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

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. 04/17

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 15223-1

November 2016

ICS 01.080.20; 11.040.01

Supersedes EN ISO 15223-1:2012

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, Corrected version 2016-12-15)

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, Version corrigée 2016-12-15)

Medizinprodukte - Bei Aufschriften von Medizinprodukten zu verwendende Symbole, Kennzeichnung und zu liefernde Informationen - Teil 1: Allgemeine Anforderungen (ISO 15223-1:2016, korrigierte Fassung 2016-12-15)

This European Standard was approved by CEN on 22 October 2016.

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.

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CEN-CENELEC Management Centre:
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European foreword

This document (EN ISO 15223-1:2016) 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 May 2017, and conflicting national standards shall be withdrawn at the latest by May 2017.

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 ISO 15223-1:2012.

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 ZA, Annex ZB and Annex ZC, which are integral parts 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/Annex ZB/Annex ZC”, 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 referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

Table 1 — 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
ISO 7000	—	ISO 7000:2014[a]
ISO 8601	—	ISO 8601:2004
ISO 14971	EN ISO 14971:2012	ISO 14971:2007
ISO 15223-2	—	ISO 15223-2:2010
[a] Available only in database format from ISO or IEC.		

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 15223-1:2016, Corrected version 2016-12-15 has been approved by CEN as EN ISO 15223-1:2016 without any modification.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC [OJ L 169] on Medical Devices

This European Standard has been prepared under a Commission's standardization request 'M/023 concerning the development of European standards related to medical devices' to provide one voluntary means of conforming to essential requirements of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices [OJ L 169].

Once this standard is cited in the Official Journal of the European Union under that Directive, 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 essential requirements of that Directive, 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 Directive 93/42/EEC as amended by 2007/47/EC. This means that risks have to be reduced "as far as possible", "to a minimum", "to the lowest possible level", "minimized" or "removed", according to the wording of the corresponding essential requirement.

NOTE 2 The manufacturer's policy for determining **acceptable risk** must be in compliance with Essential Requirements 1, 2, 5, 6, 7, 8, 9, 11 and 12 of the Directive.

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 an Essential 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 Directive 93/42/EEC [OJ L 169]

Essential Requirements (ERs) of Directive 93/42/EEC	Clause(s)/subclause(s) of this European Standard	Qualifying remarks/Notes
8.7	5.2.7	Provided that the symbol is provided according to the general requirements indicated in the ER 13.1 of Directive 93/42/EEC and only for non-sterile products.
13.2	4.2, 4.3	Only the first sentence of this ERs is covered, provided that the symbol is provided on the label and according to the general requirements indicated in the ER 13.1 of Directive 93/42/EEC.

13.3 (a)	5.1.1, 5.1.2	Provided that the symbol is provided on the label and according to the general requirements indicated in the ER 13.1 of Directive 93/42/EEC.
13.3 (c)	5.2.1, 5.2.2, 5.2.3, 5.2.4, 5.2.5, 5.2.9	Provided that the symbol is provided on the label and according to the general requirements indicated in the ER 13.1 of Directive 93/42/EEC.
13.3 (d)	5.1.5, 5.1.7	Provided that the symbol is provided on the label and according to the general requirements indicated in the ER 13.1 of Directive 93/42/EEC. If a Serial number is not provided the symbol for 'LOT' must precede the batch code.
13.3 (e)	5.1.4	Provided that the symbol is provided on the label and according to the general requirements indicated in the ER 13.1 of Directive 93/42/EEC, the “use-by” date must be expressed as, at least, the year and the month.
13.3 (f)	5.4.2	Only the first sentence of this ER is covered, provided that the symbol is provided on the label and according to the general requirements indicated in the ER 13.1 of Directive 93/42/EEC.
13.3 (i)	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	Provided that the symbol is provided on the label and according to the general requirements indicated in the ER 13.1 of Directive 93/42/EEC, the ER is only covered with respect to the conditions indicated by the symbols. For other conditions, other symbols or other means of indication may be needed.

13.3 (k)	5.2.6, 5.2.7, 5.2.8, 5.4.1, 5.4.4, 5.4.5	Provided that the symbol is provided on the label and according to the general requirements indicated in the ER 13.1 of Directive 93/42/EEC, the ER is only covered with respect to the warnings indicated by the symbols. For other warnings, other symbols or other means of indication may be needed.
13.3 (l)	5.1.3	Provided that the symbol is provided on the label and according to the general requirements indicated in the ER 13.1 of Directive 93/42/EEC. Active medical devices must be labelled with at least the year of manufacture unless a “use-by” date (5.1.4) is given. The date of manufacture may be included in the batch or serial number (5.1.5, 5.1.7).
13.3 (m)	5.2.2, 5.2.3, 5.2.4, 5.2.5	Provided that the symbol is provided on the label and according to the general requirements indicated in the ER 13.1 of Directive 93/42/EEC, the ER is only covered with respect to the conditions indicated by the symbols.

WARNING 1 — Presumption of conformity stays valid only as long as a reference to this European standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 — 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 Directive 90/385/EEC [OJ L 189] aimed to be covered

This European standard has been prepared under a Commission's standardisation request 'M/023 concerning the development of European standards related to medical devices' to provide one voluntary means of conforming to essential requirements of Council Directive of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices [OJ L 189].

Once this standard is cited in the Official Journal of the European Union under that Directive, compliance with the normative 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.

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 Directive 90/385/EEC as amended by 2007/47/EC. This means that risks have to be reduced "as far as possible", "to a minimum", "to the lowest possible level", "minimized" or "removed", according to the wording of the corresponding essential requirement.

NOTE 2 The manufacturer's policy for determining **acceptable risk** must be in compliance with Essential Requirements 1, 4, 5, 8, 9 and 10 of the Directive.

NOTE 3 This Annex ZB 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 an Essential Requirement does not appear in Table ZB.1, it means that it is not addressed by this European Standard.

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

Essential Requirements (ERs) of Directive 90/385/EEC	Clause(s)/subclause(s) of this European Standard	Qualifying remarks/Notes
11	5.1.5, 5.1.6, 5.1.7	ER is covered only for indication of batch code or serial number. Components are not covered".
14.1, 1st indent	5.2.2, 5.2.3, 5.2.4, 5.2.5	Provided that the symbol is provided on the sterile pack, This ER is only covered with respect to the conditions indicated by the symbols. For other warnings, other symbols or other means of indication may be needed.
14.1, 2nd indent	5.2.1, 5.2.2, 5.2.3, 5.2.4. 5.2.5	Provided that the symbol is provided on the sterile pack.

14.1, 3rd indent	5.1.1	Provided that the symbol is provided on the sterile pack.
14.1, 7th indent	5.2.1, 5.2.2, 5.2.3, 5.2.4, 5.2.5	Provided that the symbol is provided on the sterile pack.
14.1, 8th indent	5.1.3	Provided that the symbol is provided on the sterile pack. Active implantable medical devices must be labelled with at least the month and year of manufacture.
14.1, 9th indent	5.1.4	Provided that the symbol is provided on the sterile pack.
14.2, 1st indent	5.1.1, 5.1.2	Provided that the symbol is provided on the sales packaging. The 'Trade name' of the manufacturer must not be used with this symbol.
14.2, 7th indent	5.2.1	Provided that the symbol is provided on the sales packaging.
14.2, 8th indent	5.1.3	Provided that the symbol is provided on the sales packaging.
14.2, 9th indent	5.1.4	Provided that the symbol is provided on the sales packaging.
14.2, 10th 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	Provided that the symbol is provided on the sales packaging, The ER is only covered in respect of the conditions indicated by the symbols. For other conditions, other symbols or other means of indication may be needed.
15, 8th indent	5.2.8	Provided that the symbol is provided in the instructions for use, only the warning “do not use the product, if the product sterile barrier system or its packaging is compromised” is addressed.

WARNING 1 — Presumption of conformity stays valid only as long as a reference to this European standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 — 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 Directive 98/79/EC [OJ L 331] aimed to be covered

This European standard has been prepared under a Commission's standardisation request 'M/252, concerning the development of European standards relating to in vitro diagnostic medical devices' to provide one voluntary means of conforming to essential requirements of Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices [OJ L 331].

Once this standard is cited in the Official Journal of the European Union under that Directive, compliance with the normative 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.

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 Directive 98/79/EC. This means that risks have to be reduced "as far as possible", "to a minimum", "to the lowest possible level", "minimized" or "removed", according to the wording of the corresponding essential requirement.

NOTE 2 The manufacturer's policy for determining acceptable risk must be in compliance with Essential Requirements Part A: 1, 2 and 5; Part B: 1.2, 2, 3, 5, 6 and 7 of the Directive.

NOTE 3 This Annex ZC 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 an Essential Requirement does not appear in Table ZC.1, it means that it is not addressed by this European Standard.

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

Essential Requirements (ERs) of Directive 98/79/EC	Clause(s)/subclause(s) of this European Standard	Qualifying remarks/Notes
B.8.2	4.2, Clause 5	Only the first two sentences of this ER are covered with regard to the use of symbols.

B.8.4 (a)	5.1.1, 5.1.2	In Directive 98/79/EC the requirements of Annex I, ER B.8.4(a) refer to the IVD device label, which must show the name and address of the manufacturer and, where necessary, also of the EC authorised representative. When the IVD device is a kit (i.e. a set of several components packaged together), the kit itself shall be labelled as above with the name and address of manufacturer and, where necessary, also of the EC authorised representative.
B.8.4 (b)	5.1.3, 5.1.6, 5.5.2, 5.5.3, 5.5.4, 5.5.5	The ER is only covered with respect to the conditions indicated by the symbols.
B.8.4 (c)	5.2.1, 5.2.2, 5.2.3, 5.2.4, 5.2.5, 5.2.9	
B.8.4 (d)	5.1.5, 5.1.7	If a Serial number is not provided the symbol for 'LOT' must precede the batch code.
B.8.4 (e)	5.1.4	The date must be expressed as the year, the month and where relevant the day, in that order.
B.8.4 (g)	5.5.1	
B.8.4 (h)	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	The ER is only covered with respect to the conditions indicated by the symbols.
B.8.4 (j)	5.2.6 , 5.2.8, 5.4.1, 5.4.2, 5.4.4, 5.4.5	The ER is only covered with respect to the conditions indicated by the symbols.
B.8.6	5.1.5, 5.1.7	

WARNING 1 — Presumption of conformity stays valid only as long as a reference to this European standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2 — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard**.**

INTERNATIONAL STANDARD

ISO 15223-1

Third edition
2016-11-01

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

Part 1: General requirements

Dispositifs médicaux — Symboles à utiliser avec les étiquettes, l'étiquetage et les informations à fournir relatifs aux dispositifs médicaux —

Partie 1: Exigences générales

Reference number
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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 on 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 the following URL: www.iso.org/iso/foreword.html.

The committee responsible for this document is ISO/TC 210, *Quality management and corresponding general aspects for medical devices*.

This third edition cancels and replaces the second edition (ISO 15223-1:2012), which has been technically revised with the following principal revisions:

— Clause 2, updated the title of ISO 7000 and added the "date of release" for each of the registered symbols to Table 1;

— symbol 5.1.1, modified the requirement related to the placement of the manufacturer's name and address on IVD labels;

— symbol 5.1.2, modified the requirement related to the placement of name and address of the authorized representative in the European Union on IVD labels;

— symbol 5.4.3, added the information used to indicate an instruction to consult an electronic instructions for use (eIFU);

— symbol 5.4.5, added the reference to ISO 7000, symbol 2725, "Contains or presence of";

— symbol 5.5.5, modified the description of the symbol and the requirement regarding use with IVD;

— A.15, added the examples of the placement of the eIFU indicator.

A list of all parts in the ISO 15223 series can be found on the ISO website.

NOTE Future symbols intended to appear in this document are to be validated in accordance with ISO 15223-2.

Introduction

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

While compiling symbols to be included in this document, 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 document 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.

INTERNATIONAL STANDARD **ISO 15223-1:2016(E)**

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

Part 1: General requirements

1 Scope

This document 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 document.

This document 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 document are not intended to apply to symbols 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 7000[1)], *Graphical symbols for use on equipment — Registered symbols*

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

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*

1) The collection of ISO 7000 graphical symbols and additional information concerning their use are available at https://www.iso.org/obp/ui/#search. Each symbol in the database has a "registration date". These dates are given in the ISO Registration Number column in Table 1.