BRITISH STANDARD

BS EN 980:2003

Graphical symbols for use in the labelling of medical devices

The European Standard EN 980:2003 has the status of a British Standard

ICS 01.080.20; 11.040.01; 11.120.01

BSI British Standards

National foreword

This British Standard is the official English language version of EN 980:2003. It supersedes BS EN 980:1997 which is withdrawn.

The UK participation in its preparation was entrusted by Technical Committee CH/210, Quality management and corresponding general aspects for medical devices, to Subcommittee CH/210/3, General terminology and symbols, which has the responsibility to:

— aid enquirers to understand the text;

— present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;

— monitor related international and European developments and promulgate them in the UK.

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

Users of EN 980:2003 are informed that the UK submitted a vote of disapproval at the voting stage of the Unique Acceptance Procedure (UAP) for the draft EN. The UK deems the following difficulties may arise in achieving conformity to this revised edition.

— "New" symbols are introduced, in a new Clause **5**, with a requirement that the symbols be explained in the documentation provided with the device. This requirement stands regardless of the status of EN 980:2003 with respect to harmonization with Medical Device Directives.

— The above requirement will apply to certain symbols, which have previously been in common and widespread use (see, for example, **5.7**, **5.8** and **5.9**).

— Notes to the requirements of EN 980:2003 do not consistently identify those parts of the Medical Device Directives with which the use of symbols may conform. Users may find uses for the symbols beyond those specified. In this case it would be prudent to justify such use in the Technical Documentation.

Cross-references

The British Standards which implement international or European publications referred to in this document may be found in the *BSI Catalogue* under the section entitled "International Standards Correspondence Index", or by using the "Search" facility of the *BSI Electronic Catalogue* or of British Standards Online.

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

Compliance with a British Standard does not of itself confer immunity from legal obligations.

This British Standard, was published under the authority of the Standards Policy and Strategy Committee on 13 August 2003

Summary of pages

This document comprises a front cover, an inside front cover, the EN title page, pages 2 to 25 and a back cover.

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Amendments issued since publication

Amd. No.	Date	Comments

ISBN 0 580 42460 X

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 980

April 2003

ICS 01.080.20; 11.040.01; 11.120.01

Supersedes EN 980:1996

English version

Graphical symbols for use in the labelling of medical devices

Symboles graphiques utilisés pour l'étiquetage des dispositifs médicaux

Graphische Symbole zur Kennzeichnung von Medizinprodukten

This European Standard was approved by CEN on 9 January 2003.

CEN 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 Management Centre or to any CEN 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 member into its own language and notified to the Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: rue de Stassart, 36 B-1050 Brussels

Ref. No. EN 980:2003 E

Contents

Foreword

This document (EN 980:2003) has been prepared by Technical Committee CEN/TC 257 "Symbols and information provided with medical devices and nomenclature for regulatory data exchange", the secretariat of which is held by SFS.

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 October 2003, and conflicting national standards shall be withdrawn at the latest by October 2003.

This document supersedes EN 980:1996 (as amended).

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 annexes ZA, ZB and C which are an integral part 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, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Annex A is informative.

This document includes a Bibliography.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Switzerland and the United Kingdom.

Introduction

This European Standard has been prepared to reduce the need for multiple translation of words into national languages, to simplify labelling wherever possible and to prevent separate development of different symbols to convey the same information. It has been prepared to align the presentation of information required by all EEC Directives on medical devices including active implantable and in vitro diagnostic medical devices.

The meaning of some of these symbols is self-evident. Some are already in widespread use and familiar to health care professionals. The meaning of others will become clear with use or when viewed in the context of the device itself. If appropriate the meaning of symbols should be explained in accompanying literature when provided. Symbols used with medical devices for use by other than health care professionals can require additional explanations.

This revision incorporates a different approach to the previously published version. The symbols in clause 4 of the existing standard have now been in general use by manufacturers for some time and users have some degree of familiarity with these. Additional symbols are now being introduced, most of these will be new to manufacturers and users. As a precaution, clause 5 of this revision to the standard requires that the meaning of these new symbols be explained in the accompanying literature. This is without prejudice to the harmonisation of the remaining requirements of this standard. It is anticipated that in time, the requirement to explain the meaning of symbols in clause 5 will be dropped. It is not always possible to develop symbols for all information presented with the device. Not all symbols are appropriate for all types of medical devices. The validity of information conveyed by a symbol can be adversely affected by subsequent events e.g. damage to a package can affect the sterility of a device.

Annex A provides examples of how some of the symbols can be used. These are illustrative only and do not represent the only ways in which the requirements of this standard can be met. An additional informative bibliography is given.

1 Scope

This European Standard specifies graphical symbols for use in the information supplied by the manufacturer with medical devices (including in vitro diagnostic medical devices).

NOTE This standard does not specify the circumstances under which particular symbols are used. Guidance on this is given in EN 1041.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text, and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

EN 375:2001, *Information supplied by the manufacturer with in vitro diagnostic reagents for professional use.*

EN 376:2002, *Information supplied by the manufacturer with in vitro diagnostic reagents for self-testing.*

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

EN 28601:1992, *Data elements and interchange formats - Information interchange - Representation of dates and times (ISO 8601:1988 and its technical corrigendum 1:1991).*

3 General requirements

Graphical symbols used to convey the information given in 4.2 to 4.11 and 5.2 to 5.9 are given in this standard.

NOTE 1 Other symbols can be used to convey other information. Where graphical symbols are not taken from a Harmonized Standard, their meaning should be described in the documentation supplied with the device. Many other standards specify symbols for particular purposes and/or for particular kinds of device. The Bibliography lists some of these standards.

Enclosures shown in 4.2, 4.4, 4.7, 4.8.1, 4.8.2, 4.8.3, 4.10, 4.11, 5.3, 5.4, 5.6 and 5.8 shall be included as part of these symbols.

NOTE 2 The use of similar enclosures around other symbols is not precluded (e.g. 4.5 and 4.9).

All symbols and accompanying information shall be legible when viewed under an illumination of 215 lx using normal vision, corrected if necessary, at a distance which takes into account the specifics and size of the individual medical device.

NOTE 3 Colours and minimum dimensions are not specified in this standard.

4 Symbols already in use

4.1 General

This clause presents symbols that are well-understood and already in use and are recognised to be suitable without need for further explanation.

4.2 Symbol for "DO NOT REUSE"

NOTE 1 This symbol is as given in ISO 7000/1051 and as symbol No. 3.2 in ISO 15223.

NOTE 2 Synonyms for "do not reuse" are "single use", "use only once".

NOTE 3 See Council Directive 93/42/EEC concerning medical devices, Annex I, 13.3 (f).

4.3 Symbol for "USE BY"

This symbol shall be accompanied by the date expressed as given in EN 28601 as four digits for the year and two digits for the month and where appropriate, two digits for the day. The date shall be adjacent to the symbol.

NOTE 1 For example, June 2002 becomes 2002-06.

NOTE 2 The relative size of the symbol and the date is not specified.

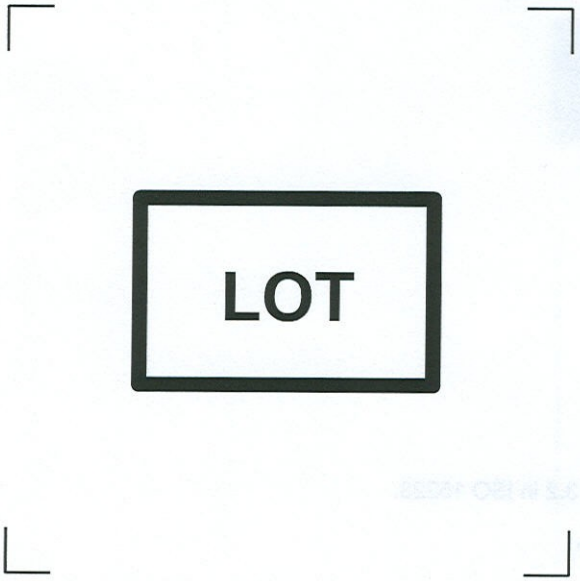
NOTE 3 The symbol is intended to indicate that the device should not be used after the end of the month shown or the day, if applicable.

NOTE 4 Synonym for "use by" is "the time limit for implanting a device safely" for active implantable medical devices only.

NOTE 5 The symbol No. 3.12 in ISO 15223 corresponds to this symbol.

NOTE 6 See Council Directive 90/385/EEC relating to active implantable medical devices, Annex I, 14.1, Council Directive 93/42/EEC concerning medical devices, Annex I, 13.3 (e) and Council Directive 98/79/EC on in vitro diagnostic medical devices, Annex I, B.8.4. (e).

4.4 Symbol for "BATCH CODE"



This symbol shall be accompanied by the manufacturer's batch code. The batch code shall be adjacent to the symbol.

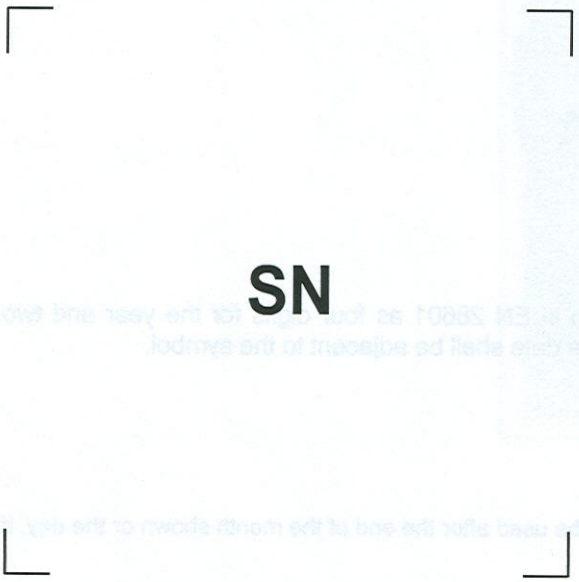
NOTE 1 Synonyms for "batch code" are "lot number", "batch number".

NOTE 2 The relative size of the symbol and the batch code is not specified.

NOTE 3 The symbol No. 3.14 in ISO 15223 corresponds to this symbol.

NOTE 4 See the Council Directive 90/385/EEC relating to active implantable medical devices, Annex I, 11, Council Directive 93/42/EEC concerning medical devices, Annex I, 13.3 (d) and Council Directive 98/79/EC on in vitro diagnostic medical devices, Annex I, B.8.4. (d).

4.5 Symbol for "SERIAL NUMBER"



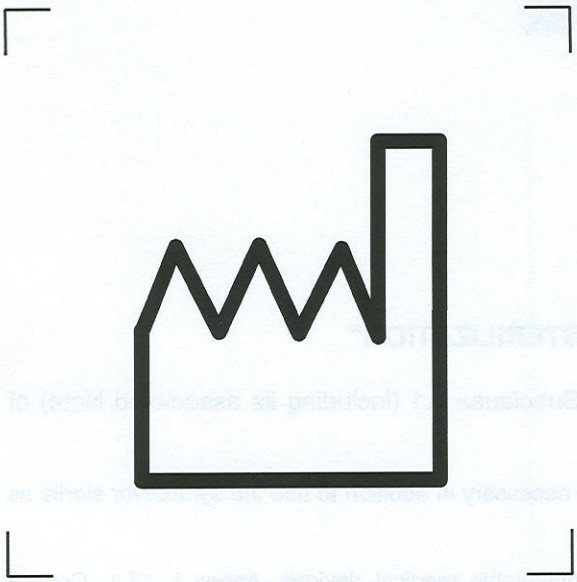
This symbol shall be accompanied by the manufacturer's serial number. The serial number shall be after or below the symbol, adjacent to it.

NOTE 1 The relative size of the symbol and the serial number are not specified.

NOTE 2 The symbol No. 3.16 in ISO 15223 corresponds to this symbol.

NOTE 3 See the Council Directive 90/385/EEC relating to active implantable medical devices, Annex I, 11, Council Directive 93/42/EEC concerning medical devices, Annex I, 13.3 (d) and Council Directive 98/79/EC on in vitro diagnostic medical devices, Annex I, B.8.4. (d).

4.6 Symbol for "DATE OF MANUFACTURE"



For active implantable medical devices, the symbol shall be adjacent to the date expressed as four digits for the year and two digits for the month. For active devices the symbol shall be accompanied by the year. The year shall be expressed as four digits in accordance with 5.2.1.2 a) of EN 28601:1992.

NOTE 1 The relative size of the symbol and the date is not specified.

NOTE 2 The symbol No. 3.13 in ISO 15223 corresponds to this symbol.

NOTE 3 See Council Directive 90/385/EEC relating to active implantable medical devices, Annex I, 14.1. and Council Directive 93/42/EEC concerning medical devices, Annex I, 13.3.(l).

4.7 Symbol for "STERILE"

This symbol is for terminally-sterilized medical devices only. Subclause 4.1 (including its associated Note) of EN 556-1:2001 applies.

NOTE 1 The symbol No. 3.20 in ISO 15223 corresponds to this symbol.

NOTE 2 See the Council Directive 90/385/EEC relating to active implantable medical devices, Annex I, 14.1, Council Directive 93/42/EEC concerning medical devices, Annex I, 13.3 (c) and Council Directive 98/79/EC on in vitro diagnostic medical devices, Annex I, B.8.4. (c).

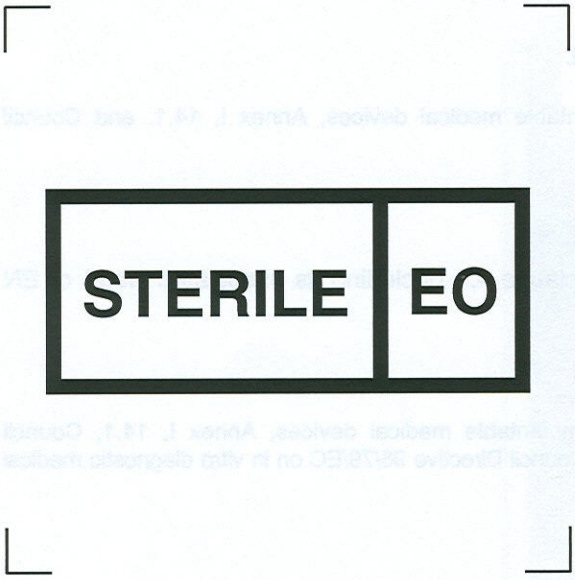
4.8 Symbols for "STERILE", including the "METHOD OF STERILIZATION"

These symbols are for terminally-sterilized medical devices only. Subclause 4.1 (including its associated Note) of EN 556-1:2001 applies.

NOTE 1 If any of the symbols given in 4.8.1 to 4.8.3 are used, it is not necessary in addition to use the symbol for sterile as shown in 4.7.

NOTE 2 See the Council Directive 90/385/EEC relating to active implantable medical devices, Annex I, 14.1, Council Directive 93/42/EEC concerning medical devices, Annex I, 13.3 (c), (m) and the Council Directive 98/79/EC on in vitro diagnostic medical devices, Annex I, B.8.4. (c)

4.8.1 Symbol for method of sterilization using ethylene oxide

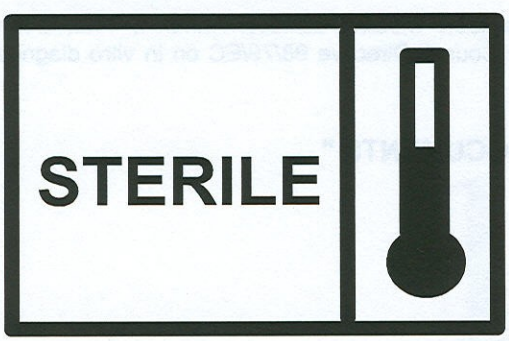


NOTE The symbol No. 3.22 in ISO 15223 corresponds to this symbol.

4.8.2 Symbol for method of sterilization using irradiation

NOTE The symbol No. 3.23 in ISO 15223 corresponds to this symbol.

4.8.3 Symbol for method of sterilization using steam or dry heat



NOTE The symbol No. 3.24 in ISO 15223 corresponds to this symbol.

4.9 Symbol for "CATALOGUE NUMBER"

REF

The manufacturer's catalogue number shall be after or below the symbol, adjacent to it.

NOTE 1 The relative size of the symbol and the catalogue number is not specified.

NOTE 2 Synonyms for "catalogue number" are "reference number", "reorder number".

NOTE 3 The symbol No. 3.15 in ISO 15223 corresponds to this symbol.

NOTE 4 See the Council Directive 90/385/EEC relating to active implantable medical devices, Annex I, 14.2, Council Directive 93/42/EEC concerning medical devices, Annex I, 13.3 (b) and the Council Directive 98/79/EC on in vitro diagnostic medical devices, Annex I, B.8.4 (b).

4.10 Symbol for "CAUTION, CONSULT ACCOMPANYING DOCUMENTS "

NOTE 1 Synonym for "Caution, consult accompanying documents" is "Attention, see instructions for use"

NOTE 2 The symbol ISO 7000/0434 ("Caution") and the symbol No 3.4 in ISO 15223 correspond to this symbol. It appears with similar meaning in other documents (e.g. EN 60601-1 and EN 61010-1).

NOTE 3 See the Council Directive 90/385/EEC relating to active implantable medical devices, Annex I, 14.2 and 15 and the Council Directive 93/42/EEC concerning medical devices, Annex I, 13.3 (j), (k).

4.11 Symbol for sterile medical devices processed using aseptic technique

NOTE 1 Aseptic technique can include filtration.

NOTE 2 A European Standard on aseptic processing is in the course of preparation.

NOTE 3 The symbol No. 3.21 in ISO 15223 corresponds to this symbol.

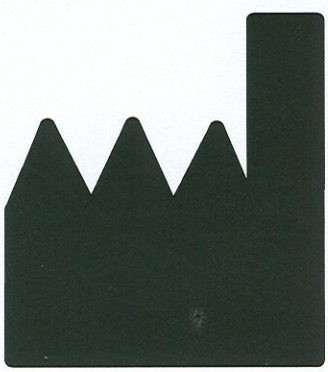
NOTE 4 See the Council Directive 90/385/EEC relating to active implantable medical devices, Annex I, 14.1, Council Directive 93/42/EEC concerning medical devices, Annex I, 13.3 (c), (m) and the Council Directive 98/79/EC on in vitro diagnostic medical devices, Annex I, B.8.4. (c)

5 New symbols

5.1 General

Symbols presented in this clause shall be explained in the documentation supplied with the device. The language(s) used shall be (an) official Community language(s), legally acceptable in the country in which the device is distributed; additional languages are optional, bearing in mind the needs of the anticipated users.

5.2 Symbol for "MANUFACTURER"

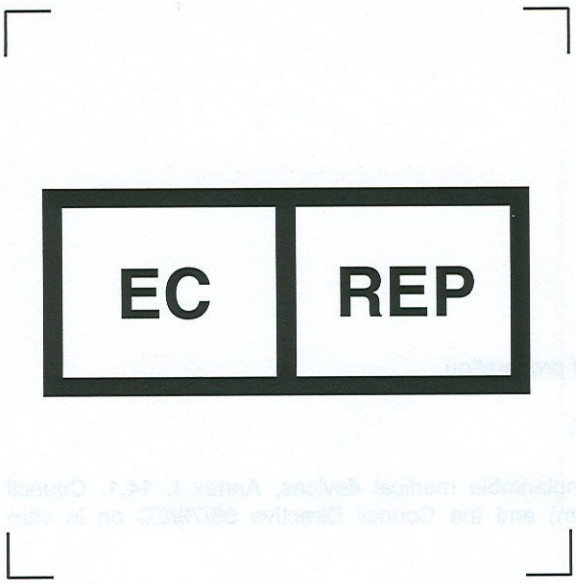


This symbol shall be accompanied by the name and the address of the manufacturer, adjacent to the symbol. The address is not required with the symbol on an immediate container as specified in EN 375 and EN 376, except when the immediate container is also the outer container.

NOTE 1 The relative size of the symbol and the name and address is not specified.

NOTE 2 See the Council Directive 90/385/EEC relating to active implantable medical devices, Annex I, 14.1 and 14.2, the Council Directive 93/42/EEC concerning medical devices, Annex I, 13.3 (a) and the Council Directive 98/79/EC on in vitro diagnostic medical devices, Annex I, B.8.4. (a).

5.3 Symbol for "AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY"

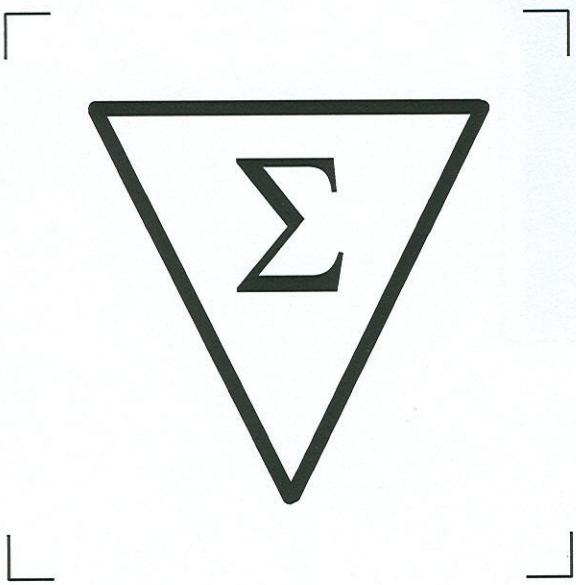


This symbol shall be accompanied by the name and the address of the authorised representative in the European Community, adjacent to the symbol. The address is not required with the symbol on an immediate container as specified in EN 375 and EN 376, except when the immediate container is also the outer container.

NOTE 1 The relative size of the symbol and the name and address is not specified.

NOTE 2 See the Council Directive 93/42/EEC concerning medical devices, Annex I, 13.3 (a) and the Council Directive 98/79/EC on in vitro diagnostic medical devices, Annex I, B.8.4. (a).

5.4 Symbol for "CONTAINS SUFFICIENT FOR <n> TESTS"



NOTE 1 The relative size of the symbol and the number of tests is not specified.

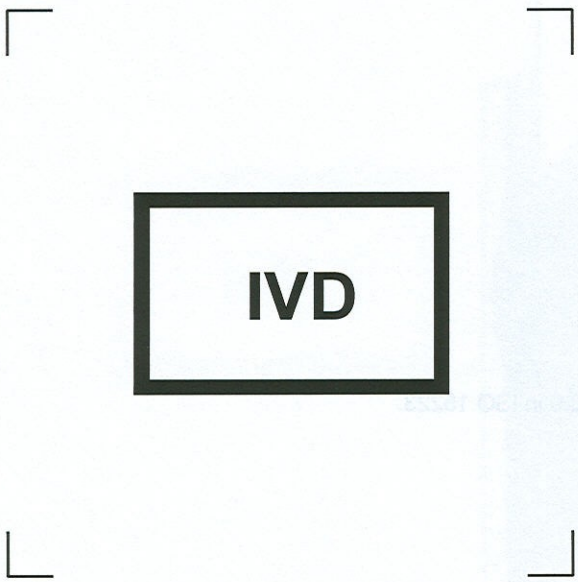
NOTE 2 This symbol corresponds to that given in ISO 7000/0518. Synonym for "contains sufficient for <n> tests" is "counting".

NOTE 3 See the Council Directive 98/79/EC on in vitro diagnostic medical devices, Annex I, B.8.4. (b).

5.5 Symbol for "FOR IVD PERFORMANCE EVALUATION ONLY "

NOTE See the Council Directive 98/79/EC on in vitro diagnostic medical devices, Annex I, B.8.4. (f).

5.6 Symbol for "IN VITRO DIAGNOSTIC MEDICAL DEVICE"



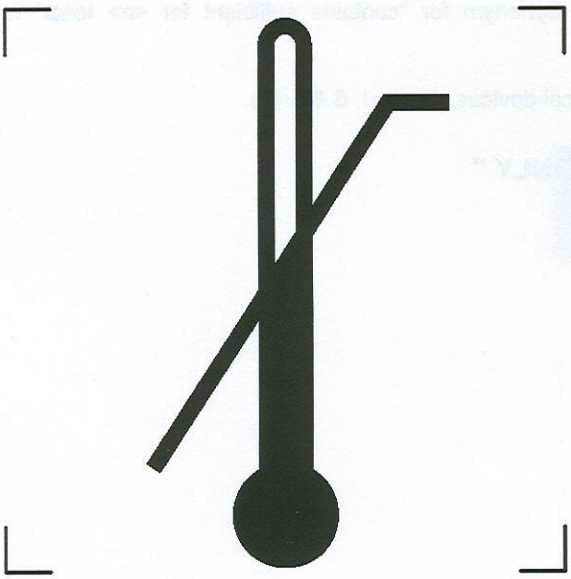
NOTE 1 The symbol No. 3.28 in ISO 15223/Amd 1 corresponds to this symbol.

NOTE 2 See the Council Directive 98/79/EC on in vitro diagnostic medical devices, Annex I, B.8.4. (g).

5.7 Symbols for temperature limits

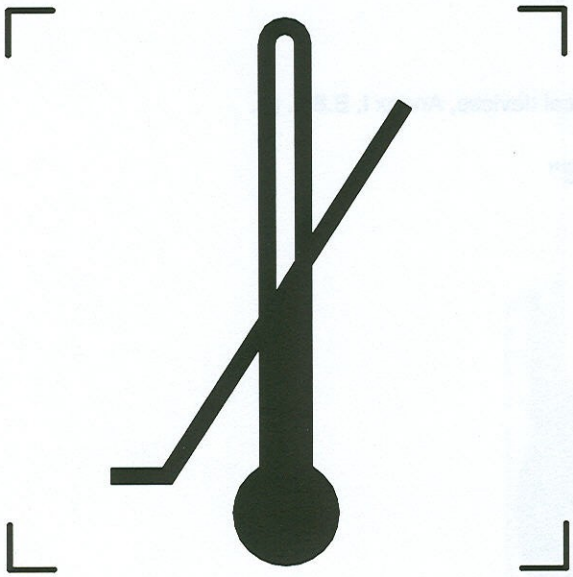
NOTE See the Council Directive 90/385/EEC relating to active implantable medical devices, Annex I, 14.2, the Council Directive 93/42/EEC concerning medical devices, Annex I, 13.3 (i), and the Council Directive 98/79/EC on in vitro diagnostic medical devices, Annex I, B.8.4. (h).

5.7.1 Symbol for "UPPER LIMIT OF TEMPERATURE"



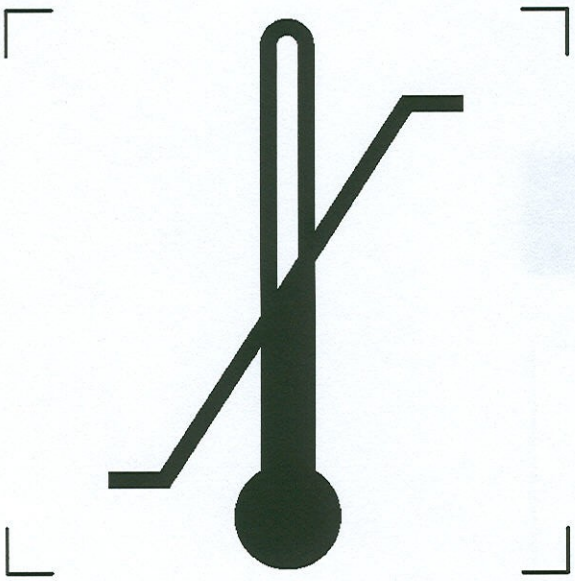
NOTE This symbol is as given in ISO 7000/0533 and as symbol No. 3.10 in ISO 15223.

5.7.2 Symbol for "LOWER LIMIT OF TEMPERATURE"



NOTE This symbol is as given in ISO 7000/0534 and as symbol No. 3.9 in ISO 15223.

5.7.3 Symbol for "TEMPERATURE LIMITATION"



NOTE This symbol is as given in ISO 7000/0632 and as symbol No. 3.11 in ISO 15223.

5.8 Symbol for "CONSULT INSTRUCTIONS FOR USE"

NOTE 1 Synonym for "Consult instructions for use" is "Consult operating instructions"

NOTE 2 This symbol is as given in ISO 7000/1641 and as symbol No. 3.3 in ISO 15223.

NOTE 3 See the Council Directive 93/42/EEC concerning medical devices, Annex I, 13.3 (j), (k) and the Council Directive 98/79/EC on in vitro diagnostic medical devices, Annex I, B.8.1.

5.9 Symbol for "BIOLOGICAL RISKS"

NOTE 1 This symbol is as given in ISO 7000/0659 and as symbol No. 3.1 in ISO 15223.

NOTE 2 See the Council Directive 98/79/EC on in vitro diagnostic medical devices, Annex I, B.8.4. (j).

Annex A
(informative)

Examples of uses of symbols given in this standard

NOTE These examples are illustrative only and do not represent the only ways in which the requirements of this standard can be met.

A.1 Examples of use of symbol for "USE BY"

2005-09-15

2005-09

A.2 Example of use of symbol for "BATCH CODE"

LOT ABC123

A.3 Examples of use of symbol for "SERIAL NUMBER"

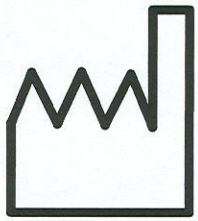
SN ABC123

SN-ABC123

SN/ABC123

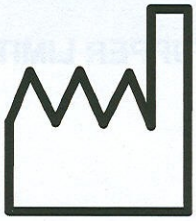
SN ABC123

A.4 Examples of use of symbol for "DATE OF MANUFACTURE"



2001-06

2002



A.5 Examples of use of symbol for "CATALOGUE NUMBER"

REF ABC123

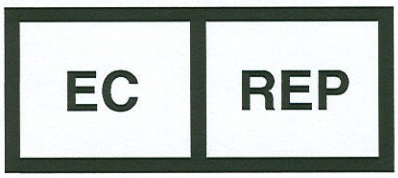
ABC123

A.6 Examples of use of symbol for "MANUFACTURER"

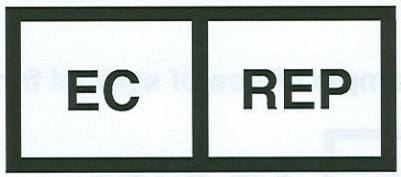
Company
Address

Company

A.7 Examples of use of symbol for " AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY"

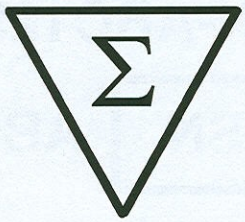


Company
Address

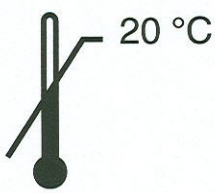


Company

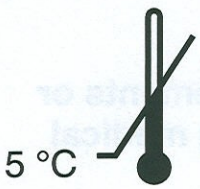
A.8 Examples of use of symbol for "CONTAINS SUFFICIENT FOR <n> TESTS"



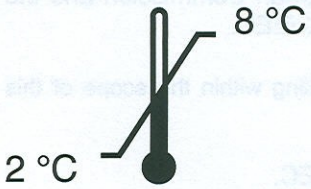
A.9 Example of use of symbol for "UPPER LIMIT OF TEMPERATURE"



A.10 Example of use of symbol for "LOWER LIMIT OF TEMPERATURE"



A.11 Example of use of symbol for "TEMPERATURE LIMITATION"



Annex ZA
(informative)

Clauses of this European Standard addressing essential requirements or other provisions of the Council Directive 93/42/EEC concerning medical devices

This European Standard 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 93/42/EEC.

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

The following clauses of this standard are likely to support requirements of Directive 93/42/EEC.

Compliance with these clauses of this standard provides one means of conforming with the specific essential requirements of the Directive concerned and associated EFTA regulations.

Table ZA.1 - Correspondence between this European Standard and Directive 93/42/EEC

Clause(s)/sub-clause(s) of this European Standard	Essential requirements from Annex I of the Council Directive concerning Medical Devices (93/42/EEC)
this standard	13.2
5.2	13.3 a)
5.3	13.3 a)
4.9	13.3 b)
4.7, 4.8.1, 4.8.2, 4.8.3	13.3 c)
4.4, 4.5	13.3 d)
4.3	13.3 e)
4.2	13.3 f)
5.7.1, 5.7.2, 5.7.3	13.3 i)
4.10, 5.8	13.3 j), k)
4.11	13.3 c), m)
4.6	13.3 l)
4.8.1, 4.8.2, 4.8.3	13.3 m)

Annex ZB
(informative)

Clauses of this European Standard addressing essential requirements or other provisions of the Council Directive 90/385/EEC relating to 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, and supports essential requirements of EU Directive 90/385/EEC.

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

The following clauses of this standard are likely to support requirements of Directive 90/385/EEC.

Compliance with these clauses of this standard provides one means of conforming with the specific essential requirements of the Directive concerned and associated EFTA regulations.

Table ZB.1 - Correspondence between this European Standard and Directive 90/385/EEC

Clause(s)/sub-clauses of this European Standard	Essential requirements from Annex I of Council Directive concerning Active Implantable Medical Devices (90/385/EEC)
4.4, 4.5	11
this standard	14
4.3, 4.6, 4.7, 4.8.1, 4.8.2, 4.8.3, 5.2	14.1
4.3, 4.6, 4.7, 4.9, 4.10, 5.2, 5.6	14.2
4.11	14.1
4.4, 4.5, 4.7, 4.8.1, 4.8.2, 4.8.3, 4.10	15

Annex ZC
(informative)

Clauses of this European Standard addressing essential requirements or other provisions of the European Parliament and the Council 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, and supports essential requirements of EU Directive 98/79/EC on in vitro diagnostic medical devices.

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

The following clauses of this standard are likely to support requirements of Directive 98/79/EC.

Compliance with these clauses of this standard provides one means of conforming with the specific essential requirements of the Directive concerned and associated EFTA regulations.

Table ZC.1 - Correspondence between this European Standard and Directive 98/79/EC

Clause(s)/Sub-clause(s) of this European Standard	Essential requirements (ERs) from Annex I of Council Directive on in vitro diagnostic medical devices (98/79/EC)
4.3	B.8.4. (e)
4.4	B.8.4. (d)
4.5	B.8.4. (d)
4.7	B.8.4. (c)
4.8.1, 4.8.2, 4.8.3	B.8.4. (c)
4.9	B.8.4. (b)
4.11	B 8.4. (c)
5.2	B.8.4. (a)
5.3	B.8.4. (a)
5.4	B.8.4. (b)
5.5	B.8.4. (f)
5.6	B.8.4. (g)
5.7.1, 5.7.2, 5.7.3	B.8.4. (h)
5.8	B.8.1.
5.9	B.8.4. (j)

Bibliography

EN 1041	*Information supplied by the manufacturer with medical devices.*
EN 60417-1	*Graphical symbols for use on equipment - Part 1: Overview and application (IEC 60417-1:2000).*
EN 60417-2	*Graphical symbols for use on equipment - Part 2: Symbol originals (IEC 60417-2:1998).*
EN 60601-1	*Medical electrical equipment - Part 1 : General requirements for safety (IEC 60601-1:1988).*
EN 61010-1	*Safety requirements for electrical equipment for measurement, control and laboratory use - Part 1: General requirements (IEC 61010-1:2001).*
EN 80416-1	*Basic principles for graphical symbols for use on equipment – Part 1: Creation of symbol originals (IEC 80416-1:2001)*
ISO 7000	*Graphical symbols for use on equipment - Index and synopsis.*
ISO 15223	*Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied.*
ISO 15223/Amd 1	*Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied – AMENDMENT 1.*
IEC 60878	*Graphical symbols for electrical equipment in medical practice.*

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