

SESSION TITLE

Conformity assessment for high-risk systems - The role of testing

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COMPETENCE CENTRE



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Conformity assessment for high-risk systems - The role of
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conformity assessment

demonstration that specified **requirements** are fulfilled

object of conformity assessment

entity to which specified **requirements** apply

ISO/IEC 17000:2020(en)

Conformity assessment — Vocabulary and general principles

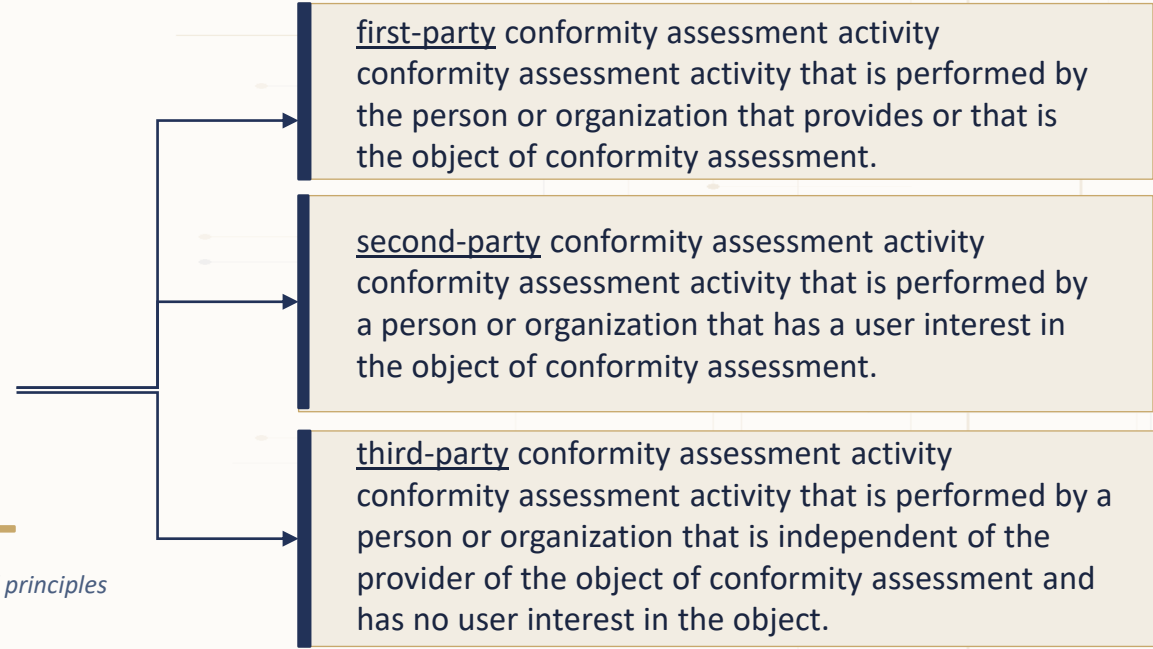
The process of conformity assessment can have a negative outcome, i.e. demonstrating that the specified requirements are not fulfilled.

Conformity assessment includes activities such as but not limited to testing, inspection, validation, verification, certification and accreditation.

Conformity assessment consist of a series of functions. Activities contributing to any of these functions can be described as conformity assessment activities.

Examples: Product, process, service, system, installation, project, data, design, material, claim, person, body or organization, or any combination thereof.

Types of conformity assessment activities



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graph LR; A[Types of conformity assessment activities] --> B["first-party conformity assessment activity  
conformity assessment activity that is performed by the person or organization that provides or that is the object of conformity assessment."]; A --> C["second-party conformity assessment activity  
conformity assessment activity that is performed by a person or organization that has a user interest in the object of conformity assessment."]; A --> D["third-party conformity assessment activity  
conformity assessment activity that is performed by a person or organization that is independent of the provider of the object of conformity assessment and has no user interest in the object."];
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ISO/IEC 17000:2020(en)

Conformity assessment — Vocabulary and general principles

first-party conformity assessment activity
conformity assessment activity that is performed by the person or organization that provides or that is the object of conformity assessment.

second-party conformity assessment activity
conformity assessment activity that is performed by a person or organization that has a user interest in the object of conformity assessment.

third-party conformity assessment activity
conformity assessment activity that is performed by a person or organization that is independent of the provider of the object of conformity assessment and has no user interest in the object.

Conformity assessment Body & Notified Body

conformity assessment body

body that performs conformity assessment activities, excluding accreditation

Notified body

A notified body is an organisation designated by an EU country to assess the conformity of certain products before being placed on the market.

ISO/IEC 17000:2020(en)
Conformity assessment — Vocabulary and general principles
Section 4, EU AI Act

Notifying authorities shall notify the Commission and the other Member States, using the electronic notification tool developed and managed by the Commission

Notified bodies shall be independent of the provider of a high-risk AI system in relation to which they perform conformity assessment activities. Notified bodies shall also be independent of any other operator having an economic interest in high-risk AI systems assessed, as well as of any competitors of the provider.

A notified body shall be established under the national law of a Member State and shall have legal personality.

Notified bodies carry out tasks related to conformity assessment procedures set out in the applicable legislation, when a third party is required. The European Commission publishes a list of such notified bodies.

Conformity assessment Body & Notified Body

https://webgate.ec.europa.eu/single-market-compliance-space/notified-bodies/free-search?filter=notificationStatus:1,legislation:168380

 EN

Single Market Compliance Space

Home Notified Bodies Market surveillance Glossary

Home > Notified Bodies > Free search

Free search

Refine list of bodies using search criteria below (by entering appropriate keywords) and click on body name to view details

Search options

Notification status

Active

Body number

Body name

Search results (0)

NOTIFICATION STATUS Active

LEGISLATION Regulation (EU) 2024/1689 on artificial intelligence (Artificial Intelligence Ac...)

CSV

Body type	Body name	Country
No data		

https://webgate.
ec.europa.eu/sin
gle-market-
compliance-
space/notified-
bodies

Conformity assessment Body & Notified Body

https://webgate.ec.europa.eu/single-market-compliance-space/notified-bodies/free-search?filter=notificationStatus:1,legislation:168380

 European Commission

EN

Single Market Compliance Space

Home Notified Bodies Market surveillance Glossary

Home > Notified Bodies > Free search

Free search

Refine list of bodies using search criteria below (by entering appropriate keywords) and click on body name to view details

Search options

Notification status
Active

Body number

Body name

Search results (35)

NOTIFICATION STATUS Active

LEGISLATION 2009/48/EC Safety of toys

CSV

Body type	Body name	Country
NB 1237	INTERTEK FRANCE	France
NB 0493	CENTEXBEL (WETENSCHAPPELIJK EN TECHNISCH CENTRUM VAN DE BELGISCHE TEXTIELNIJVERHEID - DIVISIE GENT)	Belgium

https://webgate.
ec.europa.eu/sin
gle-market-
compliance-
space/notified-
bodies

object of conformity assessment

Biometrics, in so far as their use is permitted under relevant Union or national law:
(a) remote biometric identification systems. (b) AI systems intended to be used for biometric categorisation, according to sensitive or protected attributes or characteristics based on the inference of those attributes or characteristics;
(c) AI systems intended to be used for emotion recognition.

Require- ments

Section 2 – Requirements for High-Risk AI Systems

Article 9 → Risk management system
Article 10 → Data and data governance
Article 11 → Technical documentation
Article 12 → Record-keeping

Article 13 → Transparency and provision of information to deployers
Article 14 → Human oversight
Article 15 → Accuracy, robustness and cybersecurity

Demons- tration

If the provider has applied harmonised standards, or, where applicable, common specifications, they choose between:

- (a) the **internal control** referred to in Annex VI; or
- (b) the **assessment of the quality management system** and the assessment of the **technical documentation**, with the involvement of a **notified body**, referred to in Annex VII.

Conformity assessment procedure based on internal control

Annex VI

Self-assessment

The provider verifies that the established quality management system is in compliance with the requirements of Article 17.

The provider examines the information contained in the technical documentation in order to assess the compliance of the AI system with the relevant essential requirements set out in Chapter III, Section 2.

The provider also verifies that the design and development process of the AI system and its post-market monitoring as referred to in Article 72 is consistent with the technical documentation.

Conformity based on an assessment of the quality management system and an assessment of the technical documentation

Annex VII

3rd party
assessment

The quality management system shall be assessed by the notified body, which shall determine whether it satisfies the requirements referred to in Article 17.

The technical documentation shall be examined by the notified body. Where relevant and limited to what is necessary to fulfil its tasks, the notified body shall be granted full access to the training, validation, and testing data sets used, including, where appropriate and subject to security safeguards, through API or other relevant technical means and tools enabling remote access.

In examining the technical documentation, the notified body may require that the provider supply further evidence or carry out further tests so as to enable a proper assessment of the conformity of the AI system with the requirements set out in Chapter III, Section 2. Where the notified body is not satisfied with the tests carried out by the provider, the notified body shall itself directly carry out adequate tests, as appropriate.

The notified body shall carry out periodic audits to make sure that the provider maintains and applies the quality management system and shall provide the provider with an audit report.

KEY CONCEPT

The technical documentation of a high-risk AI system shall be drawn up before that system is placed on the market or put into service and shall be kept up-to date.

ARTICLE 11

The technical documentation shall be drawn up in such a way as to demonstrate that the high-risk AI system complies with the requirements set out in Section 2 and to provide national competent authorities and notified bodies with the necessary information in a clear and comprehensive form to assess the compliance of the AI system with those requirements.

It shall contain, at a minimum, the elements set out in Annex IV.

SMEs, including start-ups, may provide the elements of the technical documentation specified in Annex IV in a simplified manner.

Demonstrating compliance

In demonstrating the compliance of a high-risk AI system with the requirements set out in Section 2, the provider shall follow the conformity assessment procedure set out in Annex VII where:

- (a) harmonised standards referred to in Article 40 do not exist, and common specifications referred to in Article 41 are not available;
- (b) the provider has not applied, or has applied only part of, the harmonised standard;
- (c) the common specifications referred to in point (a) exist, but the provider has not applied them;
- (d) one or more of the harmonised standards referred to in point (a) has been published with a restriction, and only on the part of the standard that was restricted.

Harmonized standards

C(2025)3871 – Standardisation request M/613

COMMISSION IMPLEMENTING DECISION of 23.6.2025 on a standardisation request to the European Committee for Standardisation and the European Committee for Electrotechnical Standardisation as regards high-risk AI-systems in support of Regulation (EU) 2024/1689 of the European Parliament and of the Council and repealing Implementing Decision C(2023)3215

Download [here](#)

Adoption date
23 June 2025
ESOs notified
CEN (accepted) , CENELEC (accepted)
Intended purpose
Harmonised standards supporting EU harmonisation legislation
Related legislation
2024/1689

https://ec.europa.eu/growth/tools-databases/enorm/mandate/613_en

List of new harmonised standards drafted

1.	Harmonised standard(s) risk management system
2.	Harmonised standard(s) governance and quality
3.	Harmonised standard(s) record keeping through
4.	Harmonised standard(s) transparency and inform
5.	Harmonised standard(s) human oversight of AI s
6.	Harmonised standard(s) accuracy specifications
7.	Harmonised standard(s) robustness specification

[https://ec.europa.eu/transparency/documents-register/detail?ref=C\(2025\)3871&lang=en](https://ec.europa.eu/transparency/documents-register/detail?ref=C(2025)3871&lang=en)

CENELEC		
CEN/CLC/JTC 21	prEN 18282 (WI=JT021029) Artificial intelligence - Cybersecurity specifications for AI Systems	Under Approval
CEN/CLC/JTC 21	prEN 18283 (WI=JT021036) Artificial Intelligence - Concepts, measures and requirements for managing bias in AI systems	Under Drafting
CEN/CLC/JTC 21	prEN 18284 (WI=JT021037) Artificial Intelligence -- Quality and governance of datasets in AI	Under Drafting
CEN/CLC/JTC 21	prEN 18285 (WI=JT021038) AI Conformity assessment framework	Under Drafting
CEN/CLC/JTC 21	prEN 18286 (WI=JT021039) Artificial intelligence - Quality management system for EU AI Act regulatory purposes	Under Approval
CEN/CLC/JTC 21	prEN 18287 (WI=JT021035) Sustainable Artificial Intelligence – Guidelines and metrics for the environmental impact of artificial intelligence systems and services	Under Drafting
CEN/CLC/JTC 21	prEN 18288 (WI=JT021044) Artificial Intelligence - Taxonomy of AI tasks in computer vision	Under Enquiry
CEN/CLC/JTC 21	prEN ISO/IEC 24970 (WI=JT021021) Artificial intelligence - AI system logging (ISO/IEC DIS 24970:2025)	Under Approval
CEN/CLC/JTC 21	prEN ISO/IEC 25029 (WI=JT021046) Artificial intelligence - AI-enhanced debugging	Under Approval

<https://standards.cencenelec.eu/ords/f?p=205:105:::;&cs=117B8E8682150D42818988EEE05C945D6>

KEY CONCEPT

The quality management system for the design, development and testing of AI systems pursuant to Article 17

ARTICLE 17

prEN 18286, Artificial Intelligence - Quality management system for EU AI Act regulatory purposes

The standard is intended to provide detailed technical specifications for establishing, implementing, and maintaining a quality management system that ensures compliance with the AI Act.

Once adopted and, assuming its reference is published in the Official Journal of the European Union, compliance with prEN 18286 will hopefully confer a presumption of conformity with the requirements of Article 17. This means providers who implement their QMS in accordance with the standard can presume they meet regulatory obligations, significantly reducing legal uncertainty and facilitating market access.

<https://adamleonsmith.substack.com/p/pren-18286>

Thank You

We look forward to the conversation.

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