Meditsiiniseadmed. Sümbolid, mida kasutatakse meditsiinseadme ja/või pakendi märgistuses ning muus kaasuvas teabes. Osa 1: Üldnõuded (ISO 15223-1:2012)

Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2012)

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN ISO 15223-1:2012 sisaldab Euroopa standardi EN ISO 15223-1:2012 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 15223-1:2012 consists of the English text of the European standard EN ISO 15223-1:2012.
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.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 01.07.2012.	Date of Availability of the European standard is 01.07.2012.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

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

July 2012

ICS 01.080.20; 11.040.01

Supersedes EN 980:2008

English version

Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2012)

Dispositifs médicaux - Symboles à utiliser avec les étiquettes, l'étiquetage et les informations à fournir relatifs aux dispositifs médicaux - Partie 1: Exigences générales (ISO 15223-1:2012)

Medizinprodukte - Bei Aufschriften von Medizinprodukten zu verwendende Symbole, Kennzeichnung und zu liefernde Informationen - Teil 1: Allgemeine Anforderungen (ISO 15223-1:2012)

This European Standard was approved by CEN on 24 May 2012.

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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

CEN-CENELEC Management Centre:
Avenue Marnix 17, B-1000 Brussels

Foreword

This document (EN ISO 15223-1:2012) has been prepared by Technical Committee ISO/TC 210 "Quality management and corresponding general aspects for medical devices" in collaboration with Technical Committee CEN/CLC/TC 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 January 2013, and conflicting national standards shall be withdrawn at the latest by January 2013.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN 980:2008.

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 Directives.

For relationship with EU Directives, see informative Annex ZA, ZB and ZC, which are integral parts of this document.

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, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 15223-1:2012 has been approved by CEN as a EN ISO 15223-1:2012 without any modification.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC on medical devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on medical devices.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the 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 Essential Requirements of that Directive and associated EFTA regulations.

Table ZA.1 — Correspondence between this European Standard and Directive 93/42/EEC on medical devices

Clauses/subclauses of this European Standard	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/notes
5.2.7	8.7	
4	13.2	Only the first two sentences of this ER are covered.
5.1.1, 5.1.2	13.3 (a)	
5.1.6	13.3 (b)	
5.2.1, 5.2.2, 5.2.3, 5.2.4, 5.2.5, 5.2.9	13.3 (c)	
5.1.5, 5.1.7	13.3 (d)	
5.1.4	13.3 (e)	
5.4.2	13.3 (f)	Only the first sentence of this ER is covered.
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	13.3 (i)	
5.4.3	13.3 (j)	
5.2.6, 5.2.7, 5.2.8, 5.4.1, 5.4.4, 5.4.5	13.3 (k)	This ER is covered only in respect of the particular warnings or precautions that these symbols indicate. For other warnings, other symbols or other means of indication may be needed.
5.1.3	13.3 (l)	
5.2.2, 5.2.3, 5.2.4, 5.2.5	13.3 (m)	

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

Annex ZB
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 90/385/EEC on active implantable medical devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 90/385/EEC on active implantable medical devices.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZB.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZB.1 — Correspondence between this European Standard and Directive 90/385/EEC on active implantable medical devices

Clauses/subclauses of this European Standard	Essential Requirements (ERs) of Directive 90/385/EEC	Qualifying remarks/notes
5.1.5, 5.1.6, 5.1.7	11	
4	14	Only with regard to the use of symbols.
5.2.2, 5.2.3, 5.2.4, 5.2.5	14.1, 1st indent	
5.1.6	14.1, 2nd indent	
5.1.1	14.1, 3rd indent	
5.1.5, 5.1.6, 5.1.7, 5.4.3, 5.4.4	14.1, 4th indent	Only identifying the model and batch or serial number, and directing users to the instructions for use for further information and precautions.
5.2.1	14.1, 7th indent	
5.1.3	14.1, 8th indent	
5.1.4	14.1, 9th indent	
5.1.1, 5.1.2	14.2, 1st indent	
5.1.5, 5.1.6, 5.1.7, 5.4.3, 5.4.4	14.2, 2nd indent	Only identifying the model and batch or serial number, and directing users to the instructions for use for further information and precautions.
5.2.6, 5.2.7	14.2, 4th indent	
5.2.1	14.2, 7th indent	
5.1.3	14.2, 8th indent	
5.1.4	14.2, 9th indent	
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	14.2, 10th indent	Only the conditions for transporting and storing the device are addressed.
5.2.8	15, 8th indent	Only the warning “do not use the product, if the product sterile barrier system or its packaging is compromised” is addressed.

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

Annex ZC
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 98/79/EC on *in vitro* diagnostic medical devices

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 98/79/EC on *in vitro* diagnostic medical devices.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in Table ZC.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZC.1 — Correspondence between this European Standard and Directive 98/79/EC on *in vitro* diagnostic medical devices

Clauses/subclauses of this European Standard	Essential Requirements (ERs) of Directive 98/79/EC	Qualifying remarks/notes
5.4.3	B.8.1	Only the second part of the fourth paragraph is covered: “If individual full labelling of each unit is not practicable, the information must be set out on the packaging and/or in the instructions for use supplied with one or more devices”.
4	B.8.2	Only the first two sentences of this ER are covered.
5.1.1, 5.1.2	B.8.4 (a)	
5.1.3, 5.1.6, 5.5.2, 5.5.3, 5.5.4, 5.5.5	B.8.4 (b)	
5.2.1, 5.2.2, 5.2.3, 5.2.4, 5.2.5, 5.2.7, 5.2.9	B.8.4 (c)	
5.1.5, 5.1.7	B.8.4 (d)	
5.1.4	B.8.4 (e)	
5.5.6	B.8.4 (f)	
5.5.1	B.8.4 (g)	
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	B.8.4 (h)	
5.4.3	B.8.4 (i)	
5.2.6 , 5.2.8, 5.4.1, 5.4.2, 5.4.4, 5.4.5	B.8.4 (j)	
5.1.5, 5.1.7	B.8.6	

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

Contents

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Introduction

This part of ISO 15223 addresses the presentation of certain items of information that are considered by regulatory authorities to be essential for the safe and proper use of medical devices. As such, the items are required to appear with the medical device in most regulatory domains. The information can be required to appear on the medical device itself, as part of the label, or provided with the medical device.

Many countries require that their own language be used to display textual information with medical devices. At the same time, manufacturers seek to take costs out of labelling by reducing or rationalizing variants. This can cause problems in relation to translation, design and logistics when multiple languages are included on a single label or piece of documentation. For example, users of medical devices labelled in a number of different languages can experience confusion and delay in locating the appropriate language.

This part of ISO 15223 proposes solutions to these problems through the use of internationally recognized symbols with precisely defined descriptions.

While compiling symbols to be included in this part of ISO 15223, ISO/TC 210 recognized the need for systematic methodology for the selection, development and validation of symbols proposed for adoption. This is the subject of ISO 15223-2.

This part of ISO 15223 is primarily intended to be used by manufacturers of medical devices who market identical products in countries where there are different language requirements for medical device labelling. It can also be of assistance to:

— distributors of medical devices or other representatives of manufacturers;

— healthcare providers responsible for training as well as those being trained;

— those responsible for post-market vigilance;

— healthcare regulatory authorities, testing organizations, certification bodies and other organizations which are responsible for implementing regulations affecting medical devices and which have responsibility for post-market surveillance; and

— consumers or end users of medical devices who draw their supplies from a number of sources and can have varied language capabilities.

This part of ISO 15223 constitutes a technical revision of both ISO 15223-1:2007 and EN 980:2008, combining the symbols and requirements of both standards for the first time. There has been a steady convergence of the symbol requirements in ISO 15223-1 and EN 980 over recent years, with many of the previous differences between the standards resolved. This part of ISO 15223 represents a significant advance in the safe and effective use of symbols to transcend language, giving manufacturers, regulators and others a single set of global symbols for use with medical devices.

Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied —

Part 1: General requirements

1 Scope

This part of ISO 15223 identifies requirements for symbols used in medical device labelling that convey information on the safe and effective use of medical devices. It also lists symbols that satisfy the requirements of this part of ISO 15223.

This part of ISO 15223 is applicable to symbols used in a broad spectrum of medical devices, which are marketed globally and therefore need to meet different regulatory requirements.

These symbols may be used on the medical device itself, on its packaging or in the associated documentation. The requirements of this part of ISO 15223 are not intended to apply to symbols specified in other standards.

2 Normative references

The following referenced documents are indispensable for the application 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 7000, *Graphical symbols for use on equipment — Index and synopsis*

ISO 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

ISO 14971, *Medical devices — Application of risk management to medical devices*

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 terms and definitions given in ISO 14971 and the following apply.

3.1
characteristic information
information that represents the property or properties of a symbol

3.2
description
normative text which defines the purpose, application and use of the symbol

NOTE Adapted from IEC 80416-1:2008, definition 3.2.