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EN ISO 15223-1

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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.

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:
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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

Corrected version
2016-12-15

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.

This corrected version of ISO 15223-1:2016 incorporates the following correction:

— in A.9, the graphical symbol of NOTE 2 has been corrected.

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.

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*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 14971 and the following apply.

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

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

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

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

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.

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

[SOURCE: IEC 80416-1:2008, 3.2]

3.3
label
written, printed or graphic information provided upon the medical device itself

[SOURCE: GHTF/SG1/N43:2005]

3.4
labelling
information supplied by the manufacturer that is provided for, associated with, or affixed to, a medical device or any of its containers or wrappers

Note 1 to entry: This information relates to the identification, technical *description* (3.2) and use of the medical device, but excludes shipping documents.

Note 2 to entry: Some regional and national regulations refer to "labelling" as "information supplied by the manufacturer".

3.5
symbol used in medical device labelling
graphical representation appearing on the *label* (3.3) and/or associated documentation of a medical device that communicates *characteristic information* (3.1) without the need for the supplier or receiver of the information to have knowledge of the language of a particular nation or people

Note 1 to entry: The symbol can be an abstract pictorial or a graphical representation, or one that uses familiar objects, including alphanumeric characters.

3.6
title
unique name by which a graphical symbol is identified and spoken of

[SOURCE: IEC 80416-1:2008, 3.9]

4 General requirements

4.1 Proposal of symbols for adoption

Symbols proposed for adoption in this document shall be validated in accordance with ISO 15223-2.

Any symbol proposed for adoption in this document shall be applicable to a range of medical devices and have global or regional applicability.

4.2 Requirements for usage

When risk management shows it to be appropriate for symbols to be used to convey information essential for proper use on the medical device, its packaging or in associated documentation, the symbols given in Table 1 may be used.

Symbols that are registered in ISO 7000 shall comply with the graphical representation in ISO 7000, especially with respect to relative dimensions, including relative line thickness, orientation and the absence or presence of filled or shaded areas.

NOTE 1 ISO and IEC jointly maintain an online database of graphical symbols for use on equipment, which contains the complete set of graphical symbols included in ISO 7000 and IEC 60417 available at https://www.iso.org/obp/ui/#search. This online collection shows each graphical symbol and identifies it by a reference number and a title (in English and French). The graphical symbols are available in different formats (e.g. AI, DWG, EPS) and some additional data as applicable is provided. Various search and navigation facilities allow for easy retrieval of graphical symbols.

As part of risk management, the manufacturer should determine the appropriate size for the symbol to be legible for its intended function.

NOTE 2 This document does not specify colours or minimum size for the symbols in Table 1, nor does it specify the relative size of symbols and that of indicated information.

It is important that symbols be used properly. Guidance on appropriate use of the general prohibition symbol and the negation symbol is given in Annex B.

Before symbols are used, the manufacturer shall carry out a risk assessment that indicates that the use of the symbol does not introduce an unacceptable risk.

NOTE 3 Additional information regarding risk assessment can be found in ISO 14971.

Symbols may be used without accompanying text. Where regulations require accompanying text, the title of the symbol given in this document should be considered sufficient. All dates and times presented in association with symbols shall use the conventions set out in ISO 8601.

4.3 Other symbols

Other standards specify additional symbols that are applicable to particular kinds or groups of medical devices or to particular situations. Examples of sources for such symbols are identified in the Bibliography. This listing is not exhaustive.

5 Symbols

When appropriate, information essential for proper use shall be indicated on the medical device, its packaging, or in the associated documentation by using the corresponding symbols given in Table 1.

A manufacturer may use any appropriate symbol regardless of category.

NOTE Table 1 has been organized into symbol categories for ease of use. The category into which a symbol is grouped does not have any significance as far as usage is concerned. The order of appearance of symbols and the categories in which they are placed are not prioritized. Examples of the use of symbols can be found in Annex A.

Table 1 — Symbols to convey information essential for proper use

Reference number of symbol	Title of symbol	Description of symbol	Requirements	Informative notes	Restrictions of use	Additional requirements	ISO 7000 Reg. no.[a]
5.1 Manufacture							
5.1.1 	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.	This symbol shall be accompanied by the name and address of the manufacturer (i.e. the person placing the medical device on the market), adjacent to the symbol.	NOTE 1 This symbol is used to indicate information that is required in Europe.[b] NOTE 2 The full definition of "manufacturer" is given in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC. NOTE 3 Guidance on the requirements for EU Directives 90/385/EEC and 93/42/EEC is given in EN 1041. NOTE 4 Guidance on the requirements for EU Directive 98/79/EC is given in ISO 18113-1, ISO 18113-2, ISO 18113-3, ISO 18113-4 and ISO 18113-5. NOTE 5 The date of manufacture, as well as the name and address of the manufacturer, can be combined in one symbol. NOTE 6 The relative size of the symbol and the size of the name and address are not specified.			3082 2011-10-02

Table 1 *(continued)*

Reference number of symbol	Title of symbol	Description of symbol	Requirements	Informative notes	Restrictions of use	Additional requirements	ISO 7000 Reg. no.[a]
5.1.2 	Authorized representative in the European Community	Indicates the authorized representative in the European Community.	This symbol shall be accompanied by the name and address of the authorized representative in the European Community, adjacent to the symbol.	NOTE 1 This symbol is used to indicate information that is required in the European Community. NOTE 2 Guidance on the requirements for EU Directives 90/385/EEC and 93/42/EEC is given in EN 1041. NOTE 3 Guidance on the requirements for EU Directive 98/79/EC is given in ISO 18113-1, ISO 18113-2, ISO 18113-3, ISO 18113-4 and ISO 18113-5. NOTE 4 The relative size of the symbol and the size of the name and address are not specified.			N/A

Table 1 *(continued)*

Reference number of symbol	Title of symbol	Description of symbol	Requirements	Informative notes	Restrictions of use	Additional requirements	ISO 7000 Reg. no.[a]
5.1.3 	Date of manufacture	Indicates the date when the medical device was manufactured.	This symbol shall be accompanied by a date to indicate the date of manufacture. This shall be expressed as in ISO 8601 as four digits for the year and, where appropriate, two digits for the month and two digits for the day. The date shall be located adjacent to the symbol.	NOTE The relative size of the symbol and the size of the date are not specified.		In Europe:[b] — the date could be a year, year and month, or year, month and day, as required in the relevant EU Directive; — this symbol may be used to identify the month and year of manufacture for active implantable medical devices, or the year of manufacture for active medical devices where no use-by date is given, as required by the appropriate EU Directive.	2497 2004-01-15

Table 1 *(continued)*

Reference number of symbol	Title of symbol	Description of symbol	Requirements	Informative notes	Restrictions of use	Additional requirements	ISO 7000 Reg. no.[a]
5.1.4 	Use-by date	Indicates the date after which the medical device is not to be used.	This symbol shall be accompanied by a date to indicate that the medical device should not be used after the end of the year, month or day shown. The date shall be expressed as in ISO 8601 as four digits for the year and, where appropriate, two digits for the month and two digits for the day. The date shall be located adjacent to the symbol.	NOTE 1 For example, June 2002 is expressed as 2002-06. NOTE 2 The relative size of the symbol and the size of the date are not specified. NOTE 3 Synonym for "use-by date" is "use by". NOTE 4 For some medical devices (e.g. IVDs), this date is only valid when the medical device is unopened.		In Europe:[b] — the date could be a year, year and month, or year, month and day, as required by the relevant EU Directive; — this symbol can be used to identify the time limit for implanting an active implantable medical device safely as required by EU Directive 90/385/EEC.	2607 2004-01-15
5.1.5 	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	This symbol shall be accompanied by the manufacturer's batch code. The batch code shall be adjacent to the symbol.	NOTE 1 The relative size of the symbol and the size of the batch code are not specified. NOTE 2 Synonyms for "batch code" are "lot number" and "batch number".			2492 2004-01-15

Table 1 *(continued)*

Reference number of symbol	Title of symbol	Description of symbol	Requirements	Informative notes	Restrictions of use	Additional requirements	ISO 7000 Reg. no.[a]
5.1.6 	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.	The manufacturer's catalogue number shall be adjacent to the symbol.	NOTE 1 The relative size of the symbol and the size of the catalogue number are not specified. NOTE 2 Synonyms for "catalogue number" are "reference number" and "reorder number".	In Europe,[b] the manufacturer's catalogue number shall be placed after or below the symbol and adjacent to it. This symbol may currently be shown without the enclosure; however, it is intended that this option be withdrawn in a future edition of this document.		2493 2004-01-15
5.1.7 	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.	This symbol shall be accompanied by the manufacturer's serial number. The serial number shall be adjacent to the symbol.	NOTE The relative size of the symbol and the size of the serial number are not specified.	In Europe,[b] the manufacturer's serial number shall be placed after or below the symbol and adjacent to it. This symbol may currently be shown without the enclosure; however, it is intended that this option be withdrawn in a future edition of this document.		2498 2004-01-15

Table 1 *(continued)*

Reference number of symbol	Title of symbol	Description of symbol	Requirements	Informative notes	Restrictions of use	Additional requirements	ISO 7000 Reg. no.[a]
5.2 Sterility							
5.2.1 	Sterile	Indicates a medical device that has been subjected to a sterilization process.		NOTE Use of this symbol precludes the use of symbols 5.2.2 to 5.2.5.	In Europe,[b] this symbol is restricted to use on terminally sterilized medical devices (EN 556-1:2001, 4.1 applies, including its associated note).		2499 2004-01-15
5.2.2 	Sterilized using aseptic processing techniques	Indicates a medical device that has been manufactured using accepted aseptic techniques.		NOTE 1 Aseptic techniques can include filtration. NOTE 2 Use of this symbol precludes the use of symbol 5.2.1.			2500 2004-01-15
5.2.3 	Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide.		NOTE Use of this symbol precludes the use of symbol 5.2.1.	In Europe,[b] this symbol is restricted to use on terminally sterilized medical devices (EN 556-1:2001, 4.1 applies, including its associated note).		2501 2004-01-15
5.2.4 	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation.		NOTE 1 This symbol can be used to indicate that the product has been subjected to irradiation processes. NOTE 2 Use of this symbol precludes the use of symbol 5.2.1.	In Europe,[b] this symbol is restricted to use on terminally sterilized medical devices (EN 556-1:2001, 4.1 applies, including its associated note).		2502 2004-01-15

Table 1 *(continued)*

Reference number of symbol	Title of symbol	Description of symbol	Requirements	Informative notes	Restrictions of use	Additional requirements	ISO 7000 Reg. no.[a]
5.2.5 	Sterilized using steam or dry heat	Indicates a medical device that has been sterilized using steam or dry heat.		NOTE Use of this symbol precludes the use of symbol 5.2.1.	In Europe,[b] this symbol is restricted to use on terminally sterilized medical devices (EN 556-1:2001, 4.1 applies, including its associated note).		2503 2004-01-15
5.2.6 	Do not resterilize	Indicates a medical device that is not to be resterilized.					2608 2004-01-15
5.2.7 	Non-sterile	Indicates a medical device that has not been subjected to a sterilization process.			This symbol should only be used to distinguish between identical or similar medical devices sold in both sterile and non-sterile conditions.		2609 2004-01-15
5.2.8 	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened.		NOTE This symbol may also mean "Do not use if the product sterile barrier system or its packaging is compromised".		In Europe,[b] this symbol shall be explained in the information supplied by the manufacturer.	2606 2004-01-15

Table 1 *(continued)*

Reference number of symbol	Title of symbol	Description of symbol	Requirements	Informative notes	Restrictions of use	Additional requirements	ISO 7000 Reg. no.[a]
5.2.9 	Sterile fluid path	Indicates the presence of a sterile fluid path within the medical device in cases when other parts of the medical device, including the exterior, might not be supplied sterile.	The method of sterilization shall be indicated in the empty box, as appropriate. The part of the medical device that is sterile shall be identified in the information supplied by the manufacturer.			In Europe,[b] this symbol shall be explained in the information supplied by the manufacturer.	3084 2011-10-05
5.3 Storage							
5.3.1 	Fragile, handle with care	Indicates a medical device that can be broken or damaged if not handled carefully.					0621 2014-06-04
5.3.2 	Keep away from sunlight	Indicates a medical device that needs protection from light sources.		NOTE This symbol can also mean "Keep away from heat", as referenced in ISO 7000.			0624 2014-06-04
5.3.3 	Protect from heat and radioactive sources	Indicates a medical device that needs protection from heat and radioactive sources.		NOTE This symbol can also mean "Keep away from sunlight and radioactive sources".		In Europe,[b] this symbol shall be explained in the information supplied by the manufacturer.	0615 2004-01-15

Table 1 *(continued)*

Reference number of symbol	Title of symbol	Description of symbol	Requirements	Informative notes	Restrictions of use	Additional requirements	ISO 7000 Reg. no.[a]
5.3.4 	Keep dry	Indicates a medical device that needs to be protected from moisture.		NOTE This symbol can also mean "Keep away from rain" as referenced in ISO 7000.			0626 2014-06-04
5.3.5 	Lower limit of temperature	Indicates the lower limit of temperature to which the medical device can be safely exposed.	The lower limit of temperature shall be indicated adjacent to the lower horizontal line.				0534 2004-01-15
5.3.6 	Upper limit of temperature	Indicates the upper limit of temperature to which the medical device can be safely exposed.	The upper limit of temperature shall be indicated adjacent to the upper horizontal line.				0533 2004-01-15
5.3.7 	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.	The upper and lower limits of temperature shall be indicated adjacent to the upper and lower horizontal lines.				0632 2014-06-04

Table 1 *(continued)*

Reference number of symbol	Title of symbol	Description of symbol	Requirements	Informative notes	Restrictions of use	Additional requirements	ISO 7000 Reg. no.[a]
5.3.8 	Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed.	The humidity limitation shall be indicated adjacent to the upper and lower horizontal lines.			In Europe,[b] this symbol shall be explained in the information supplied by the manufacturer.	2620 2004-01-15
5.3.9 	Atmospheric pressure limitation	Indicates the range of atmospheric pressure to which the medical device can be safely exposed.	The atmospheric pressure limitations shall be indicated adjacent to the upper and lower horizontal lines.			In Europe,[b] this symbol shall be explained in the information supplied by the manufacturer.	2621 2004-01-15
5.4 Safe use							
5.4.1 	Biological risks	Indicates that there are potential biological risks associated with the medical device.	NOTE This symbol is not to be confused with the "Biohazard" sign intended to be used in the workplace.	See ISO 7010.			0659 2004-01-15
5.4.2 	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.		NOTE Synonyms for "Do not re-use" are "single use" and "use only once".			1051 2004-01-15

Table 1 *(continued)*

Reference number of symbol	Title of symbol	Description of symbol	Requirements	Informative notes	Restrictions of use	Additional requirements	ISO 7000 Reg. no.[a]
5.4.3 	Consult instructions for use	Indicates the need for the user to consult the instructions for use.		NOTE 1 Synonym for "Consult instructions for use" is "Consult operating instructions". NOTE 2 Consider the difference between the description of this symbol and that of symbol 5.4.4.		When used to indicate an instruction to consult an electronic instructions for use (eIFU), this symbol is accompanied by an eIFU indicator. This indicator may represent the manufacturer's eIFU website or any other appropriate indication on the use of eIFU. The indicator may be placed either alongside, beneath or surrounding the symbol (see A.15).	1641 2004-01-15
5.4.4 	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	The symbol variant ISO 7000, symbol 0434B ("Caution") may be used.	NOTE 1 Consider the difference between the description of this symbol and that of symbol 5.4.3. NOTE 2 This symbol is essentially a cautionary symbol and is used to highlight the fact that there are specific warnings or precautions associated with the medical device, which are not otherwise found on the label.	This symbol is not to be confused with the "Caution" sign intended to be used in the workplace.		0434A 2004-01-15

Table 1 *(continued)*

Reference number of symbol	Title of symbol	Description of symbol	Requirements	Informative notes	Restrictions of use	Additional requirements	ISO 7000 Reg. no.[a]
5.4.5 	Contains or presence of natural rubber latex	Indicates the presence of natural rubber or dry natural rubber latex as a material of construction within the medical device or the packaging of a medical device.		NOTE This symbol is intended to warn those people who may have allergic reactions to certain proteins in latex.	This symbol should not be used for medical devices containing "synthetic rubber".	In Europe,[b] this symbol shall be explained in the information supplied by the manufacturer.	Application of ISO 7000, symbol 2725 2005-09-08
5.5 IVD-specific							
5.5.1 	*In vitro* diagnostic medical device	Indicates a medical device that is intended to be used as an *in vitro* diagnostic medical device.			This symbol should only be used to identify *in vitro* diagnostic medical devices and not to specify that the medical device is for "*in vitro* use".	In Europe,[b] this symbol is only used to identify *in vitro* diagnostic medical devices as defined in EU Directive 98/79/EC.	N/A
5.5.2 	Control	Indicates a control material that is intended to verify the performance characteristics of another medical device.		NOTE For negative controls, use symbol 5.5.3 and for positive controls, use symbol 5.5.4.			N/A NOTE ISO 7000-2494 was withdrawn by ISO/TC 145/SC 3. Letters and words are not registered as graphical symbols in ISO 7000.
5.5.3 	Negative control	Indicates a control material that is intended to verify the results in the expected negative range.					2495 2004-01-15

Table 1 *(continued)*

Reference number of symbol	Title of symbol	Description of symbol	Requirements	Informative notes	Restrictions of use	Additional requirements	ISO 7000 Reg. no.[a]
5.5.4 	Positive control	Indicates a control material that is intended to verify the results in the expected positive range.					2496 2004-01-15
5.5.5 	Contains sufficient for <*n*> tests	Indicates the total number of IVD tests that can be performed with the IVD.	The number of tests that can be performed with the IVD shall appear adjacent to the symbol.	NOTE The relative size of the symbol and the number of tests performed can vary.			Application of ISO 7000, symbol 0518 2004-01-15

Table 1 *(continued)*

Reference number of symbol	Title of symbol	Description of symbol	Requirements	Informative notes	Restrictions of use	Additional requirements	ISO 7000 Reg. no.[a]
5.5.6 	For IVD performance evaluation only	Indicates an IVD device that is intended to be used only for evaluating its performance characteristics before it is placed on the market for medical diagnostic use.		NOTE 1 A synonym is "IVD for investigational use only". NOTE 2 A medical device that is for IVD performance evaluation only is not intended to be used for an *in vitro* diagnostic examination for medical purposes (i.e. to yield diagnostic results).	This symbol shall not appear jointly on the label or in the labelling of an IVD device bearing the symbol  which means that the medical device is an in vitro diagnostic medical device intended by the manufacturer to be used for an in vitro diagnostic examination.		Application of ISO 7000, symbol 3083 2011-10-03
5.6 Transfusion/infusion							
5.6.1 	Sampling site	Indicates a medical device or blood processing application that includes a system dedicated to the collection of samples of a given substance stored in the medical device or blood container.		NOTE This is not to be associated with a site on a patient where samples are taken.		In Europe,[b] this symbol shall be explained in the information supplied by the manufacturer.	2715 2005-09-08

Table 1 *(continued)*

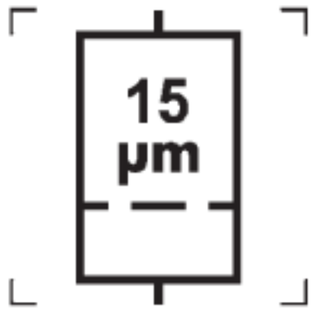
Reference number of symbol	Title of symbol	Description of symbol	Requirements	Informative notes	Restrictions of use	Additional requirements	ISO 7000 Reg. no.[a]
5.6.2 	Fluid path	Indicates the presence of a fluid path.				In Europe,[b] this symbol shall be explained in the information supplied by the manufacturer.	2722 2005-09-08
5.6.3 	Non-pyrogenic	Indicates a medical device that is non-pyrogenic.				In Europe,[b] this symbol shall be explained in the information supplied by the manufacturer.	2724 2005-09-08
5.6.4 	Drops per millilitre	Indicates the number of drops per millilitre.		NOTE The number of drops per millilitre is specified; 20 is shown as an example and will be replaced by the appropriate number of drops per millilitre.		In Europe,[b] this symbol shall be explained in the information supplied by the manufacturer.	2726 2005-09-08
5.6.5 	Liquid filter with pore size	Indicates an infusion or transfusion system of the medical device that contains a filter of a particular nominal pore size.		NOTE The nominal pore size of the filter is specified; 15 is shown as an example and will be replaced by the appropriate pore size.		In Europe,[b] this symbol shall be explained in the information supplied by the manufacturer.	2727 2005-09-08

Table 1 *(continued)*

Reference number of symbol	Title of symbol	Description of symbol	Requirements	Informative notes	Restrictions of use	Additional requirements	ISO 7000 Reg. no.[a]
5.6.6 	One-way valve	Indicates a medical device with a valve that allows flow in only one direction.		NOTE It is important for the user to know that the flow is only possible in one direction and cannot be reversed.		In Europe,[b] this symbol shall be explained in the information supplied by the manufacturer.	2728 2005-09-08
5.7 Others							
5.7.1 	Patient number	Indicates a unique number associated with an individual patient.				In Europe,[b] this symbol shall be explained in the information supplied by the manufacturer.	2610 2004-01-15

[a] Each symbol in the ISO/IEC symbols database (available at https://www.iso.org/obp/ui) has a "registration date". This date is shown below the Registration Number.

[b] At the moment, only countries applying the principles laid down in the EU Directives have this requirement or restriction.

Annex A
(informative)

Examples

A.1 Example of use of symbol 5.1.1, “Manufacturer”

Name Address

A.2 Example of use of symbol 5.1.1, “Manufacturer”, combined with 5.1.3, “Date of manufacture”

Name Address 2015-06

A.3 Example of use of symbol 5.1.2, “Authorized representative in the European Community”

Name Address

A.4 Examples of use of symbol 5.1.3, “Date of manufacture”

2015-06

2015

A.5 Examples of use of symbol 5.1.4, “Use-by date”

2015-06

2015-06-15

A.6 Example of use of symbol 5.1.5, “Batch code”

ABC123

A.7 Example of use of symbol 5.1.6, “Catalogue number”

ABC123

A.8 Example of use of symbol 5.1.7, “Serial number”

ABC123

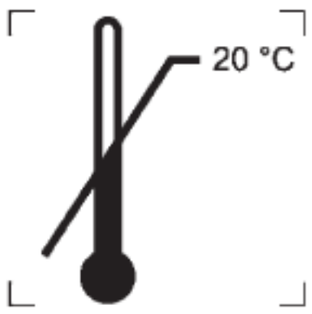
A.9 Examples of use of symbols for “Sterile fluid path”

NOTE 1 Medical device contains a sterile fluid path that has been sterilized using ethylene oxide.

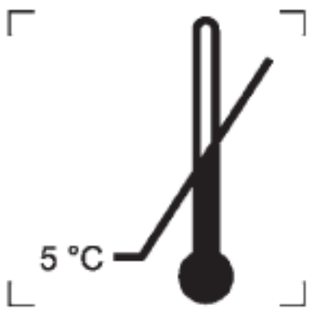
NOTE 2 Medical device contains a sterile fluid path that has been sterilized using irradiation.

NOTE 3 Medical device contains a sterile fluid path that has been sterilized using steam or dry heat.

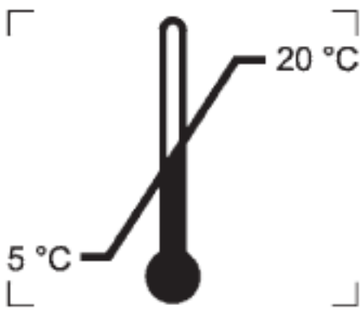
A.10 Examples of use of symbols for temperature limits



Upper limit of temperature

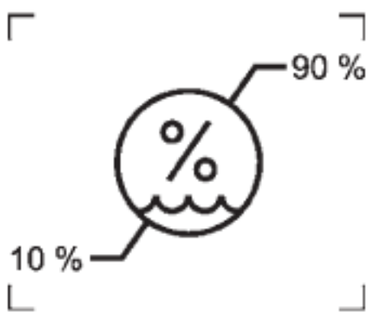


Lower limit of temperature

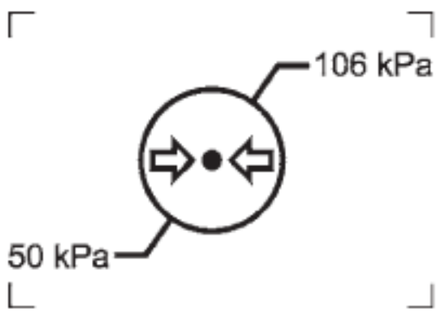


Temperature limit

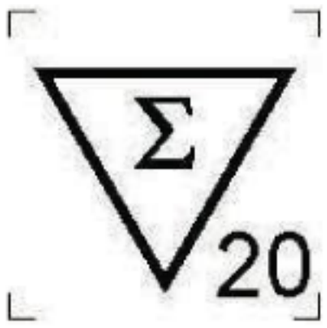
A.11 Examples of use of symbol 5.3.8, "Humidity limitation"

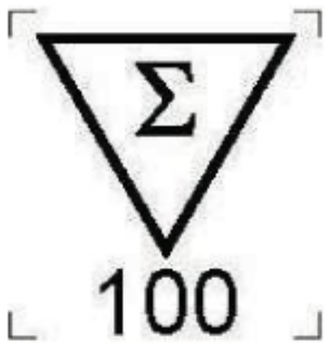


A.12 Example of use of symbol 5.3.9, "Atmospheric pressure limitation"



A.13 Examples of use of symbol 5.5.5, "Contains sufficient for <*n*> tests"





A.14 Example of use of symbol 5.7.1, "Patient number"

ABC123

A.15 Example of use of symbol 5.4.3, "Consult instructions for use" for an electronic instruction for use (eIFU)

eIFU indicator

eIFU indicator

NOTE The eIFU indicator can be a manufacturer's website URL or some other appropriate indication that the instructions for use are available in an electronic format.

Annex B
(informative)

Use of general prohibition symbol and negation symbol

B.1 General prohibition symbol

The general prohibition symbol (as used in ISO 3864-1) is intended to indicate a prohibited action. For medical device labelling, the prohibition circle with a diagonal bar should be used to mean “do not”, e.g. symbol 5.4.2 “Do not re-use”. It is sometimes used out of context in medical device labelling, e.g. to mean “does not contain”. It is important that usage be consistent with the intended meaning so that hazards do not arise from misunderstanding.

B.2 Negation symbol

Manufacturers wishing to communicate the meaning “does not” or “is not” where a symbol expressing this meaning does not exist, should follow the method set out in IEC 80416-3:2002, Clause 7 (a large “X” placed over the symbol). Although it is not generally recommended that this symbology be used with any of the symbols given in this document, the use of the negation symbol is permitted.

Bibliography

[1] ISO 3864-1, *Graphical symbols — Safety colours and safety signs — Part 1: Design principles for safety signs and safety markings*

[2] ISO 7010, *Graphical symbols — Safety colours and safety signs — Registered safety signs*

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

[4] ISO 18113-1, *In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 1: Terms, definitions and general requirements*

[5] ISO 18113-2[2)], *In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 2: In vitro diagnostic reagents for professional use*

[6] ISO 18113-3[3)], *In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 3: In vitro diagnostic instruments for professional use*

[7] ISO 18113-4[4)], *In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 4: In vitro diagnostic reagents for self-testing*

[8] ISO 18113-5[5)], *In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 5: In vitro diagnostic instruments for self-testing*

[9] IEC 60417, *Graphical symbols for use on equipment*

[10] IEC 80416-1, *Basic principles for graphical symbols for use on equipment — Part 1: Creation of graphical symbols for registration*

[11] IEC 80416-3:2002, *Basic principles for graphical symbols for use on equipment — Part 3: Guidelines for the application of graphical symbols*

[12] EN 556-1:2001, *Sterilization of medical devices — Requirements for medical devices to be designated "STERILE" — Part 1: Requirements for terminally sterilized medical devices*

[13] EN 1041, *Information supplied by the manufacturer of medical devices*

[14] GHTF/SG1/N43. 2005, Labelling for medical devices. Available at: http://www.imdrf.org/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n43-2005-labelling-medical-devices-050603.pdf

2) Cancels and replaces EN 375:2001.

3) Cancels and replaces EN 591:2001.

4) Cancels and replaces EN 376:2002.

5) Cancels and replaces EN 592:2002.

ICS 01.080.20; 11.040.01

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