BS EN ISO 15223-1:2012

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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)

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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 It supersedes BS EN 980:2008 which will be withdrawn on 31 January 2013.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.

Amendments/Corrigenda issued since publication

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

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 15223-1

July 2012

ICS 01.080.20; 11.040.01

Supersedes EN 980:2008

English version

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

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

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

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

CEN and CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN and CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN and CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN and CENELEC members are the national standards bodies and national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

CEN-CENELEC Management Centre:
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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.

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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.

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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.

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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.

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Introduction

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

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

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

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

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

— distributors of medical devices or other representatives of manufacturers;

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

— those responsible for post-market vigilance;

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

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

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

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