SLOVENSKI STANDARD
SIST-TS CEN ISO/TS 24971-2:2026

01-september-2026

Medicinski pripomočki - Navodilo za uporabo ISO 14971 - 2. del: Strojno učenje v umetni inteligenci (ISO/TS 24971-2:2026)

Medical devices - Guidance on the application of ISO 14971 - Part 2: Machine learning in artificial intelligence (ISO/TS 24971-2:2026)

Medizinprodukte- Leitfaden zur Anwendung von ISO 14971- Teil 2: Maschinelles Lernen in der künstlichen Intelligenz (ISO/TS 24971-2:2026)

Dispositifs médicaux - Recommandations pour l'application de l'ISO 14971 - Partie 2: Apprentissage automatique dans le cadre de l'intelligence artificielle (ISO/TS 24971-2:2026)

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11.040.01	Medicinska oprema na splošno	Medical equipment in general
35.240.80	Uporabniške rešitve IT v zdravstveni tehniki	IT applications in health care technology

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Medical devices - Guidance on the application of ISO 14971 - Part 2: Machine learning in artificial intelligence (ISO/TS 24971-2:2026)

Dispositifs médicaux - Recommandations relatives à l'application de l'ISO 14971 - Partie 2: Apprentissage automatique en intelligence artificielle (ISO/TS 24971-2:2026)

Medizinprodukte - Leitfaden zur Anwendung von ISO 14971 - Teil 2: Maschinelles Lernen in der künstlichen Intelligenz (ISO/TS 24971-2:2026)

This Technical Specification (CEN/TS) was approved by CEN on 22 June 2026 for provisional application.

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European foreword

This document (CEN ISO/TS 24971-2:2026) has been prepared by Technical Committee ISO/TC 210 "Quality management and corresponding general aspects for products with a health purpose including medical devices" in collaboration with Technical Committee CEN-CENELEC/ JTC 3 “Quality management and corresponding general aspects for medical devices” the secretariat of which is held by NEN.

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Endorsement notice

The text of ISO/TS 24971-2:2026 has been approved by CEN-CENELEC as CEN ISO/TS 24971-2:2026 without any modification.

Technical Specification

ISO/TS 24971-2

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Medical devices — Guidance on the application of ISO 14971 —

Part 2: Machine learning in artificial intelligence

Dispositifs médicaux — Recommandations relatives à l'application de l'ISO 14971 —

Partie 2: Apprentissage automatique en intelligence artificielle

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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This document was prepared by Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for products with a health purpose including medical devices*, in collaboration with Technical Committee IEC/TC 62, *Medical equipment, software, and systems*, Subcommittee SC 62A, *Common aspects of medical equipment, software, and systems*, and with the European Committee for Standardization (CEN) Technical Committee CEN/CLC/JTC 3, *Quality management and corresponding general aspects for medical devices*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

A list of all parts in the ISO 24971 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Artificial intelligence (AI) is rapidly advancing and offers transformative potential for the healthcare sector. These advantages can be related to improved *benefits* for the patient, increased efficiency in clinical workflows and more effective management of healthcare overall. However, the implementation of new technologies such as AI can also present new *risks* and can, for example, jeopardize patient *safety*, affect privacy and security, influence user actions, undermine trust in healthcare or adversely affect the management of healthcare.

The *safety* and effectiveness of AI in *medical devices* was explored in an AAMI-BSI document[16], which identified three ways in which AI-based *medical devices* differed from "traditional" (non-AI) *medical devices*:

a) *Training*. These *medical devices* can process large amounts of data and learn from these data to improve their results. Thus, they can have positive effects on patient health within the scope of the *intended use* of the *medical device*.

b) Level of autonomy. These *medical devices* can generate different treatment options, select the best option based on a trained model and execute the selected option (see for example IEC/TR 60601-4-1[8]). These steps can be performed with reduced or even without direct user action. Therefore, human oversight is critical for their safe application.

c) *Explainability*. These *medical devices* often rely on complex algorithms and large datasets to generate output. However, the inherent opacity of these algorithms makes it challenging to interpret how specific conclusions or recommendations are derived. This aspect is sometimes referred to as the "black-box problem". This can make it difficult for clinicians, other healthcare personnel and individuals without specialist knowledge to understand the rationale for the output.

Many different AI-based technologies and algorithms exist today, which are differentiated by data topology and model architecture, including decision trees, genetic algorithms and deep learning-based technologies such as generative AI and neural networks. ISO/IEC 22989[4] and ISO/IEC 23894[6] provide general guidance on AI concepts, terminology and *risk management*, but they do not specifically address the application of AI to *medical devices*. It is noted that "risk" is defined in these documents as the effect of uncertainties on objectives (see also ISO 31000[3]). This definition is useful for organizational or business *risk management*. The term "*risk*" used in the healthcare sector is different and is defined in ISO 14971:2019 as the combination of the probability of occurrence of *harm* and the *severity* of that *harm*.

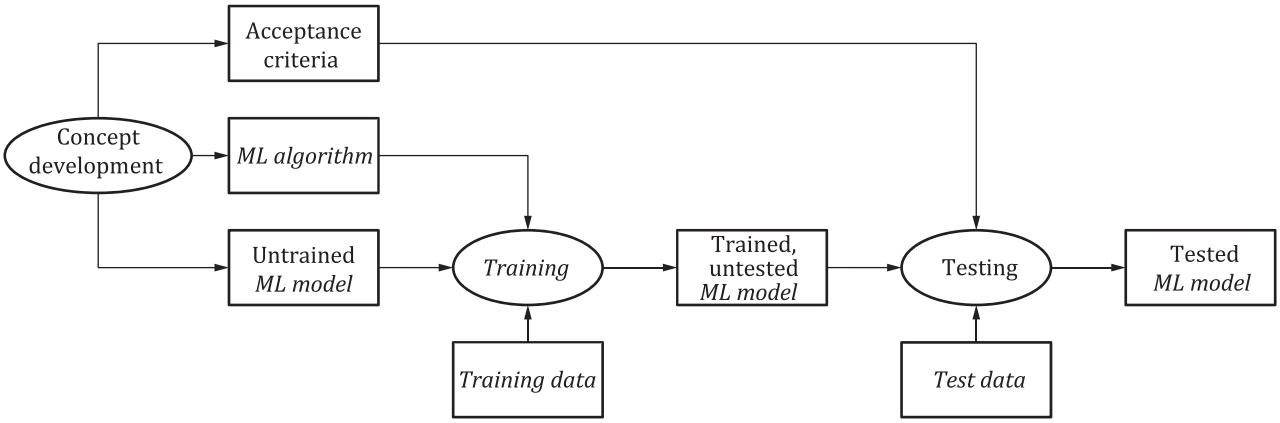

Figure 1 — Concept development, *training* and testing stages of the *ML model* and its relationship with the *ML algorithm*, the *training data* and the *test data*

This document focuses on *machine learning* (*ML*) techniques and is restricted to *ML-enabled medical devices* (*MLMD*). *Machine learning* is considered a subset of AI that involves an *ML model* and an *ML algorithm*. See Figure 1. The *ML model* and the *ML algorithm* are the results of the concept development for a new *MLMD*, together with acceptance criteria for the eventual *MLMD*. It is noted that the supporting infrastructure (computing framework, hardware, network and other IT components) can be an important aspect in concept development. The *MLMD* acceptance criteria are different from the criteria for *risk* acceptability. It

is important to establish the *MLMD* acceptance criteria at the start, as part of concept development, and not at the end of the *MLMD* development. Otherwise, the results of *MLMD* testing could influence the decisions when establishing those criteria.

After concept development, the *ML model* is trained by using an *ML algorithm* enabling it to learn patterns from *training data* without being explicitly programmed. Next, the trained *ML model* is applied to *test data* to verify its performance. The *training data* and the *test data* are different (disjoint) sets. They can be actual patient data or synthetic data, i.e. data created to simulate a patient for *training* or testing purposes. The tested *ML model* can then be applied to new patient data in a clinical setting. More information on *MLMD* can be found in IMDRF documents N67[21] and N88[23] and in guidance documents[17][18] from FDA, Health Canada and MHRA.

It is recognized that the *ML model* can require retraining after a period of use to redefine its parameters and to ensure its continued performance. This can be achieved by planned retraining with collected patient data or on a continuous basis with each new patient data. The latter is referred to as “continuous learning” throughout this document and sometimes as “adaptive” in other documents.

All *medical devices* come with inherent *risks*. *Manufacturers* are required to demonstrate that their *medical devices* do not pose unacceptable *risks*, and that the *benefits* of the *intended use* outweigh the overall *residual risk*. ISO 14971 details how *manufacturers* can identify, assess and control *risks* to protect the patients, the users and other persons as well as property (for example objects, data, other equipment) and the environment. This includes *risks* related to data and systems security and cybersecurity. Guidance on the application of ISO 14971 is provided in document ISO/TR 24971[2]. Additionally, IEC 80001-1[11] and IEC/TR 80002-1[12] address software internal to a *medical device* that can support AI or *ML*.

This document was developed to provide specific guidance on the application of ISO 14971 to *MLMD*. It does not provide a new *risk management process*, nor does it expand the requirements of ISO 14971. This document addresses *risks* related to *machine learning* and topics such as data management, feature extraction, unwanted *bias*, information security, *training* the *ML model* by an *ML algorithm*, evaluation and testing of the trained *ML model*. See Annex A for an explanation of *bias*. The report AAMI TIR34971[14] provided valuable input for this document.