SLOVENSKI STANDARD
oSIST prEN 18286:2026

01-januar-2026

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**

ICS:

03.100.70	Sistemi vodenja	Management systems
03.120.10	Vodenje in zagotavljanje kakovosti	Quality management and quality assurance
35.240.01	Uporabniške rešitve informacijske tehnike in tehnologije na splošno	Application of information technology in general

oSIST prEN 18286:2026 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

DRAFT
prEN 18286

October 2025

ICS 03.100.70; 35.240.01

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.

This draft European Standard was established by CEN and CENELEC in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN and CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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.

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.

Warning : This document is not a European Standard. It is distributed for review and comments. It is subject to change without notice and shall not be referred to as a European Standard.

Contents

Page

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.

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.