



SLOVENSKI STANDARD

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Umetna inteligenca - Sistem vodenja kakovosti za namene regulativnih zahtev Akta EU o UI

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

Künstliche Intelligenz - Qualitätsmanagementsystem für EU AI Act Regulierungszwecke

Intelligence artificielle - Système de gestion de la qualité à des fins réglementaires dans
le cadre de la loi européenne sur l'IA

Ta slovenski standard je istoveten z: prEN 18286

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35.240.01	Uporabniške rešitve informacijske tehnike in tehnologije na splošno	Application of information technology in general

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English version

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

Intelligence artificielle - Système de gestion de la
qualité à des fins réglementaires dans le cadre de la loi
européenne sur l'IA

Künstliche Intelligenz - Qualitätsmanagementsystem
für EU AI Act Regulierungszwecke

This draft European Standard is submitted to CEN members for enquiry. It has been drawn up by the Technical Committee CEN/CLC/JTC 21.

If this draft becomes a European Standard, CEN and CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation. Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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Contents

Page

European foreword	4
Introduction	5
1 Scope.....	7
2 Normative references.....	7
3 Terms and definitions	7
3.1 Terms relating to management systems	7
3.2 Terms relating to the AI Act	13
3.3 Terms relating to AI systems.....	14
3.4 Terms related to risk management.....	16
4 Quality management system	17
4.1 General.....	17
4.2 Identifying regulatory requirements	17
4.3 Determining the scope of the quality management system	18
4.4 Strategy for regulatory compliance	18
4.5 Documented information.....	19
5 Management responsibility	21
5.1 General.....	21
5.2 Quality policy.....	22
5.3 Roles, responsibility, and authorities	22
6 Planning	23
6.1 Actions to address risks related to the functioning of the quality management system	23
6.2 Quality objectives and planning to achieve them	24
7 Support	24
7.1 Resources.....	24
7.2 Competence.....	25
7.3 Communication	26
8 Product realization	27
8.1 Actions to address risks.....	27
8.2 Determining the stages of the life cycle	28
8.3 Inception, design and development.....	30
8.4 Verification and validation.....	32
8.5 Data management.....	33
8.6 Environmental sustainability.....	33
8.7 Product documentation.....	34
9 Operation and control.....	34
9.1 Deployment, operation and monitoring.....	34
9.2 Supply chain.....	35
9.3 Changes to AI systems	37
9.4 Post-market monitoring.....	39
9.5 Reporting serious incidents.....	41
9.6 Nonconformities.....	42
10 Performance evaluation.....	43

10.1	General	43
10.2	Review	43
10.3	Improvement.....	45
10.4	Planning of changes	45
Annex A (informative)	Consultation with interested parties regarding fundamental rights	46
A.1	General	46
A.2	Estimating risk and impact on affected persons	47
Annex B (informative)	Relationship between this document and other harmonized standards.....	48
B.1	Introduction	48
B.2	Selection of technical specifications	48
B.3	Harmonized standard interactions.....	49
B.4	Supporting harmonized standards	50
Annex C (informative)	Correspondence between this document and ISO 9001:2015	51
Annex D (informative)	Correspondence between this document and ISO/IEC 42001:202352	51
Annex ZA (informative)	Relationship between this European Standard and the essential requirements of Regulation (EU) 2024/1689 aimed to be covered	53
Bibliography		55

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prEN 18286:2025 (E)**European foreword**

This document (prEN 18286:2025) has been prepared by Technical Committee CEN/CLC/JTC 21 “Artificial Intelligence”, the secretariat of which is held by DS.

This document is currently submitted to the CEN Enquiry.

This document has been prepared under a standardization request addressed to CEN 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.

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Introduction

0.1 General

The EU's Artificial Intelligence (AI) Act [1] regulates *AI systems* through the product safety system established under the New Legislative Framework. An *AI system* subject to the EU AI Act can be a product or a component of a product.

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 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 deployed for internal use.

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

A *quality management system*, while being implemented by a *provider*, can be directly associated with one or more *AI systems* that are intended to be put into service or placed on the market. *Quality*, in this context can be understood as compliance with all of the *regulatory requirements* of the EU AI Act that apply to *providers*.

Depending on the context of the *AI system*, the *provider* can be required to show *conformity* with the industry specific *quality management system requirements* under sector specific legislation. This document does not require the *provider* to maintain a separate *quality management system*, but can be used as a complementary to existing *requirements* depending on the applicable *regulatory requirements* for the *AI system*.

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

This document specifies *requirements* for a *quality management system* that complies with applicable *regulatory requirements* (as described in Annex ZA) throughout the entire *life cycle* of the *AI system*. These *requirements* apply to a broad range of *AI systems*, and include explicit *requirements* to address *risks* to health, safety and *fundamental rights* which can arise.

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 *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*.

Annex A describes *procedures* for consultation with *interested parties* about *fundamental rights*, Annex B describes the relationship of this document with other *harmonized standards*, Annex C contains the correspondence between the clauses of this document and ISO 9001:2015 [2], and Annex D contains the correspondence with ISO/IEC 42001:2023 [3].

0.2 Fundamental rights

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.