SLOVENSKI STANDARD
SIST EN ISO 15223-1:2017/oprA1:2019

01-december-2019

Medicinski pripomočki - Simboli za označevanje medicinskih pripomočkov, označevanje in podatki, ki jih mora podati dobavitelj - 1. del: Splošne zahteve (ISO 15223-1:2016)

Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016)

Medizinprodukte - Bei Aufschriften von Medizinprodukten zu verwendende Symbole, Kennzeichnung und zu liefernde Informationen - Teil 1: Allgemeine Anforderungen (ISO 15223-1:2016)

Dispositifs médicaux - Symboles à utiliser avec les étiquettes, l'étiquetage et les informations à fournir relatifs aux dispositifs médicaux - Partie 1: Exigences générales (ISO 15223-1:2016)

Ta slovenski standard je istoveten z: **EN ISO 15223-1:2016/prA1**

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 15223-1:2017/oprA1:2019 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

DRAFT
EN ISO 15223-1:2016

prA1

October 2019

ICS 01.080.20; 11.040.01

English version

Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016)

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This draft amendment is submitted to CEN members for enquiry. It has been drawn up by the Technical Committee CEN/CLC/JTC 3.

This draft amendment A1, if approved, will modify the European Standard EN ISO 15223-1:2016. If this draft becomes an amendment, 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.

This draft amendment was established by CEN and CENELEC 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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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

Warning : This document is not a European Standard. It is distributed for review and comments. It is subject to change without notice and shall not be referred to as a European Standard.

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European foreword

The text of ISO 15223-1:2016 has been prepared by Technical Committee ISO/TC 210 “Quality management and corresponding general aspects for medical devices” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 15223-1:2016/prA1:2019 by Technical Committee CEN/CLC/TC 3 “Quality management and corresponding general aspects for medical devices” the secretariat of which is held by NEN.

This document is currently submitted to the CEN Enquiry.

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

For relationship with EU Directive(s), see informative Annex ZD and ZE, which are an integral part of this document.

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”, 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

Endorsement notice

The text of ISO 15223-1:2016 has been approved by CEN as EN ISO 15223-1:/prA1:2019 without any modification.

Annex ZD
(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 M/xxx 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 ZD.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)	5.4.4	Partially covered: used to draw user's attention on the labelling to the safety information placed in the instructions for use and of any residual risks and need for training for users. Not covered: does not provide further information for safety nor training.
10.4.5	5.4.4	Partially covered: used on labelling to alert users to 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	Partially covered: used as part of the labelling to identify sterile or non-sterile products. Not covered: Design, manufacture and packaging.
11.8	5.2.1 5.2.7	Partially covered: used as part of the labelling to identify sterile or non-sterile products. Not covered: the additional labelling required to distinguish between identical or similar sterile and non-sterile product.
22.1	5	Partially covered: used to convey specific labelling 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	5.1.1	Partially covered: used as part of the labelling information to identify the manufacturer and registered place of business (address). Not covered: the information needed to identify the device and its manufacturer, safety and performance information.
23.1 (a)	5	Partially covered: used to convey labelling information in a format that is easy to understand. Not covered: the medium, format, content, legibility and location of the label and instructions for use; 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 labelling information directly on a 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 device; which information can be placed on the device or the packaging.
23.1 (c)	5	Partially covered: used to provide labelling information in a human readable format that would be otherwise impracticable by use of text. Not covered: machine-readable information.
23.1 (g)	5.4.4	Partially covered: may be used to draw user's attention on the labelling 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 5.1 are used on labelling without a description of the symbol in the instructions for use to convey information. Not covered: the use of other symbols will require a description of the symbol in the instructions for use.
23.2, (b)	5.1.6 5.1.7	Partially covered: used as part of the labelling information to identify the device and the packaging contents. Not covered: the intended purpose of the device.
23.2 (c)	5.1.1	Partially covered: used as part of the labelling 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 labelling information to identify the authorised representative and registered place of business (address).
23.2, (f)	5.4.4	Partially covered: used on labelling to alert users to the presence of substances that are carcinogenic, mutagenic, toxic to reproduction and/or having endocrine-disrupting properties.
23.2 (g)	5.1.5	Covered: symbol used to replace the words 'LOT NUMBER'.
23.2 (g)	5.1.7	Covered: this symbol used to replace the words 'SERIAL NUMBER'.
23.2 (i)	5.1.4	Covered: this symbol used to indicate the time limit information for use or implant of the device, accompanied by the date (at least year and month).
23.2 (j)	5.1.3	Covered: this symbol used to indicate the date of manufacture information for the device, accompanied by the date (that will be clearly identifiable).
23.2 (k)	5.3.1	Covered: this symbol used to indicate that the device is fragile.
23.2 (k)	5.3.2	Covered: this symbol used to indicate that the device needs protection from sunlight and other light sources.
23.2 (k)	5.3.3	Covered: this symbol used to indicate that the device needs protection from heat and radioactive sources.
23.2 (k)	5.3.4	Covered: this symbol used to indicate that the device needs protection from moisture.
23.2 (k)	5.3.5	Covered: this symbol used to indicate the lower limit of temperature that the device may be safely exposed to, accompanied by the temperature

		value.
23.2 (k)	5.3.6	Partially covered: this symbol used to indicate the upper limit of temperature that the device may be safely exposed to, accompanied by the temperature value.
23.2 (k)	5.3.7	Partially covered: this symbol used to indicate the upper and lower limits of temperature that the device may be safely exposed to, accompanied by the upper and lower temperature values.
23.2 (k)	5.3.8	Partially covered: this symbol used to indicate the upper and lower limits of humidity that the device may be safely exposed to. It will be accompanied by the upper and lower humidity values.
23.2 (k)	5.3.9	Partially covered: this symbol used to indicate the upper and lower limits of pressure that the device may be safely exposed to, accompanied by the upper and lower pressure values.
23.2 (l)	5.2.1	Partially covered: used to indicate that a device is sterile. Not covered: the method of sterilization is not specified (see symbols 5.2.2, 5.2.3, 5.2.4, 5.2.5).
23.2 (l)	5.2.2 5.2.3 5.2.4	Covered: used on the labelling to specify an indication of the device's sterile state and the method of sterilization.
23.2 (l)	5.2.5	Partially covered: used to indicate that a device is heat-sterilized. Not covered: the method of sterilization (dry heat, moist heat).
23.2 (m)	5.4.3	Partially covered: used to draw user's attention on the labelling to the more detailed warnings or precautions found in the instructions for use. Not covered: warnings or precautions.
23.2 (n)	5.4.2	Covered: used to specify on the labelling that the device is intended for single use.
23.2 (s)	5.1.5	Covered: this symbol used to replace the words 'LOT NUMBER'.
23.2 (s)	5.1.7	Covered: this symbol used to replace the words 'SERIAL NUMBER'.
23.3 (b)	5.2.1 5.2.2 5.2.3 5.2.4 5.2.5	Covered; used as part of the labelling to identify the device is sterile.
23.3 (c)	5.2.2 5.2.3 5.2.4	Covered: used to specify on the labelling the method of sterilization.
23.3 (c)	5.2.5	Partially covered: used to indicate that a device is heat-sterilized. Not covered: the method of sterilization (dry heat, moist heat).
23.3 (d)	5.1.1	Covered: used as part of the labelling information to identify the manufacturer and registered place of