SLOVENSKI STANDARD
SIST EN ISO 15223-1:2021/A1:2026

01-januar-2026

Medicinski pripomočki - Simboli za označevanje podatkov, ki jih mora zagotoviti dobavitelj - 1. del: Splošne zahteve - Dopolnilo 1: Dodajanje opredeljenega izraza za pooblaščenega zastopnika in sprememba simbola EC REP, ne da bi bil ta vezan na točno določeno državo ali regijo (ISO 15223 1:2021/Amd 1:2025)

Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements - Amendment 1: Addition of defined term for authorized representative and modified EC REP symbol to not be country or region specific (ISO 15223 1:2021/Amd 1:2025)

Medizinprodukte - Symbole zur Verwendung im Rahmen der vom Hersteller bereitzustellenden Informationen - Teil 1: Allgemeine Anforderungen - Änderung 1 (ISO 15223 1:2021/Amd 1:2025)

Dispositifs médicaux - Symboles à utiliser avec les informations à fournir par le fabricant - Partie 1: Exigences générales - Amendement 1: Ajout du terme défini représentant autorisé (mandataire) et modification du symbole EC REP pour ne pas être spécifique d’un pays ou d’une région (ISO 15223 1:2021/Amd 1:2025)

Ta slovenski standard je istoveten z: **EN ISO 15223-1:2021/A1:2025**

ICS:

01.080.20	Grafični simboli za posebno opremo	Graphical symbols for use on specific equipment
11.040.01	Medicinska oprema na splošno	Medical equipment in general

SIST EN ISO 15223-1:2021/A1:2026 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 15223-1:2021/A1

November 2025

ICS 11.040.01; 01.080.20

English version

Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements - Amendment 1: Addition of defined term for authorized representative and modified EC REP symbol to not be country or region specific (ISO 15223 1:2021/Amd 1:2025)

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This amendment A1 modifies the European Standard EN ISO 15223-1:2021; it was approved by CEN on 16 September 2024.

CEN and CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN and CENELEC member.

This amendment exists 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.

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European foreword

This document (EN ISO 15223-1:2021/A1:2025) 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.

This Amendment to the European Standard EN ISO 15223-1:2021 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by May 2026, and conflicting national standards shall be withdrawn at the latest by May 2026.

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 and 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 and ZB, which are an integral parts of this document.

Any feedback and questions on this document should be directed to the users’ national standards body/national committee. A complete listing of these bodies can be found on the CEN and CENELEC websites.

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.

Endorsement notice

The text of ISO 15223-1:2021/Amd 1:2025 has been approved by CEN-CENELEC as EN ISO 15223-1:2021/A1:2025 without any modification.

Annex ZA
(informative)

Relationship between this European standard and the General Safety and Performance Requirements of Regulation (EU) 2017/745 aimed to be covered

This European standard has been prepared under M/575 to provide one voluntary means of conforming to the General Safety and Performance Requirements of Regulation (EU) 2017/745 of 5 April 2017 concerning medical devices [OJ L 117] and to system or process requirements including those relating to quality management systems, risk management, post-market surveillance systems, clinical investigations, clinical evaluation or post-market clinical follow-up.

Once this standard is cited in the Official Journal of the European Union under that Regulation, compliance with the normative clauses of this standard given in Table ZA.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding General Safety and Performance Requirements of that Regulation, and associated EFTA Regulations.

Where a definition in this standard differs from a definition of the same term set out in Regulation (EU) 2017/745, the differences shall be indicated in this Annex Z. For the purpose of using this standard in support of the requirements set out in Regulation (EU) 2017/745, the definitions set out in this Regulation prevail.

Where the European standard is an adoption of an International Standard, the scope of this standard can differ from the scope of the European Regulation that it supports. As the scope of the applicable regulatory requirements differ from nation to nation and region to region, the standard can only support European regulatory requirements to the extent of the scope of the European regulation for medical devices (EU) 2017/745).

NOTE 1 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Regulation (EU) 2017/745. This means that risks have to be 'reduced as far as possible', 'reduced to the lowest possible level', 'reduced as far as possible and appropriate', 'removed or reduced as far as possible', 'eliminated or reduced as far as possible', 'removed or minimized as far as possible', or 'minimized', according to the wording of the corresponding General Safety and Performance Requirement.

NOTE 2 The manufacturer's policy for determining **acceptable risk** must be in compliance with General Safety and Performance Requirements 1, 2, 3, 4, 5, 8, 9, 10, 11, 14, 16, 17, 18, 19, 20, 21 and 22 of the Regulation.

NOTE 3 When a General Safety and Performance Requirement does not appear in Table ZA.1, it means that it is not addressed by this European Standard.