



# Deciphering the Maze: Clarifying Conformity Assessments

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## 2. High-Risk AI Systems: Understanding obligations and criteria.

<p><b>2.1 Identification of High-Risk Systems</b></p> <p><i>Criteria for classifying high-risk AI systems.</i></p>	<p><b>2.2 Obligations for Providers</b></p> <p><i>Compliance requirements for high-risk AI systems.</i></p>	<p><b>2.3 Conformity Assessment</b></p> <p><i>Procedures for verifying compliance with the Act.</i></p>	<p><b>2.4 Registration Requirements</b></p> <p><i>The necessity for high-risk AI systems to be registered.</i></p>
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### Introduction

The European Union's ("EU") Artificial Intelligence ("AI") Act (the "EU AI Act") represents a pioneering step towards regulating AI technologies, setting a global benchmark for ensuring these systems are safe, ethical, and respect fundamental rights. At the heart of this legislative framework is the categorization of high-risk AI systems, which are subject to stringent oversight due to their potential impact on individuals' rights and safety. High-risk AI systems include those deployed in critical sectors such as healthcare, policing, and employment, where their decisions can significantly affect people's lives.





Conformity assessments are critical within this context, serving as the mechanism through which providers of high-risk AI systems demonstrate compliance with the Act's requirements. These assessments ensure that AI systems are rigorously evaluated against established standards for safety, transparency, and accountability before they are introduced to the market or put into service. Notified bodies, designated under the Act, play a pivotal role in this process, verifying that high-risk AI systems meet the necessary criteria to safeguard users and the public..

This structured approach to conformity assessments underlines the EU's commitment to fostering innovation in AI while prioritizing the protection of fundamental rights.

## Understanding High-Risk AI Systems

High-risk AI systems, as defined by the EU AI Act, are those AI technologies that, due to their application or the sector in which they are used, pose significant risks to the health, safety, or fundamental rights of individuals. These systems are subject to stringent regulatory oversight to ensure they meet robust standards of safety, transparency, and accountability before they can be deployed.

The Act classifies AI systems as high-risk based on two main criteria: their intended use and the severity of the risk they pose. Specifically, an AI system is considered high-risk if it is intended to be used as a safety component of a product or if it is itself a product that is covered by Union harmonisation legislation and is required to undergo a third-party conformity assessment. Additionally, AI systems referred to in Annex III of the Act, which include those used in critical infrastructure, education, employment, law enforcement, and several other key sectors, are also classified as high-risk.

This classification underscores the EU's commitment to ensuring that AI systems are deployed responsibly and ethically, with a clear focus on safeguarding public interests and individual rights. By delineating specific criteria for high-risk AI systems, the Act provides a framework for identifying those technologies that require closer scrutiny, thereby fostering a safer and more trustworthy AI ecosystem.

## The Role of Notified Bodies

Notified bodies are essential entities within the EU's regulatory framework for high-risk AI systems, tasked with verifying the conformity of these systems against the stringent requirements set out in the EU AI Act. Their role is pivotal in the conformity assessment process, ensuring that AI systems meet the necessary safety, transparency, and accountability standards before they are deployed in the market.

One of the key operational obligations of notified bodies is to minimize administrative burdens for providers, particularly for micro- and small enterprises. This is crucial in maintaining a balance between rigorous compliance and the practical capabilities of smaller organizations. Notified bodies are required to consider the size of the provider, the sector in which it operates, its structure, and the complexity of the high-risk AI system concerned. This tailored approach helps in reducing compliance costs and administrative hurdles for smaller entities, without compromising the level of protection and the rigor needed for the compliance of high-risk AI systems.

By fulfilling these responsibilities, notified bodies play a critical role in facilitating innovation and ensuring that the deployment of AI technologies is both safe and compliant with EU regulations. Their work supports the broader goal of the EU AI Act to foster trust and safety in AI applications across the Union.





## Conformity Assessment Procedures

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The EU AI Act delineates specific conformity assessment procedures for high-risk AI systems, ensuring their compliance with established safety and ethical standards. Providers of high-risk AI systems have the option to choose between two main conformity assessment procedures: internal control or an assessment involving a notified body.

The internal control procedure allows providers to verify their AI systems' compliance through established quality management systems, assessing the technical documentation against the essential requirements set out in the Act 3. This procedure is generally applicable to high-risk AI systems not requiring the involvement of a notified body, offering a streamlined path to demonstrate compliance.

Alternatively, providers may opt for a more rigorous assessment that involves a notified body, especially when harmonized standards are not fully applied or common specifications are not available. This procedure includes an assessment of the quality management system and the technical documentation by the notified body, ensuring a comprehensive evaluation of the AI system's compliance.

The choice between these procedures depends on specific conditions, such as the existence of harmonized standards or common specifications and the extent to which they have been applied by the provider. Harmonized standards and common specifications play a crucial role in demonstrating compliance, as adherence to these standards presumes conformity with the Act's requirements, simplifying the assessment process.

This structured approach to conformity assessments under the EU AI Act ensures that high-risk AI systems meet the necessary standards for safety and ethics, fostering trust and reliability in AI technologies.

## Overview of Providers

Under the EU AI Act, providers of high-risk AI systems are entrusted with a series of critical responsibilities to ensure the safety, transparency, and accountability of their technologies. Key among these duties is the obligation to ensure that their AI systems comply with the stringent requirements set out in the Act. This includes undergoing rigorous conformity assessments to verify that these systems meet the established standards before they are placed on the market or put into service.

A cornerstone of these obligations is the establishment and maintenance of a comprehensive quality management system. This system must be meticulously documented, encompassing policies, procedures, and instructions that cover a wide array of aspects. These range from regulatory compliance strategies, design and development processes, to risk management and post-market monitoring systems. The quality management system is fundamental not only for demonstrating compliance but also for facilitating the conformity assessment process. It ensures that high-risk AI systems are designed, developed, and tested under a framework that prioritizes quality, safety, and compliance from the outset.

Moreover, providers are required to keep detailed documentation and logs generated by their AI systems, which are crucial for the conformity assessment and for demonstrating compliance upon request by competent authorities. This structured approach underscores the EU's commitment to fostering innovation within a framework that ensures AI technologies are deployed responsibly and ethically, safeguarding public interests and individual rights.





## Conclusion

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Conformity assessments stand as a cornerstone in the deployment of high-risk AI systems, ensuring they align with the EU's stringent standards for safety, transparency, and ethical considerations.

These assessments, as outlined in the EU AI Act, provide a structured pathway for providers to demonstrate their AI systems' compliance with regulatory requirements, thereby fostering trust among users and stakeholders. The Act specifies procedures for conformity assessments, including the choice between internal control and external evaluation by notified bodies, depending on the application of harmonized standards or common specifications.

For providers navigating this compliance landscape, understanding the nuances of these procedures is paramount. The Act's framework, including the roles of notified bodies and the importance of quality management systems, guides providers through the necessary steps to ensure their AI systems meet the required safety and ethical standards before market deployment. This meticulous approach not only safeguards public interests but also underscores the EU's commitment to harmonizing innovation with consumer and societal protection. As the AI landscape evolves, staying abreast of these requirements will be crucial for providers aiming to lead in the ethical deployment of AI technologies.





## 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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