

Role of Notified Bodies in AI Regulation

Who certifies AI system compliance.

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Introduction to Notified Bodies

Within the framework of the EU AI Act, **notified bodies** play a central role in ensuring that high-risk AI systems meet legal and technical standards before entering the European market. These are independent, third-party organizations officially designated by EU Member States to carry out specific conformity assessment tasks.

Their primary function is to evaluate whether certain high-risk AI systems comply with the essential requirements laid out in the AI Act, especially when the provider does not—or cannot—use harmonized standards. Notified bodies act as gatekeepers of trust, verifying system safety, accuracy, transparency, and robustness in complex or sensitive use cases.



Legal Designation and Accreditation

Notified bodies are not self-appointed. They must be **designated by a national authority** within an EU Member State and subsequently notified to the European Commission. To receive this designation, an organization must demonstrate:

- Technical competence in AI system assessment
- Independence and impartiality in operations
- Adequate infrastructure, staff, and procedures
- Legal and financial accountability

Once approved, they are listed in the **NANDO (New Approach Notified and Designated Organisations) database**, making their credentials publicly accessible across the EU. They are subject to ongoing oversight, re-evaluation, and revocation if standards are not maintained.

Each notified body is assigned a unique identification number and a **defined scope of activity**, meaning they may specialize in particular sectors (e.g., healthcare or biometric identification) or system types.

Scope of Responsibilities

Notified bodies are responsible for conducting **third-party conformity assessments** when required under the AI Act. These assessments are typically necessary when:

- The provider does not fully rely on harmonized standards
- The AI system belongs to a particularly sensitive category
- A quality management system approach is being used
- Regulatory authorities require independent evaluation

Their core duties include:

- Reviewing technical documentation and risk management files
- Verifying data governance, testing procedures, and human oversight mechanisms
- Conducting audits, inspections, or simulations
- Evaluating cybersecurity, robustness, and transparency features
- Issuing **certificates of conformity** or **refusing certification** based on findings

Notified bodies may also participate in **post-certification surveillance**, helping ensure continued compliance after the AI system is on the market.

Interaction with Providers

AI system providers must engage notified bodies directly when their conformity assessment route requires external validation. This interaction typically involves:

- Submitting a formal application and compliance dossier
- Providing access to internal documentation, source materials, and logs



- Supporting on-site inspections, system testing, or simulations
- Addressing feedback, deficiencies, or corrective action requests

The process is formal, regulated, and includes timelines for decision-making, appeals, and revisions. Providers are responsible for covering the costs of these assessments.

While the provider retains ultimate responsibility for system compliance, certification by a notified body provides strong legal assurance and enables the affixing of the **CE marking**, which is mandatory for market access.

Issuance of EU-Type Examination Certificates

One of the key outcomes of a successful conformity assessment conducted by a notified body is the issuance of an **EU-type examination certificate**. This certificate confirms that:

- The system has been independently assessed
- All essential requirements have been verified
- The provider may now lawfully market the system in the EU

This certificate must be retained by the provider and presented to authorities upon request. It includes:

- The name and identification of the notified body
- Description of the AI system and its intended purpose
- Reference to applicable standards or common specifications
- Scope of assessment and results
- Validity conditions and limitations

If a notified body refuses certification, the provider must address the non-compliance issues and re-apply or choose an alternative conformity route if available.

Role in Quality Management System Assessments

In addition to individual system reviews, notified bodies also assess **quality management systems (QMS)** used by providers of high-risk AI systems. This route is often used by organizations that produce multiple systems or operate at scale.

In this context, the notified body evaluates:

- Design, development, and testing procedures
- Risk assessment and mitigation frameworks
- Internal audit and corrective action protocols
- Staff training and competence
- Change management processes

If the quality management system is deemed compliant, the provider can self-certify systems falling under that scope—subject to ongoing monitoring and re-assessment by the notified body.



This approach allows for efficient scaling of compliant AI development while maintaining high standards of accountability and traceability.

Surveillance and Continued Oversight

Notified bodies are not limited to pre-market assessment. They are also involved in **post-market activities**, including:

- Periodic audits of certified systems or QMS
- Follow-up inspections after serious incidents
- Re-assessment following significant system changes
- Review of monitoring logs, user complaints, or non-compliance reports

They may suspend or withdraw certification if they discover that the system no longer complies with the AI Act. Such actions must be reported to the relevant market surveillance authorities and may result in regulatory enforcement.

Providers must maintain regular communication with notified bodies and notify them of:

- Substantial system modifications
- Security breaches or major incidents
- Changes to the quality management system
- Updates to training data or algorithmic design

These obligations ensure that certification remains valid and aligned with real-world system behavior.

Relationship with Authorities and the AI Office

Notified bodies operate under the supervision of national **designating authorities**, which monitor their performance, independence, and regulatory alignment. These authorities conduct periodic evaluations and can suspend or revoke notified status in case of deficiencies.

Additionally, notified bodies coordinate with the **European Artificial Intelligence Office (EAIO)** and other EU-level entities to:

- Share best practices and standardize methodologies
- Participate in working groups and technical committees
- Receive updates on harmonized standards or common specifications
- Contribute to policy development and enforcement alignment

This multi-level governance structure ensures coherence and consistency in how AI regulation is implemented across the EU.



Use of Harmonized Standards and Common Specifications

When notified bodies assess AI systems, they consider whether the provider has used **harmonized standards** or **common specifications**. These documents serve as official benchmarks for compliance, making the assessment process more structured and transparent.

If harmonized standards are followed, notified bodies verify:

- Proper application of technical protocols
- Adequacy of validation methods and benchmarks
- Alignment with known performance thresholds

If standards are not used, the notified body must perform a more comprehensive evaluation, applying expert judgment and sector-specific criteria to determine compliance with the essential requirements.

This flexibility ensures that innovation is not constrained, while maintaining rigorous checks where predefined standards are unavailable or unsuitable.

Independence and Conflict of Interest

To preserve integrity and public trust, notified bodies must operate with **full independence** from the AI providers they assess. This includes:

- No ownership or financial control links with the provider
- No consultancy or development services related to the assessed system
- Transparent procedures for handling appeals or disagreements
- Internal safeguards against bias or external pressure

EU law imposes strict obligations around transparency, impartiality, and professional conduct. Non-compliance with these principles can result in loss of designation and legal liability.

Transparency and Accountability

Notified bodies must maintain detailed records of all assessments, decisions, and communications. These records may be:

- Audited by national authorities
- Requested by the European Commission or the AI Office
- Shared with other notified bodies in cross-border or multi-sectoral cases

Summaries of conformity assessments, particularly EU-type examination certificates, may also be published to inform regulators, deployers, and the public.

This accountability framework ensures that certification processes are consistent, justifiable, and aligned with public interest objectives.



Conclusion

Notified bodies are essential actors in the implementation of the EU AI Act. As independent assessors, they provide the technical and legal scrutiny needed to certify high-risk AI systems for safe use in the EU.

Through rigorous evaluation of system design, functionality, and risk management, notified bodies help enforce regulatory standards and safeguard fundamental rights. Their role bridges the gap between innovation and regulation, offering providers a clear pathway to compliance while protecting users from untested or unsafe technologies.

As AI deployment accelerates, the expertise and oversight provided by notified bodies will remain critical to fostering a trustworthy, lawful, and harmonized AI ecosystem across the European Union.



Glossary

Act or EU AI Act: European Union Artificial Intelligence Act

AI: Artificial Intelligence

Board: European Union Artificial Intelligence Board

EU: European Union

SME: Small and Medium-Sized Enterprise

How can we help?



AI & Partners ‘—AI That You Can Trust’

At AI & Partners, we’re here to help you navigate the complexities of the EU AI Act, so you can focus on what matters—using AI to grow your business. We specialize in guiding companies through compliance with tailored solutions that fit your needs. Why us? Because we combine deep AI expertise with practical, actionable strategies to ensure you stay compliant and responsible, without losing sight of your goals. With our support, you get AI you can trust—safe, accountable, and aligned with the law.

To find out how we can help you, email contact@ai-and-partners.com or visit <https://www.ai-and-partners.com>.

