Nemko Digital Webinar Report - EU AI Act: Making Sense of Conformity Assessments

1. Webinar Overview

Title: EU AI Act: Making Sense of Conformity Assessments
Date: 27 May 2025
Organiser: Nemko Digital (part of Nemko Group)
Presenters:

- **Bas Overtoom**, Global Business Development Director, Nemko Digital
- **Monica Fernandez**, Head of AI Assurance, Nemko Digital

Objectives:

- Explain the EU AI Act's risk-based approach.
- Clarify which AI systems are in scope.
- Detail roles, obligations, and conformity assessment routes.
- Provide actionable steps for organisations preparing for CE marking.

2. Nemko Digital Background

- Established in Amsterdam; part of Nemko Group with 90 years of product-compliance expertise.
- Services include:
    - AI management systems (ISO 42000 series), maturity models, data governance tools, and data literacy.
    - Advisory on global AI regulations and trustmark certification.

3. The EU AI Act at a Glance

3.1 Risk-Based Approach

- **Prohibited AI:** Practices deemed unacceptable (e.g., social scoring).
- **High-Risk AI:** Significant impact on safety or fundamental rights.
- **Limited-Risk AI:** Transparency obligations (e.g., chatbots).

- **Low-Risk AI:** No mandatory obligations; voluntary codes of conduct.
- **General-Purpose AI (GPAI):** Own category with emerging rules.

3.2 Definition of AI System

- Broadly covers any machine-based system with autonomy, adaptability post-deployment, and output generation (predictions, content, decisions).
- **Includes:** Standalone software; embedded AI in products; connected safety components; AI modules in larger systems.
- **Excludes:** Static rule-based devices (e.g., simple thermostats), spreadsheets, hard-coded scripts.

4. Risk Categories and Obligations

Risk Level	Obligations	Assessment Required?
Prohibited	N/A (banned)	N/A
High-Risk	Full set of requirements; CE marking; register	Yes (internal or notified)
Limited-Risk	Transparency (user information)	No
Low-Risk	Voluntary codes of conduct	No
General-Purpose	Specific emerging obligations	TBD

5. High-Risk AI Systems

5.1 Embedded in Regulated Products

- AI that contributes to safety of cars, medical devices, machinery (products under existing EU law).
- If those products already require third-party conformity, AI is high-risk (Annex I, Section A).

5.2 Standalone in Sensitive Domains

- AI used in education, employment, law enforcement, essential services, infrastructure, migration, justice, biometric identification (Annex III).
- Must register in the EU database and meet high-risk obligations.

6. Roles and Responsibilities

Actor	Primary Obligations
Provider	Perform conformity assessment; affix CE mark; maintain QMS and documentation for 10 years.
Deployer	Ensure system is assessed; obtain provider's information; transparency; risk monitoring.
Importer	Verify compliance; cooperate with authorities.
Distributor	Ensure products bear CE marking; maintain traceability.
Product Manufacturer	Align with sector-specific rules (e.g., MDR for medical devices).

Note: Roles can shift (e.g., deployer becomes provider if modifying or repurposing an AI system).

7. Conformity Assessments & CE Marking

7.1 CE Marking Requirements

Under Article 48, CE marking certifies:

1. Compliance with the AI Act's requirements.
2. Free circulation within the EU market.

7.2 Types of Assessments

1. **Internal Control (Self-Assessment)**
    a. Use harmonized EU standards/common specifications.
    b. Key steps:
        i. Implement an AI-specific Quality Management System (QMS).
        ii. Prepare technical documentation (design, development, risk management, post-market monitoring).
        iii. Draft and sign a Declaration of Conformity.
        iv. Retain documentation for 10 years.
        v. Affix CE marking (digital/physical).
2. **Notified-Body Assessment (Third-Party)**
    a. Required if harmonized standards are unavailable or not applied.

b. Notified body reviews QMS and documentation, inspects premises, audits processes, conducts tests, and may request model/data access.
c. More rigorous but ensures market access without common standards.

7.3 Assessment Routes by Annex

Annex	Scope	Route if Standards Exist	Route if Not
I Section A	AI in MLFW-regulated products (medical, toys, radio)	Internal Control	Notified-Body
I Section B	AI in vehicles, trains, planes (partial application)	Monitor sector laws	Monitor sector laws
III (Critical Areas)	Education, employment, law enforcement, etc.	Internal Control	Notified-Body
III Biometric	Facial recognition, emotion detection	Internal Control	Notified-Body

8. Timeline & Preparing Now

- **Summer 2024:** Act adopted.
- **2025 Q4:** Harmonized standards expected.
- **27 Aug 2025:** National regulatory authorities designated; notified-body designation begins.
- **2026:** Full enforcement.

Interim Preparations:

- Adopt draft or equivalent ISO standards (e.g., ISO 42001).
- Draft technical documentation aligned with anticipated harmonized standards.
- Enhance QMS and post-market monitoring.

9. Step 0: Preparatory Questions

Organisations should first:

1. Confirm whether their system qualifies as AI under the Act.
2. Determine if it is high-risk.
3. Clarify their role(s): provider, deployer, etc.
4. Identify applicable conformity assessment route.
5. Assess current state of sectoral regulations and standard availability.
6. Plan steps to issue a Declaration of Conformity.

10. Nemko Digital's AI Trustmark Process

1. **Awareness Session:** Intro to the EU AI Act.
2. **In-House Consultation:** Deep dive on your AI systems.
3. **Product Questionnaire:** Gather detailed system information.
4. **Risk Categorization:** Methodology aligned to the AI Act.
5. **Deliverables:**
    a. Evaluation report with compliance recommendations.
    b. Evaluation statement and roadmap.

Benefits: Demonstrates transparency, reliability, regulatory alignment, and boosts market credibility.

11. Audience Engagement & Poll Results

- ~200 attendees participated in a live poll:
    - 3% have formally categorized AI risk.
    - 56% have a general idea of their systems' risk levels.
    - 26% plan to categorize soon.
    - 15% are unsure how to start.

12. Promotional Offer

- **50% discount** on Nemko Digital's standalone risk-categorization project (normally €6 000) for webinar attendees.
- Voucher valid for 3 months post-webinar.

13. Q&A Highlights

- **Preparation Time:** Varies by use case and organisational maturity; typically 4–6 weeks with strong governance in place.
- **Deployers vs. Providers:** Deployers rely on provider's assessment and focus on transparency and monitoring.
- **Notified Bodies:** None yet designated under the AI Act; expected in late 2025. Medical-device AI continues under existing MDR notified bodies.

14. Conclusion

- Webinar materials (slides, recording) will be shared via email and Nemko Digital's website.
- Upcoming webinars: AI Trustmark (end of June), Data Literacy.

- Follow Nemko Digital on LinkedIn for regulatory updates.
- For tailored support, contact Nemko Digital at digital@nemko.com or visit digital.nemko.com.

Key Takeaways

- **Begin Now:** Early alignment with draft standards and QMS development reduces last-minute pressure.
- **Clarify Roles:** Understand how your organisation's integration or modification of AI affects duties under the Act.
- **Document Thoroughly:** Robust technical documentation and risk monitoring are non-negotiable.
- **Choose the Right Route:** Leverage harmonized standards for self-assessment where available; plan for notified-body review otherwise.
- **Leverage Expertise:** Consider external support (e.g., Nemko Digital's AI Trustmark) to streamline compliance and build stakeholder trust.