

TECHNICAL REPORT

CEN/CLC/TR 17894

RAPPORT TECHNIQUE

TECHNISCHER REPORT

December 2024

ICS 03.120.20; 35.240.01

English version

Artificial Intelligence - Artificial Intelligence Conformity Assessment

Intelligence Artificielle - Évaluation de la conformité
liée à l'Intelligence Artificielle

Künstliche Intelligenz - Konformitätsbewertung von
Künstlicher Intelligenz

This Technical Report was approved by CEN on 25 November 2024. It has been drawn up by the Technical Committee CEN/CLC/JTC 21.

CEN and CENELEC members are the national standards bodies and national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and United Kingdom.



**CEN-CENELEC Management Centre:
Rue de la Science 23, B-1040 Brussels**

Contents

Page

European foreword.....	4
1 Scope.....	5
2 Normative references.....	5
3 Terms and definitions.....	5
4 Framework of conformity assessment and objects of conformity assessment.....	6
4.1 General.....	6
4.2 International accreditation and conformity assessment framework.....	6
4.2.1 General.....	6
4.2.2 Level 5.....	7
4.2.3 Level 4.....	8
4.2.4 Level 3.....	8
4.2.5 Level 2.....	9
4.2.6 Level 1.....	9
4.3 Conformity assessment modules.....	9
4.3.1 Conformity assessment modules of Decision No 768/2008/EC.....	9
4.3.2 Conformity assessment modules of the EU AI Act.....	12
4.3.3 Conformity assessment modules following the EU AI Act Annex II Section A.....	14
4.3.4 Conformity assessment modules under sectorial legislation.....	14
4.4 Considerations on the interplay of conformity assessment under EU AI Act and sectorial legislation.....	21
4.4.1 General.....	21
4.4.2 Interplay between notified body requirements under EU AI Act and its Annex II Section A legislation.....	21
4.4.3 Possible interplay between conformity assessment in the Machinery Regulation and the EU AI Act.....	22
4.4.4 Possible interplay between conformity assessment in the medical devices sectorial legislation and the EU AI Act.....	23
4.4.5 Conformity assessment in the automotive sectorial legislation.....	23
4.4.6 Conformity assessment of representative AI system (aka ‘sampling’).....	24
5 Mapping of horizontal and vertical standard items to the level system and assignment to conformity assessment activities.....	26
5.1 Mapping of AI horizontal standard items to conformity assessment activities.....	26
5.1.1 General.....	26
5.1.2 Management system certification according to EN ISO/IEC 17021-1.....	27
5.1.3 Inspection according to EN ISO/IEC 17020.....	27
5.1.4 Testing according to EN ISO/IEC 17025.....	28
5.1.5 Verification and Validation according to EN ISO/IEC 17029.....	28
5.1.6 Product, process or service certification according to EN ISO/IEC 17065.....	29
6 Supporting compliance to EU AI Act.....	29
6.1 Analysis of conformity assessment elements in EU AI Act.....	29
6.1.1 Conformity assessment requirements for high-risk AI systems according to EU C(2023)3215 – Standardization request M/593.....	29
6.1.2 Interdependencies of EU AI Act provisions.....	30
6.1.3 Article 17 “quality management system” in the EU AI Act.....	32
6.2 EN ISO/IEC 17065 certification approach related to EU AI Act.....	33
6.2.1 General.....	33
6.2.2 Potential certification process according to EN ISO/IEC 17065.....	34

6.2.3	Accreditation of certification bodies according to EN ISO/IEC 17065 within the field of AI.....	36
6.3	Role of testing for conformity assessments	37
6.3.1	General	37
6.3.2	Testing of general purpose AI models and general purpose AI models with systemic risk.....	38
6.4	Measurement, measures and metrics	38
7	Existing horizontal certifications possibly relevant for the AI area	41
7.1	General	41
7.2	Data related certifications: the example of GDPR-CARPA national level certification	41
7.3	Cybersecurity related certification	42
8	Observations and identified gaps	42
8.1	General	42
8.2	Challenges of terms and definitions operationalisation for AI conformity assessment	44
8.2.1	General	44
8.2.2	Identified differences of terms definition	44
	Annex A (informative) Tools to support operationalisation of AI conformity assessment..	45
	Bibliography	46

European foreword

This document (CEN/CLC/TR 17894:2024) has been prepared by Technical Committee CEN/CENELEC JTC 21 "Artificial Intelligence", the secretariat of which is held by Danish Standards (DS).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

Any feedback and questions on this document should be directed to the users' national standards body. A complete listing of these bodies can be found on the CEN website.

This document is a preview generated by EVS

1 Scope

This document sets out a review of the current methods and practices (including tools, assets, and conditions of acceptability) for conformity assessment as relevant for the development and use of AI systems. Among others, it addresses the conformity assessment for products, services, processes, management systems and organizations. It includes an industry horizontal (vertical agnostic) perspective and an industry vertical perspective.

This document focuses only on the process and gap analysis of conformity assessments. It defines the **objects of conformity** related to AI systems and all other aspects of the conformity assessment process. The document also reviews to what extent AI poses specific challenges with respect to assessment of, for example, software engineering, data quality and engineering processes.

This document takes into account requirements and orientations from policy frameworks such as the EU AI strategy and those from CEN and CENELEC member countries.

This document is intended for technologists, standards bodies, regulators and interest groups.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

- IEC Electropedia: available at <http://www.electropedia.org/>
- ISO Online browsing platform: available at <http://www.iso.org/obp>

3.1

conformity assessment

demonstration that *specified requirements* (3.2) relating to a product, process, system, person or body are fulfilled

Note 1 to entry: The process of conformity assessment as described in the functional approach in Annex A can have a negative outcome, i.e. demonstrating that the specified requirements are not fulfilled.

Note 2 to entry: Conformity assessment includes activities defined elsewhere in this document, such as but not limited to [testing \(6.2\)](#), [inspection \(6.3\)](#), [validation \(6.5\)](#), [verification \(6.6\)](#), [certification \(7.6\)](#), and [accreditation \(7.7\)](#).

Note 3 to entry: Conformity assessment is explained in Annex A as a series of functions. Activities contributing to any of these functions can be described as conformity assessment activities.

[SOURCE: EN ISO/IEC 17000:2020]

3.2

specified requirement

need or expectation that is stated

Note 1 to entry: Specified requirements can be stated in normative documents such as regulations, standards and technical specifications.

Note 2 to entry: Specified requirements can be detailed or general.