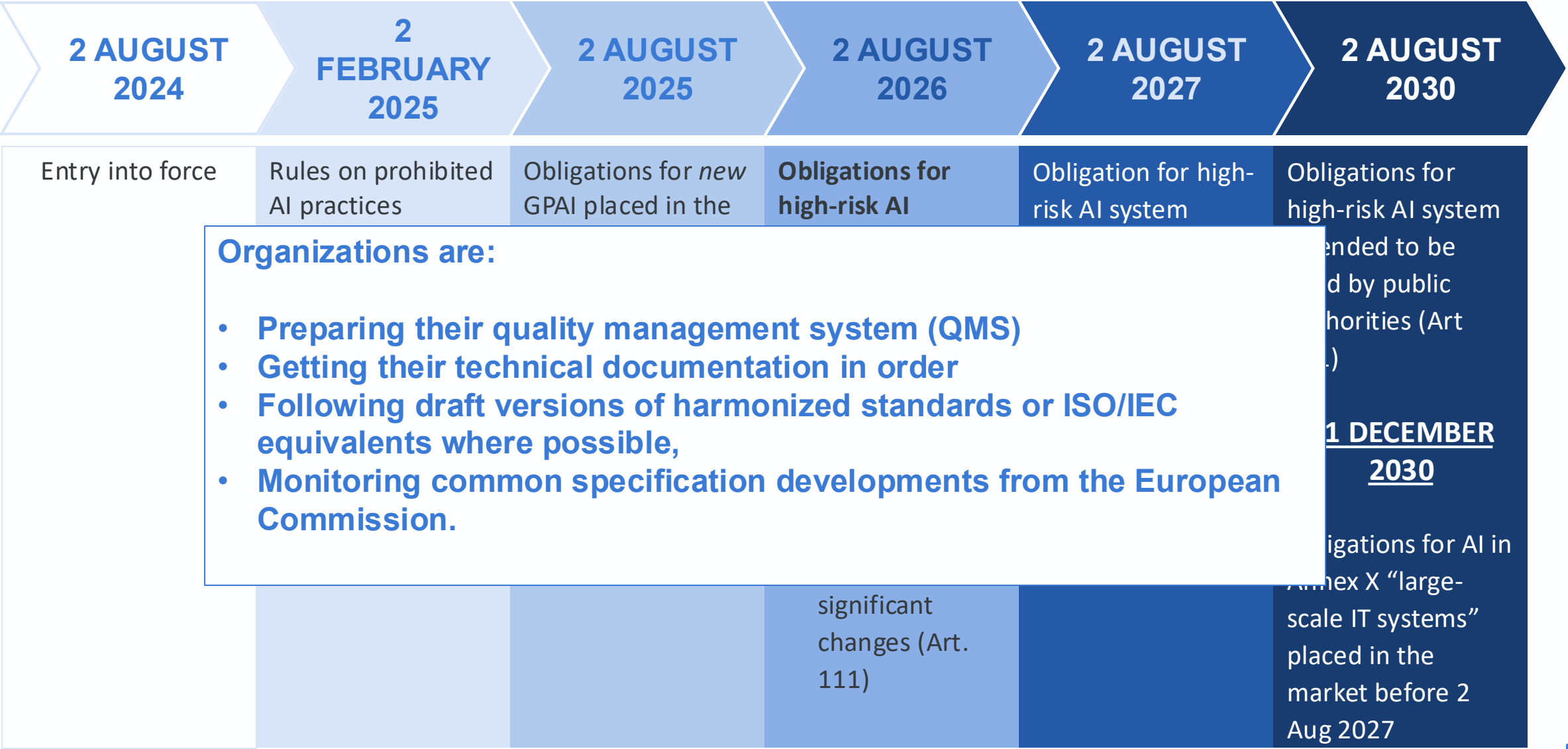


EU AI Act Timeline

2 AUGUST 2024	2 FEBRUARY 2025	2 AUGUST 2025	2 AUGUST 2026	2 AUGUST 2027	2 AUGUST 2030
Entry into force	Rules on prohibited AI practices (Chapter II) Rules on AI literacy (Art 4)	Obligations for <i>new</i> GPAI placed in the market (placed after this date) (Chapter V) National regulatory bodies appointed Penalties (Art 99, 100)	Obligations for high-risk AI systems – Except for: <ul style="list-style-type: none">High risk AI system covered by product legislationHigh risk AI placed before this date that do not undergo significant changes (Art. 111)	Obligation for high-risk AI system covered by product legislation Obligations for GPAI placed in the market before 2 Aug 2025 (Art 111)	Obligations for high-risk AI system intended to be used by public authorities (Art 111) <u>31 DECEMBER 2030</u> Obligations for AI in Annex X “large-scale IT systems” placed in the market before 2 Aug 2027



EU AI Act Timeline





What to do today!

Understand your use case

1. Are you dealing with an AI system?
2. Is it considered high risk?
3. What is your role? (Especially in relation to integrations and use of GPAI)
4. What conformity assessment route can you take? What is the state of product regulations and harmonised standards?
5. What actions will you take to draw your DoC?

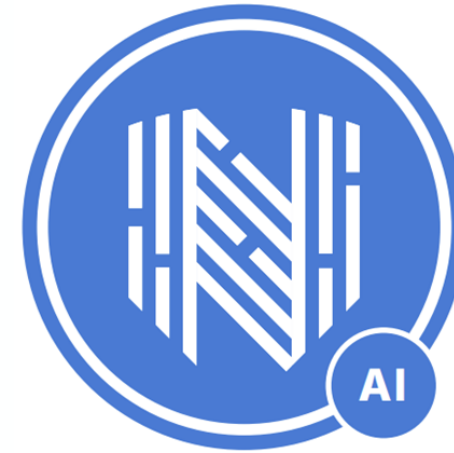


Act today with Nemko's AI Trust Mark

Our AI trust mark answers all your use case questions.

It uses a risk-based approach* to define a path that assesses your AI against regulatory obligations including those of the EU AI Act.

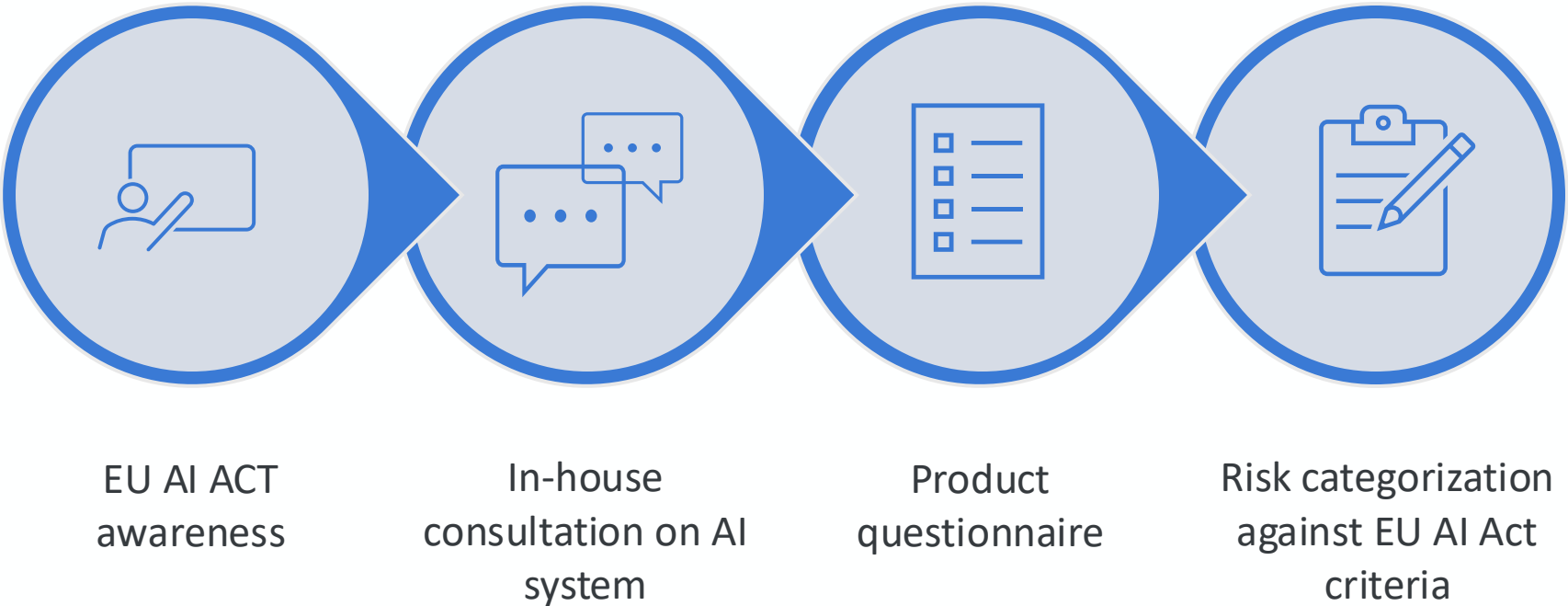
*Our **risk categorisation approach** is therefore included



AI Trust Mark

An AI Trust Mark for products and services assures clients of transparency, reliability, and regulatory alignment, enhancing user confidence and market credibility.

Risk Categorization: Our Approach



DELIVERABLE



Evaluation Report + Recommendations



Evaluation statement



Nemko Digital

Key interests and Service Offerings

Upcoming 30-min webinars

June 12th



AI Literacy

Our AI literacy program guides organization on how to assess, prepare, and train your teams and departments on AI Literacy.

June 24th



AI Trust Mark

Our AI Trust Mark assures clients of transparency, reliability, and regulatory alignment, enhancing user confidence and market credibility.

July 9th

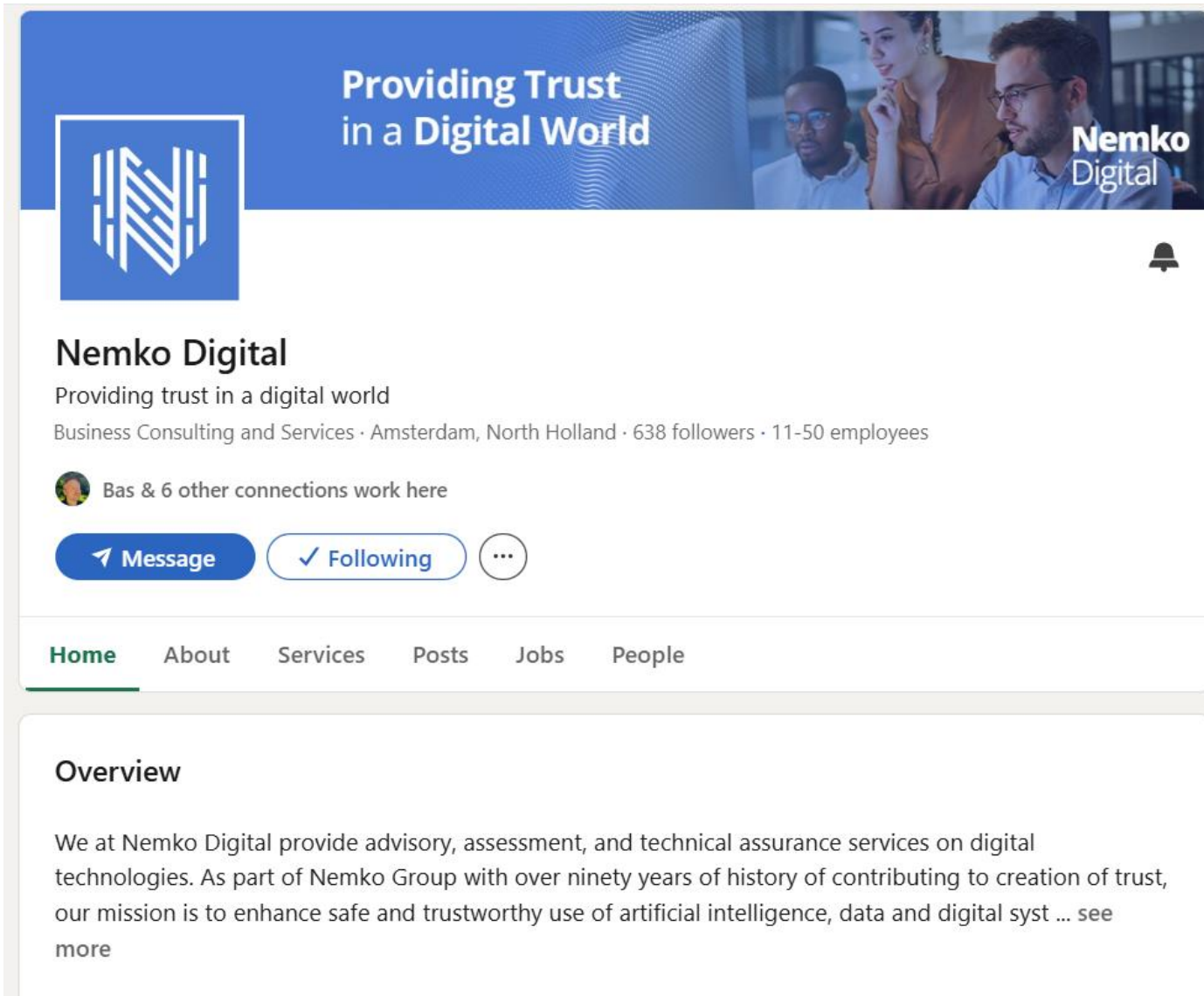


AI Maturity Model

Our maturity scan helps clients identify gaps, mitigate risks, and enhance compliance, ensuring responsible and effective AI implementation.



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Join us on LinkedIn or at the AI Hub, where we regularly share insights, videos, news, webinars, and other engaging content.



For complete details about our services, visit digital.nemko.com or explore our brochure.



Opportunity! Risk Categorization at a discounted price

As a thank you for joining us today, we're happy to offer **an exclusive discounted rate** on our **AI Risk Categorization Service**.

- Understand your system's AI risk level under the EU AI Act
- Get expert guidance tailored to your product
- Save time and reduce compliance costs
- Become one step ahead to obtaining our AI Trust Mark

This special offer is only available to webinar participants!



Fill in your details for the promotion here!





Thank you!

Q&A

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