ICS 01.080.20, 11.040.01 SLOVENSKÁ TECHNICKÁ NORMA Február 2026

STN	**Zdravotnícke pomôcky Značky na používanie s informáciami poskytovanými výrobcom Časť 1: Všeobecné požiadavky Zmena A1: Pridanie definovaného termínu pre autorizovaného zástupcu a modifikovaného symbolu EC REP, ktorý nie je špecifický pre krajinu alebo región (ISO 15223-1: 2021/Amd 1: 2025)**	**STN EN ISO 15223-1/A1** 85 0005

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)

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 01/26

Obsahuje: EN ISO 15223-1:2021/A1:2025, ISO 15223-1:2021/Amd 1:2025

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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)

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)

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

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

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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.

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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.

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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.

International Standard

ISO 15223-1

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

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

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Foreword

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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 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).

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