

BSI Standards Publication

Artificial intelligence — Quality management
system for EU AI Act regulatory purposes



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The UK participation in its preparation was entrusted to Technical Committee ART/1, Artificial Intelligence.

A list of organizations represented on this committee can be obtained on request to its committee manager.

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English version

Artificial intelligence - Quality management system for EU AI Act regulatory purposes

Intelligence artificielle - Système de management de la
qualité pour le règlement européen sur l'IA

Künstliche Intelligenz - Qualitätsmanagementsystem
für EU-AI-Act-Regulierungszwecke

This European Standard was approved by CEN on 12 July 2026.

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

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European foreword

This document (EN 18286:2026) has been prepared by the Joint Technical Committee CEN/CLC/JTC 21 “Artificial Intelligence”, the secretariat of which is held by DS.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by January 2027 and conflicting national standards shall be withdrawn at the latest by January 2027.

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

This document has been prepared under a standardization request addressed to CEN-CENELEC by the European Commission. The Standing Committee of the EFTA States subsequently approves these requests for its Member States.

For the relationship with EU Legislation, see informative Annex ZA, which is an integral part of this document.

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-CENELEC website.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: 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 the United Kingdom.

0 Introduction

0.1 General

The EU's Artificial Intelligence Act (EU AI Act) [1] regulates *AI systems* through the product safety system established under the New Legislative Framework. An *AI system* that is classified as high-risk and must comply with the relevant EU AI Act obligations can be a product or a component of a product.

NOTE 1 Classification rules for high-risk *AI systems* can be found in the EU AI Act, Article 6.

AI systems must be in compliance with applicable *regulatory requirements* at the moment that the *AI system* is placed on the market or put into service. An *AI system* is placed on the market when it is supplied for first distribution or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge. An *AI system* is put into service when it is supplied for the first use directly to the *deployer* or for own use in the Union for its *intended purpose*.

EXAMPLE 1 An in-house developed *AI system* is put into service when it is used internally.

EXAMPLE 2 An *AI system* is placed on the market when it is offered for sale on a website.

The *quality* management system defined in this document can be used by a *provider* for one or more *AI systems* that are intended to be placed on the market or put into service. *Quality*, in this context can be understood as compliance with all of the *regulatory requirements* of the EU AI Act.

Depending on the intended purpose of the *AI system*, sector-specific regulations including obligations for a *quality* management system, can apply. The *provider* can extend a *quality* management system following a sector-specific regulation in such a way that it fulfils the *requirements* of the EU AI Act regulation instead of using a separate *quality* management system.

EXAMPLE 3 Medical devices are commonly compliant to EN ISO 13485 [2] *quality* management system requirements. Incorporating the *requirements* of this document within the existing *processes* is desirable when achieving *compliance* with this document.

This document is intended for use by *providers* that provide *AI systems* irrespective of size, nature or location. The *requirements* and guidance in this document are, however, specifically tailored to support *providers* that operate inside of the European Union, and those located outside of the Union who are active in the European Union market or who intend to enter that market.

The *requirements* in this document are the practical implementation from specific *requirements* from the EU AI Act (see Annex ZA) by relying on state of the art practices from other widely used standards where possible (see informative references throughout this document).

The *quality* management system in this document is described in a way that the implementation can take into account the size of the *provider*, while providing the degree of rigour and level of protection required by applicable *regulatory requirements*.

Clause 1 defines the scope of applicability of this document, while Clause 2 identifies normative references essential for its application, although there are none in this document.

Clause 3 establishes the terms and definitions used throughout this document, including terminology related to management systems, the EU AI Act, *AI systems*, and *risk management*, to ensure consistent interpretation. References to how most of these concepts are based on other standards are also provided in Clause 3.

Clause 4 specifies the *requirements* for establishing, implementing and maintaining the *quality* management system, including the identification of *regulatory requirements*, determination of scope, strategy for *regulatory compliance*, and control of *documented information*. After reading the Introduction and Clause 1, this is a good place to start for readers new to management system standards.

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Clause 5 addresses management responsibility, defining leadership commitment, *quality* policy, and the assignment of roles, *responsibilities*, and *authorities*.

Clause 6 focuses on planning, including actions to address *risks* to the *quality* management system and the setting and achievement of *quality objectives*.

Clause 7 describes the support *processes* required for the effective operation of the management system, covering resources, *competence*, communication and awareness.

Clause 8 addresses *AI system* realization, detailing *requirements* across the *AI system lifecycle*, not least the “design and development” and “verification and validation” phases as well as requirements regarding data management, retirement, identification of the *AI system* and product documentation. Clause 8 also contains a subclause on continuous learning *AI systems* and their predetermined changes.

Clause 9 covers operations and control, during deployment, including *monitoring*, supply chain management, change control, post-market *monitoring*, incident reporting, and handling of *non-compliance*.

Finally, Clause 10 specifies *requirements* for *performance* evaluation of the management system, including reviews and planning of changes to ensure ongoing *effectiveness* and *compliance*.

Annex A describes *procedures* for *consultation* with *interested parties* about risks to health, safety and *fundamental rights*, Annex B contains the correspondence between the clauses of this document and EN ISO 9001:2015 [3], and Annex C contains the correspondence with EN ISO/IEC 42001:2026 [4].

NOTE 2 Italicised terms are defined in Clause 3.

0.2 Verbal forms

In this document, the following verbal forms are used:

- “shall” indicates a *requirement*;
- “should” indicates a recommendation;
- “may” indicates a permission;
- “can” indicates a possibility or a capability.

0.3 Fundamental rights

The EU AI Act aims to ensure the protection of health, safety and *fundamental rights* in relation to *AI systems* and this document sets out technical *requirements* to achieve this regulatory objective through a *quality* management system.

Fundamental rights are universal legal guarantees without which individuals and groups cannot secure their fundamental freedoms and human dignity and which apply equally to every human being regardless of nationality, place of residence, sex, national or ethnic origin, colour, religion, language or any other status as per the legal system of a country without any conditions.

The EU Charter of Fundamental Rights [5] sets out and codifies the European approach to these *fundamental rights* in law which is applicable throughout the EU.

NOTE Further information about their scope and strength can be found in the Charter. Additional EU and country-specific *regulatory requirements* can apply.

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1 Scope

This document specifies the requirements and provides guidance for the definition, implementation and maintenance of a quality management system for organizations that provide AI systems.

This document is intended to support the organization in meeting applicable regulatory requirements. It is primarily intended for organizations placing on the market or putting into service high-risk AI systems and is not specific to any particular sector.

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:

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

3.1 Terms relating to management systems

3.1.1 audit

systematic (3.1.30) and independent *process* (3.1.22) for obtaining evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled

Note 1 to entry: An audit can be an internal audit (first party) or an external audit (second party or third party), and it can be a combined audit (combining two or more disciplines).

Note 2 to entry: An internal audit is conducted by the *organization* (3.1.18) itself, or by an external party on its behalf.

Note 3 to entry: “Audit criteria” is defined in EN ISO 19011.

[SOURCE: ISO/IEC Directives Part 1, Consolidated ISO Supplement, Annex SL Appendix 2 (rev 4 2024), 3.1.18, modified — Removed “audit evidence and” from Note 3.]

3.1.2 authority

authorities

ability of an individual, group or *organization* (3.1.18) to do something without intervention by another function on the details of that action

3.1.3 competence

ability to apply knowledge and skills to achieve intended results

[SOURCE: ISO/IEC Directives Part 1, Consolidated ISO Supplement, Annex SL Appendix 2 (rev 4 2024), 3.9]

3.1.4 compliance

fulfilment of all applicable *regulatory requirements* (3.1.26)