Conformity Assessment Procedures

Pre-market compliance evaluations explained.

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3. Compliance and Conformity Assessment — Standards, Checks, Monitoring, Enforcement

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Introduction to Conformity Assessment

Under the EU AI Act, high-risk AI systems must undergo a **conformity assessment** before being placed on the market or put into service within the EU. This assessment serves as a structured, pre-market evaluation to ensure that the AI system complies with all applicable legal requirements — particularly those related to safety, transparency, data governance, and human oversight.

The conformity assessment acts as a regulatory checkpoint. It provides a documented demonstration that the system has been developed and tested in accordance with the obligations outlined in the Act. Without a successful conformity assessment, high-risk AI systems cannot receive the required CE marking and are therefore barred from commercial or operational deployment in the EU.

Purpose and Scope

The conformity assessment process is designed to:

- Ensure that the system performs reliably under expected conditions
- Verify compliance with fundamental rights and safety protections
- Provide transparency and accountability in system development and use
- Prevent deployment of systems that pose unacceptable or unmitigated risks

While it applies specifically to **high-risk systems**, the conformity assessment framework also complements broader regulatory goals around responsible AI development and public trust.

The procedure does not assess business models or general innovation practices. It focuses narrowly on the **technical, operational, and ethical compliance** of the AI system in relation to its intended use.

When and How the Assessment Applies

Conformity assessments are **mandatory before market placement** or commissioning of a high-risk AI system. This includes:

- AI systems developed entirely within the EU
- Imported AI systems from third countries
- Systems undergoing substantial modification post-deployment

The assessment must be completed **before any commercial sale, public use, or internal deployment** involving real users or sensitive environments.

A reassessment is also required if the system undergoes significant updates that affect its compliance—such as changes to core functionality, training datasets, or deployment context. A new conformity assessment is required under the EU AI Act where the AI system is subject to a substantial modification. However, the activities of a high-risk AI system that continues to learn after being operational on the market in a way that is pre-determined by the provider and is set out in the technical documentation will not be considered to be a substantial modification.

Available Conformity Assessment Routes

The EU AI Act provides different pathways for conformity assessment, depending on the nature of the system and whether harmonized standards are used. The rules are:

1. Stand alone high-risk AI systems using biometrics

   For these AI systems, if the provider has applied harmonised standards or common specifications, the provider can decide to either follow the internal control conformity assessment process (essentially a self-assessment) or a third party notified body assessment of the quality management system and technical documentation.

2. Remaining stand alone high-risk AI systems

   For these AI systems, the provider should always follow the internal control conformity assessment where there is no third party notified body involvement.

3. High-risk AI systems covered by EU harmonisation legislation

For these AI systems based on the New Legislative Framework, the provider must follow the conformity assessment procedure required by the specific EU legislative framework that regulates that product. In this scenario, the notified body which is relevant under the specific EU legislative framework is entitled to control the conformity assessment under the EU AI Act. If the relevant EU legislative framework enables a product manufacturer to opt out from a third party conformity assessment, that manufacturer can only rely on that option if it has also applied harmonised standards or common specifications.

Contents of the Conformity Assessment

Regardless of the route taken, all conformity assessments must verify that the AI system meets the core legal obligations for high-risk systems. This includes:

- A **comprehensive risk management system** addressing all stages of development and use
- High-quality and appropriately governed training and validation **datasets**
- Accurate, complete, and current **technical documentation**
- Mechanisms for **traceability**, including automatic logging
- Embedded **human oversight** features to ensure controllability and intervention
- Evidence of **accuracy, robustness, and cybersecurity resilience**
- Clear and accessible **instructions for use**
- Internal procedures for **post-market monitoring and incident reporting**

Each of these elements must be documented, traceable, and available for review by regulators or market surveillance authorities.

CE Marking and the Declaration of Conformity

The provider issues an **EU Declaration of Conformity** to demonstrate that the AI system meets the core requirements for high-risk AI systems specified under the EU AI Act. This legal document confirms that the system complies with the AI Act and any other applicable EU legislation, such as product safety or cybersecurity regulations. The EU AI Act specifically states that a single declaration of conformity can be used for all EU law applicable to the high-risk AI system.

The provider must then:

- Affix the **CE marking** visibly and permanently to the system
- Ensure that all packaging, manuals, and accompanying materials include the required markings and declarations
- Retain the declaration and technical documentation for at least **ten years** after the last unit has been placed on the market

The CE mark is not merely a symbol — it is a legal affirmation that the system meets EU standards and can circulate freely across the European market.

Role of Harmonized Standards and Common Specifications

To support conformity assessments, the European Commission will publish a list of **harmonized standards** that outline specific methods, metrics, and benchmarks for evaluating AI systems and GPAI models. These standards serve as a blueprint for compliance, simplifying the internal assessment process and offering legal certainty. Standards are devised by European standardisation organisations and must be clear and consistent.

In the absence of relevant harmonized standards, the Commission may draft and issue **common specifications**—alternative technical guidance that carries the same legal weight, albeit seen as an exceptional fallback where harmonized standards are not available. The European Commission may issue such common specifications under certain conditions which include:

- Where the Commission has requested European standardization organizations to draft a harmonized standard, but the request has not been accepted, or the standards are not delivered on time, or they insufficiently address fundamental rights concerns, or they do not comply with the request; and
- There is no published reference to harmonized standards covering the requirements in the Official Journal of the European Union, and no such reference is expected to be published within a reasonable period.

Common specifications are adopted by the Commission through implementing acts.

Relying on harmonized standards or common specifications is not mandatory, but it provides a **presumption of conformity** — making regulatory approval more predictable and efficient.

Monitoring and Surveillance After Certification

Conformity assessments are not a one-time event. Providers must maintain an active **post-market surveillance system** to ensure the AI system continues to meet requirements once deployed.

This includes:

- Collecting and analyzing operational data
- Monitoring system performance over time
- Reporting serious incidents or systemic failures
- Updating technical documentation based on real-world findings

Regulatory authorities may conduct periodic audits, request documentation, or require additional testing if concerns arise. The **CE marking may be withdrawn** if the system is found to no longer meet legal standards.

Enforcement and Penalties for Non-Compliance

Non-compliance with conformity assessment obligations carries serious consequences. Enforcement actions can include:

- Fines up to €15 million or 3% of global annual turnover
- Suspension of system deployment

- Mandatory product recalls
- Revocation of CE marking

Regulatory enforcement is coordinated across the EU through national authorities and the **European Artificial Intelligence Office**, ensuring consistency and proportionality in how rules are applied.

Special Cases and Exceptions

Certain AI systems may qualify for **derogations** or alternative compliance mechanisms in limited circumstances, such as:

- Emergency deployment for public security
- Exceptional circumstances for the protection of life and health of persons
- Environmental protection or protection of key industrial and infrastructural assets

But it is the market surveillance authority who authorises the placing on the market of high-risk AI systems that have not been subject to a conformity assessment – a provider cannot unilaterally make that decision.

Regulatory **sandboxes** may also offer providers a controlled environment to test innovative systems with regulatory supervision. These sandboxes help facilitate safe experimentation while preparing the system for formal conformity assessment.

Conclusion

Conformity assessment procedures are central to the EU's approach to AI regulation. They ensure that high-risk AI systems are vetted, documented, and validated **before** they can be deployed in real-world environments. By combining technical review, procedural oversight, and legal accountability, the assessment framework strengthens public trust and market integrity.

Providers must engage with the process early in system development, integrating compliance planning into design, testing, and risk management. Where a conformity assessment involves a third party notified body, a provider should plan carefully bearing in mind the time it will take to apply to and liaise with the notified body. With a clear structure, defined routes, and supporting tools like harmonized standards, the conformity assessment process offers both **regulatory clarity** and **consumer protection** — anchoring the EU's commitment to safe and ethical AI.

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

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