MEDITSIINISEADMED. TOOTJAINFOS KASUTATAVAD TINGMÄRGID. OSA 1: ÜLDNÕUDED

Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021)

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 15223-1:2021 sisaldab Euroopa standardi EN ISO 15223-1:2021 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 15223-1:2021 consists of the English text of the European standard EN ISO 15223-1:2021.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 29.09.2021.	Date of Availability of the European standard is 29.09.2021.
Standard on kättesaadav Eesti Standardimis- ja Akrediteerimiskeskusest.	The standard is available from the Estonian Centre for Standardisation and Accreditation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

ICS 01.080.20, 11.040.01

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 15223-1

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ICS 01.080.20; 11.040.01

Supersedes EN ISO 15223-1:2016

English version

Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021)

Dispositifs médicaux - Symboles à utiliser avec les informations à fournir par le fabricant - Partie 1: Exigences générales (ISO 15223-1:2021)

Medizinprodukte - Zu verwendende Symbole mit durch den Hersteller bereitgestellten Informationen - Teil 1: Allgemeine Anforderungen (ISO 15223-1:2021)

This European Standard was approved by CEN on 4 June 2021.

This European Standard was corrected and reissued by the CEN-CENELEC Management Centre on 13 October 2021.

CEN-CENELEC Management Centre:
Rue de la Science 23, B-1040 Brussels

European foreword

This document (EN ISO 15223-1:2021) has been prepared by Technical Committee ISO/TC 210 "Quality management and corresponding general aspects for 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 European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by March 2022, and conflicting national standards shall be withdrawn at the latest by March 2022.

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 supersedes EN ISO 15223-1:2016.

This document has been prepared under a Standardization Request given to CEN and CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s) / Regulation(s).

For the relationship with EU Directive(s) / Regulation(s), see informative Annex ZA and ZB, which is an integral part 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.

This document is an adoption of an International Standard. The definitions in applicable regulatory requirements differ from nation to nation and region to region. As a result, the definitions in this document can differ in wording from those in European Regulations. For use in support of European requirements, definitions in the European regulations for medical devices take precedence.

The following referenced documents are indispensable for the application of this document. For undated references, the latest edition of the referenced document (including any amendments) applies. For dated references, only the edition cited applies. However, for any use of this standard “within the meaning of Annex ZA and Annex ZB”, the user should always check that any referenced document has not been superseded and that its relevant contents can still be considered the generally acknowledged state-of-art.

When an IEC or ISO standard is referred to in the ISO standard text, this shall be understood as a normative reference to the corresponding EN standard, if available, and otherwise to the dated version of the ISO or IEC standard, as listed below.

NOTE The way in which these references documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

Table — Correlations between normative references and dated EN and ISO standards

Normative references as listed in Clause 2 of the ISO standard	Equivalent dated standard	
	EN	ISO or IEC
ISO 8601-1	--	ISO 8601-1:2019[a]
ISO 8601-2	--	ISO 8601-2:2019[a]
ISO 15223-2	--	ISO 15223-2:2010
ISO 3166-1	EN ISO 3166-1:2020	ISO 3166-1: 2020

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, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 15223-1:2021 has been approved by CEN-CENELEC as EN ISO 15223-1:2021 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 a Commission's standardisation request 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].

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.

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 This Annex ZA is based on normative references according to the table of references in the European Foreword, replacing the references in the core text.

NOTE 4 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.

Table ZA.1 – Correspondence between this European standard and Annex I of Regulation (EU) 2017/745 [OJ L 117]

General Safety and Performance Requirements of Regulation (EU) 2017/745	Clause(s) / sub-clause(s) of this EN	Remarks / Notes
4 (c)	5.2.6 5.2.7 5.2.8 5.3.1 5.3.2 5.3.3 5.3.4 5.3.5 5.3.6 5.3.7 5.3.8 5.3.9 5.4.1 5.4.2 5.4.3 5.4.4 5.4.5 5.4.6 5.4.7 5.4.8 5.4.9 5.4.10 5.4.11 5.4.12	Partially covered: used to draw user's attention on the label to the safety information such as warnings/precautions/contraindications only for the aspects dealt with by these symbols placed in the instructions for use or accompanying information and of any residual risks and need for training for users. Not covered: does not provide further information for safety about warning/precautions/contraindications other than the ones dealt with by these symbols, nor training.
10.4.5	5.4.3 5.4.10	Partially covered: used to draw user's attention on the label to the safety information placed in the instructions for use or accompanying information of the presence of substances that are carcinogenic, mutagenic, toxic to reproduction and/or having endocrine-disrupting properties.
11.3	5.2.1 5.2.2 5.2.3 5.2.4 5.2.5 5.2.7 5.2.10	Partially covered: used as part of the label to identify sterile or non-sterile medical devices. Not covered: Design, manufacture, and packaging.

11.8	5.2.1 5.2.3 5.2.4 5.2.5 5.2.7 5.2.10	Covered: used as part of the label to distinguish between identical sterile and non-sterile medical devices.
14.1	5.4.3 5.4.4	Partially covered: used to draw user's attention on the labelling to the safety information in the instructions for use.
22.1	5	Partially covered: used to convey specific label information in a format that is easy for the intended user to understand. Not covered: the design and manufacture for appropriate performance, taking user's skills into account; the understanding and application of the instructions for use.
23.1 (first sentence)	5.1.1 5.1.3 5.1.5 5.1.6 5.1.7 5.1.10 5.1.11	Partially covered: used to identify the medical device and its manufacturer.
23.1 (a)	5	Partially covered: used to convey label information in a format that is easy to understand. Not covered: the medium, format, content, legibility and location of the label, instructions for use, and accompanying information; the technical knowledge, experience, and training of the intended user; understanding of the intended use, drawings, or diagrams.
23.1 (b)	5	Partially covered: used to provide label information directly on a medical device in a symbol format that would be otherwise impracticable by use of text. Not covered: the information that is required on the label and/or medical device, but that can be placed on the medical device or the packaging.
23.1 (c)	5	Partially covered: used to provide label information in a human readable format that would be otherwise impracticable by

		use of text. Not covered: machine-readable information.
23.1 (g)	5.4.3 5.4.4	Partially covered: may be used to draw user's attention on the label to the safety information concerning limitation, contra-indications, precautions, or warnings. Not covered: the residual risks required to be communicated by way of limitations, contra-indications, precautions, or warnings.
23.1 (h)	4.2 5	Covered: symbols used to convey information in combination with risk management. Symbols addressed in 5 are used on labels without a description of the symbol required in the instructions for use or accompanying information to convey information. Not covered: the use of other symbols will require a description of the symbol in the instructions for use or accompanying information.
23.2 (b)	5.1.6 5.1.10 5.7.10	Partially covered: used as part of the label information to identify the medical device and the packaging contents. Not covered: the intended purpose of the medical device.
23.2 (c)	5.1.1	Partially covered: used as part of the label information to identify the manufacturer and registered place of business (address). Not covered: the trade name or registered trademark.
23.2 (d)	5.1.2	Covered: used as part of the label information to identify the authorised representative and registered place of business (address).
23.2 (e)	5.4.6 5.4.7 5.4.8 5.4.9	Covered: used as part of the label information to identify that the medical device contains or incorporates a medicinal substance, including a human blood or plasma derivative; or tissues or cells, or their derivatives, of human origin; or tissues or cells of animal origin, or their derivatives.