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

September 2021

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.

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. 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 European Standard 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, Turkey and United Kingdom.

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.

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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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for 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).

This fourth edition cancels and replaces the third edition (ISO 15223-1:2016), which has been technically revised.

The main changes compared to the previous edition are as follows:

— addition of 20 *symbols* that were validated as per ISO 15223-2;

— addition of 5 *symbols* previously published in ISO 7000, ISO 7001 and IEC 60417;

— deletion of the defined term "labelling";

— inclusion of defined terms from ISO 20417, ISO 13485 and ISO 14971;

— expansion of the examples given in Annex A;

— information about European regulations has been moved to informative notes throughout.

A list of all parts in the ISO 15223 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

Medical device *manufacturers* and others in the supply chain must provide specific information on the *medical device* itself, as part of the packaging, or in the *accompanying information*. For simplicity and to avoid translation of text, this information can be provided as *symbols* that have a specific meaning. This document does not specify the information that needs to be provided, but does specify internationally recognized *symbols* for the provision of this specific information.

The *symbols* included in this document have been published in ISO 7000, ISO 7001, IEC 60417 or have been subjected to a formal *symbol* validation process.

This document is intended to be used by *manufacturers* of *medical devices* who market products in countries where there are specific language requirements. These *symbols* allow for a consistent portrayal of information. It can also be used by consumers or end users of *medical devices* who draw their supplies from a number of sources and can have varied language capabilities.

In this document, the conjunctive "or" is used as an "inclusive or"; so a statement is true if any combination of the conditions is true.

Terms defined in Clause 3 are shown in *italic type* throughout the document.

In this document, the following verbal forms are used:

— "shall" indicates a requirement;

— "should" indicates a recommendation;

— "may" indicates a permission;

— "can" indicates a possibility or a capability;

— "must" indicates an external constraint that is not a requirement of the document.

Information marked as "NOTE" is intended to assist the understanding or use of the document. "Notes to entry" used in Clause 3 provide additional information that supplements the terminological data and can contain provisions relating to the use of a term.

Symbols added during the revision of this document were placed at the end of the pertinent section of Table 1 to preserve the numbering of existing *symbols* and facilitate easy referencing of existing *symbols* in other documents.

NOTE Numbers given in square brackets throughout the document refer to the Bibliography.

Medical devices — Symbols to be used with information to be supplied by the manufacturer —

Part 1: General requirements

1 Scope

This document specifies *symbols* used to express information supplied for a *medical device*. This document is applicable to *symbol*s used in a broad spectrum of *medical devices*, that are available globally and need to meet different regulatory requirements.

These *symbol*s can be used on the *medical device* itself, on its packaging or in the *accompanying information*. The requirements of this document are not intended to apply to *symbol*s specified in other standards.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 3166-1, *Codes for the representation of names of countries and their subdivisions — Part 1: Country code*

ISO 8601-1, *Date and time — Representations for information interchange — Part 1: Basic rules*

ISO 8601-2, *Date and time — Representations for information interchange — Part 2: Extensions*

ISO 15223-2, *Medical devices — Symbols to be used with medical device labels, labelling, and information to be supplied — Part 2: Symbol development, selection and validation*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
accompanying information
information accompanying or *marked* on a *medical device* or accessory for the user or those accountable for the installation, use, processing, maintenance, decommissioning and disposal of the *medical device* or accessory, particularly regarding safe use

Note 1 to entry: The *accompanying information* shall be regarded as part of the *medical device* or accessory.

Note 2 to entry: The *accompanying information* can consist of the *label*, *marking*, *instructions for use*, technical description, installation manual, quick reference guide, etc.