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Incorporating corrigendum July 2012

BSI Standards Publication

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

Part 1: General requirements
(ISO 15223-1:2012)

National foreword

This British Standard is the UK implementation of EN ISO 15223-1:2012. It supersedes BS EN 980:2008 which will be withdrawn on 31 January 2013.

The UK participation in its preparation was entrusted to Technical Committee CH/210/3, General terminology and symbols for Medical Devices.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 July 2012.

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Date	Text affected
31 July 2012	Date of withdrawal added to supersession

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 15223-1

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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-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.

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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.

ISO 15223-1 was prepared by Technical Committee ISO/TC 210, *Quality management and corresponding general aspects for medical devices*.

This second edition cancels and replaces the first edition (ISO 15223-1:2007) and EN 980:2008, which have been technically revised. It also incorporates the amendment ISO 15223-1:2007/Amd.1:2008.

ISO 15223 consists of the following parts, under the general title *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied*:

— *Part 1: General requirements*

— *Part 2: Symbol development, selection and validation*

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

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.

INTERNATIONAL **ISO 15223-1:2012(E)**

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.

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

NOTE Adapted from 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 This information relates to the identification, technical description and use of the medical device, but excludes shipping documents.

NOTE 2 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 and/or associated documentation of a medical device that communicates characteristic information without the need for the supplier or receiver of the information to have knowledge of the language of a particular nation or people

NOTE 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

NOTE Adapted from IEC 80416-1:2008, definition 3.9.

4 General requirements

4.1 Proposal of symbols for adoption

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

Any symbol proposed for adoption in this part of ISO 15223 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. In that database, each graphical symbol is identified by a reference number and contains a title (in English and French), a graphical representation in GIF and vectorized PDF format, and some additional data as applicable. Various search and navigation facilities allow for easy retrieval of graphical symbols. Information on how to subscribe in order to access this database is available through the ISO Store, the IEC Web Store or by contacting your local national standards body.

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 part of ISO 15223 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 part of ISO 15223 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

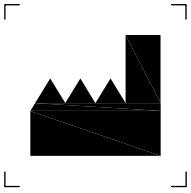
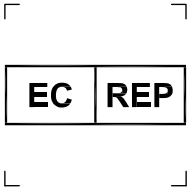
Reference number of symbol	Title of symbol	Description of symbol[a]	Requirements	Informative notes	Restrictions of use	Additional requirements	ISO 7000 Reg. no.
5.1 Manufacture							
5.1.1 	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 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. According to EU Directive 98/79/EC, the address is not required with the symbol on an IVD medical device's immediate container, as specified in ISO 18113-2, ISO 18113-3, ISO 18113-4 and ISO 18113-5, except when the immediate container is also the outer container.	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 The date of manufacture, as well as the name and address of the manufacturer, can be combined in one symbol. NOTE 5 The relative size of the symbol and the size of the name and address are not specified.			3082
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. The address is not required with the symbol on an *in vitro* diagnostic medical device's immediate container, as specified in ISO 18113-2, ISO 18113-3, ISO 18113-4 and ISO 18113-5, except when the immediate container is also the outer container.	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 The relative size of the symbol and the size of the name and address are not specified.			

Table 1 (*continued*)

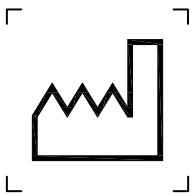
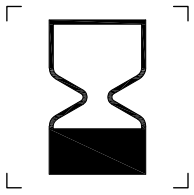
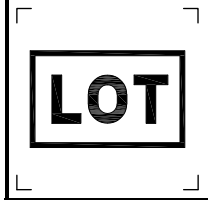
Reference number of symbol	Title of symbol	Description of symbol[a]	Requirements	Informative notes	Restrictions of use	Additional requirements	ISO 7000 Reg. no.
5.1.3 	Date of manufacture	Indicates the date when the medical device was manufactured.	This symbol shall be accompanied by a date to indicate 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 1 The relative size of the symbol and the size of the date are not specified. NOTE 2 This symbol can be filled or unfilled. If filled, the date of manufacture as well as the name and address of the manufacture can be combined in one symbol.		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
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
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

Table 1 (*continued*)

Reference number of symbol	Title of symbol	Description of symbol[a]	Requirements	Informative notes	Restrictions of use	Additional requirements	ISO 7000 Reg. no.
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 part of ISO 15223.		2493
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 part of ISO 15223.		2498
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 (4.1 of EN 556-1:2001 applies, including its associated note).		2499

Table 1 (*continued*)

Reference number of symbol	Title of symbol	Description of symbol[a]	Requirements	Informative notes	Restrictions of use	Additional requirements	ISO 7000 Reg. no.
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
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 (4.1 of EN 556-1:2001 applies, including its associated note).		2501
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 (4.1 of EN 556-1:2001 applies, including its associated note).		2502
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 (4.1 of EN 556-1:2001 applies, including its associated note).		2503

Table 1 (*continued*)

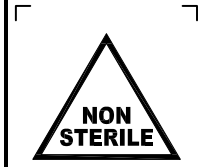
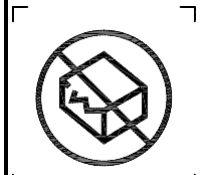
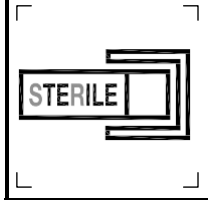
Reference number of symbol	Title of symbol	Description of symbol[a]	Requirements	Informative notes	Restrictions of use	Additional requirements	ISO 7000 Reg. no.
5.2.6 	Do not resterilize	Indicates a medical device that is not to be resterilized.					2608
5.2.7 	Non-sterile	Indicates a medical device 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
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
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

Table 1 (*continued*)

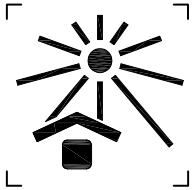
Reference number of symbol	Title of symbol	Description of symbol[a]	Requirements	Informative notes	Restrictions of use	Additional requirements	ISO 7000 Reg. no.
5.3 Storage							
5.3.1 	Fragile, handle with care	Indicates a medical device that can be broken or damaged if not handled carefully.					0621
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 7000:1989.			0624
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
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

Table 1 (*continued*)

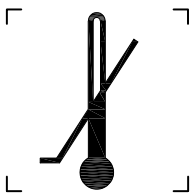
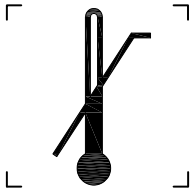
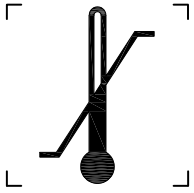
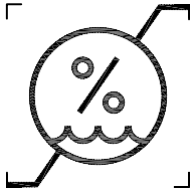
Reference number of symbol	Title of symbol	Description of symbol[a]	Requirements	Informative notes	Restrictions of use	Additional requirements	ISO 7000 Reg. no.
5.3.5 	Lower limit of temperature	Indicates the lower limit of temperature to which the medical device can be safely exposed.	The lower limit of temperature shall be indicated adjacent to the lower horizontal line.				0534
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
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
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

Table 1 (*continued*)

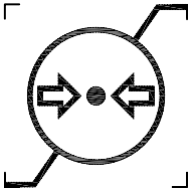
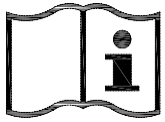
Reference number of symbol	Title of symbol	Description of symbol[a]	Requirements	Informative notes	Restrictions of use	Additional requirements	ISO 7000 Reg. no.
5.3.9 	Atmospheric pressure limitation	Indicates the range of atmospheric pressure to which the medical device can be safely exposed.	The atmospheric 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
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
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
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.			1641

Table 1 (*continued*)

Reference number of symbol	Title of symbol	Description of symbol[a]	Requirements	Informative notes	Restrictions of use	Additional requirements	ISO 7000 Reg. no.
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 7000-0434B ("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 should be 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
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.	N/A
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.	

Table 1 (*continued*)

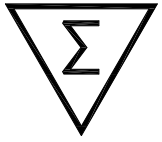
Reference number of symbol	Title of symbol	Description of symbol[a]	Requirements	Informative notes	Restrictions of use	Additional requirements	ISO 7000 Reg. no.
5.5.2 	Control	Indicates a control material that is intended to verify the performance characteristics of another medical device.		NOTE For negative controls, use symbol 5.5.3 and for positive controls, use symbol 5.5.4.			2494
5.5.3 	Negative control	Indicates a control material that is intended to verify the results in the expected negative range.					2495
5.5.4 	Positive control	Indicates a control material that is intended to verify the results in the expected positive range.					2496
5.5.5 	Contains sufficient for <*n*> tests	Indicates the total number of IVD tests that can be performed with the IVD kit reagents.	The number of tests that can be performed with the kit reagents shall appear adjacent to the symbol.	NOTE The relative size of the symbol and the number of tests performed can vary.			0518

Table 1 (*continued*)

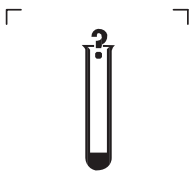
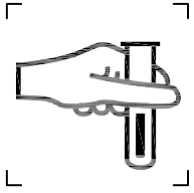
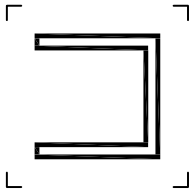
Reference number of symbol	Title of symbol	Description of symbol[a]	Requirements	Informative notes	Restrictions of use	Additional requirements	ISO 7000 Reg. no.
5.5.6 	For IVD performance evaluation only	Indicates an IVD device that is intended to be used only for evaluating its performance characteristics 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 7000-3083
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
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

Table 1 (*continued*)

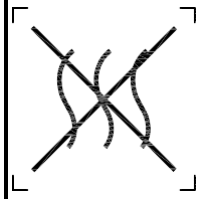
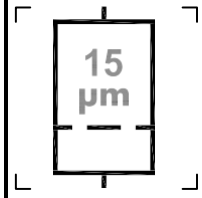
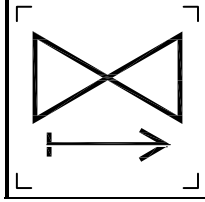
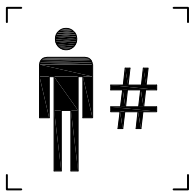
Reference number of symbol	Title of symbol	Description of symbol[a]	Requirements	Informative notes	Restrictions of use	Additional requirements	ISO 7000 Reg. no.
5.6.3 	Non-pyrogenic	Indicates a medical device that is non-pyrogenic.				In Europe [b], this symbol shall be explained in the information supplied by the manufacturer.	2724
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 should 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
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 should be replaced by the appropriate pore size.		In Europe [b], this symbol shall be explained in the information supplied by the manufacturer.	2727
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

Table 1 (*continued*)

Reference number of symbol	Title of symbol	Description of symbol[a]	Requirements	Informative notes	Restrictions of use	Additional requirements	ISO 7000 Reg. no.
5.7 Other							
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

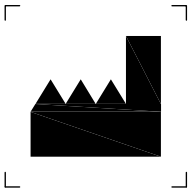
[a] This column is a new addition, not previously existing in either ISO 15223-1 or EN 980.

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

Annex A
(informative)

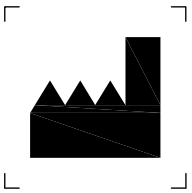
Examples

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



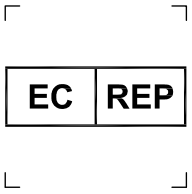
Name Address

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



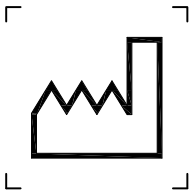
Name Address 2005-06

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



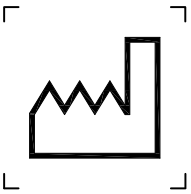
Name Address

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

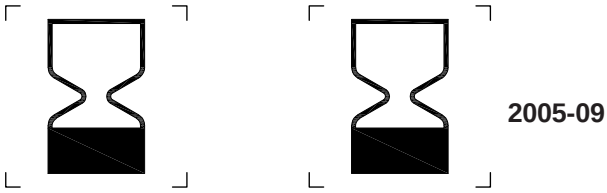


2004-06

2004



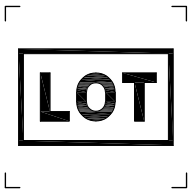
A.5 Examples of use of symbol 5.1.4, “Use-by date”



2005-09

2005-09-15

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

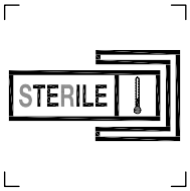
A.8 Example of use of symbol 5.1.7, “Serial number”

ABC123

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

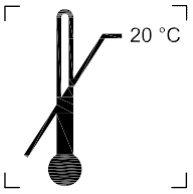
NOTE 1 Medical device contains a sterile fluid path that has been sterilized using ethylene oxide.

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

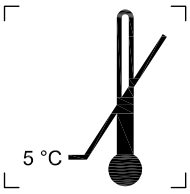


NOTE 3 Medical device contains a sterile fluid path that has been sterilized using steam or dry heat.

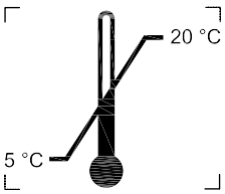
A.10 Examples of use of symbols for temperature limits



Upper limit of temperature

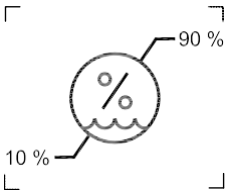


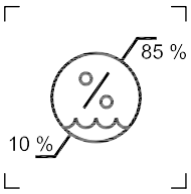
Lower limit of temperature



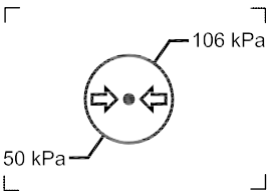
Temperature limit

A.11 Examples of use of symbol 5.3.8, “Humidity limitation”

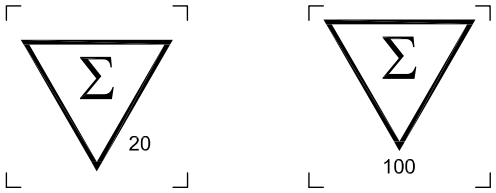




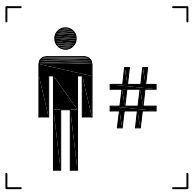
A.12 Example of use of symbol 5.3.9, “Atmospheric pressure limitation”



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

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 Clause 7 of IEC 80416-3:2002 (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 part of ISO 152231, 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 7000:1989, *Graphical symbols for use on equipment — Index and synopsis*[1)]

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

[4] ISO/TR 7239, *Development and principles for application of public information symbols*[2)]

[5] ISO 15225, *Medical devices — Quality management — Medical device nomenclature data structure*

[6] ISO 18113-2, In vitro *diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 2:* In vitro *diagnostic reagents for professional use*[3)]

[7] ISO 18113-3, In vitro *diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 3:* In vitro *diagnostic instruments for professional use*[4)]

[8] ISO 18113-4, In vitro *diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 4:* In vitro *diagnostic reagents for self-testing*[5)]

[9] ISO 18113-5, In vitro *diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 5:* In vitro *diagnostic instruments for self-testing*[6)]

[10] ISO 80416-2, *Basic principles for graphical symbols for use on equipment — Part 2: Form and use of arrows*

[11] ISO/IEC 13251, *Collection of graphical symbols for office equipment*

[12] IEC 60417 ISO 7000-DB, *Graphical symbols for use on equipment*

[13] IEC/TR 60878, *Graphical symbols for electrical equipment in medical practice*

[14] IEC 62366, *Medical devices — Application of usability engineering to medical devices*

[15] IEC 80416-1:2008, *Basic principles for graphical symbols for use on equipment — Part 1: Creation of graphical symbols for registration*

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

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

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1) Withdrawn. The graphical symbol collections of ISO 7000, ISO 7001 and ISO 7010 are also available online in the ISO webstore. For more information, go to http://www.iso.org/iso/publications_and_e-products/databases.htm.

2) Withdrawn.

3) Cancels and replaces EN 375:2001.

4) Cancels and replaces EN 591:2001.

5) Cancels and replaces EN 376:2002.

6) Cancels and replaces EN 592:2002.

[18] EN 980:2008, *Symbols for use in the labelling of medical devices*

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

[20] GHTF/SG1/N43:2005, *Labelling for Medical Devices* Available at: http://www.ghtf.org/documents/sg1/sg1final-n43.pdf

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