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NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 980

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English version

Symbols for use in the labelling of medical devices

Symboles utilisés pour l'étiquetage des dispostifs médicaux

Symbole zur Kennzeichnung von Medizinprodukten

This European Standard was approved by CEN on 18 April 2008.

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Contents

Foreword 4
Introduction 5
1 Scope 6
2 Normative references 6
3 Terms and definitions 6
4 General requirements 7
4.1 Proposal of symbols for adoption 7
4.2 Requirements for usage 7
5 Symbols already in use 8
5.1 General 8
5.2 Symbol for "DO NOT REUSE" 8
5.3 Symbol for "USE BY" 9
5.4 Symbol for "BATCH CODE" 9
5.5 Symbol for "SERIAL NUMBER" 10
5.6 Symbol for "DATE OF MANUFACTURE" 10
5.7 Symbol for "STERILE" 11
5.8 Symbols for "STERILE", including the method of sterilization 11
5.9 Symbol for “STERILE USING ASEPTIC PROCESSING TECHNIQUES” 12
5.10 Symbol for "CATALOGUE NUMBER" 13
5.11 Symbol for "CAUTION" 13
5.12 Symbol for "MANUFACTURER" 14
5.13 Symbol for "AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY" 14
5.14 Symbol for " SUFFICIENT FOR " 15
5.15 Symbol for "FOR IVD PERFORMANCE EVALUATION ONLY" 15
5.16 Symbol for "IN VITRO DIAGNOSTIC MEDICAL DEVICE" 16
5.17 Symbols for "TEMPERATURE LIMITS” including indication of limits of temperature 16
5.18 Symbol for "CONSULT INSTRUCTIONS FOR USE" 18
5.19 Symbol for "BIOLOGICAL RISKS" 18
5.20 Symbol for “KEEP AWAY FROM SUNLIGHT” 18
5.21 Symbol for “KEEP DRY” 19
5.22 Symbol for “DO NOT RESTERILIZE” 19
5.23 Symbol for “NON-STERILE” 20
5.24 Symbol for “CONTROL” 20
5.25 Symbol for “NEGATIVE CONTROL” 21
5.26 Symbol for “POSITIVE CONTROL” 21
6 New symbols 21
6.1 General 21
6.2 Symbol for “CONTAINS OR PRESENCE OF NATURAL RUBBER LATEX” 22
6.3 Symbol for “DO NOT USE IF PACKAGE IS DAMAGED” 22
6.4 Symbol for “STERILE FLUID PATH” 22
Annex A (informative) Examples of uses of symbols given in this standard 24
A.1 Examples of use of symbol for "USE BY" 24
A.2 Example of use of symbol for "BATCH CODE" 24
A.3 Examples of use of symbol for "SERIAL NUMBER" 24
A.4 Examples of use of symbol for "DATE OF MANUFACTURE" 24
A.5 Examples of use of symbol for "CATALOGUE NUMBER" 25
A.6 Example of use of symbol for "MANUFACTURER" 25
A.7 Example of use of symbol for “MANUFACTURER” combined with “DATE OF MANUFACTURE” 25
A.8 Example of use of symbol for " AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY" 25
A.9 Examples of use of symbol for " SUFFICIENT FOR" 26

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Document Sharing Hub

Full document details: EN 980:2008 Symbols for use in the labelling of medical devices

A.10 Example of use of symbol for "UPPER LIMIT OF TEMPERATURE" 26
A.11 Example of use of symbol for "LOWER LIMIT OF TEMPERATURE" 26
A.12 Example of use of symbol for "TEMPERATURE LIMITATION" 26
A.13 Examples of use of symbol for “STERILE FLUID PATH” 27

Annex B (informative) Use of the general prohibition symbol and the negation symbol 28
B.1 The general prohibition symbol 28
B.2 The negation symbol 28

Annex ZA (informative) Clauses of this European Standard addressing essential requirements or other provisions of the Council Directive 93/42/EEC concerning medical devices 29

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 31

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 32

Bibliography 34

Documents
Document Sharing Hub

Full document details: EN 980:2008 Symbols for use in the labelling of medical devices

Foreword

This document (EN 980:2008) has been prepared by Technical Committee CEN/CLC/TC 3 "Quality management and corresponding general aspects for medical devices" (former CEN/TC 257 “Symbols and information provided with medical devices and nomenclature for regulatory data exchange”), 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 November 2008, and conflicting national standards shall be withdrawn at the latest by May 2010.

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 980:2003.

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 EC Directive(s).

For relationship with EC Directive(s), see informative Annex ZA, ZB, and ZC, 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, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

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Introduction

This European Standard has been prepared to give expression to the legislative preference within the European Union for the use of symbols in medical device labelling, thereby reducing the need for multiple translations of words into national languages. It is also intended 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 European Directives on medical devices.

The meaning of some of these symbols is self-evident. Some are already in widespread use and familiar to healthcare professionals. The meaning of others will become clear with use or when viewed in the context of the device itself. Symbols used with medical devices for use by other than healthcare professionals can require additional explanations. In this respect, attention is drawn to the fact that risk management, e.g. the use of EN ISO 14971, is an integral element in medical device design and manufacturing. The use of appropriate symbols can, therefore, be an important element in risk reduction, which is a key part of risk management and is also specifically referred to in the relevant medical device directives. Symbols should only be used without explanation when risk assessment by the manufacturer indicates that it is appropriate.

The symbols in Clause 5 of this European Standard have been in general use for some time and users have some degree of familiarity with them. Additional symbols are now being introduced in Clause 6 which may be new or unfamiliar to users. As a precaution, Clause 6 requires that the meaning of these new symbols be explained in the information supplied by the manufacturer. This is without prejudice to the harmonization of this European Standard and the symbols therein.

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.

Annex B provides information about the use of the general prohibition symbol.

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1 Scope

This European Standard specifies symbols for use in the information supplied by the manufacturer with medical devices. The requirements of this European Standard are not intended to apply to symbols specified in other standards. However, every effort should be made to prevent the specifying of different symbols with the same meaning. This standard does not specify the requirements for information to be supplied with medical devices, which are addressed by EN 375, EN 376, EN 591, EN 592 and EN 1041.

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.

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

EN 376, *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 591, *Instructions for use for in vitro diagnostic instruments for professional use*

EN 592, *Instructions for use for in vitro diagnostic instruments for self-testing*

EN 1041, *Information supplied by the manufacturer with medical devices*

EN ISO 15225, *Nomenclature – Specification for a nomenclature system for medical devices for the purpose of regulatory data exchange (ISO 15225: 2000)*

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

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1
symbol used in medical device labelling
object presented on the label and/or on the device itself and/or associated documentation of a medical device, which may utilise symbolic or iconic presentation, that communicates characteristic information (see 3.4) without relying on knowledge of the language of a particular nation or people by the giver or receiver of the information

3.2
symbolic presentation
abstract pictorial or graphic representation

3.3
iconic presentation
pictorial or graphic representation using familiar objects including alphanumeric characters

3.4
characteristic information
mental representation of a property or properties of an object or set of objects

[EN 12264:2005]

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4 General requirements

4.1 Proposal of symbols for adoption

4.1.1 Proposals for symbols for adoption into this European Standard shall be submitted by a body contributing to CEN/CLC/TC 3, that is, one in association, liaison or participating in the work of that committee.

4.1.2 Symbols should only be proposed when they represent requirements already defined in a published standard. E.g., the requirements represented by 5.8 are defined in EN 556-1.

4.1.3 Symbols being proposed shall be presented following the dimensional criteria and design principles set out in ISO/IEC 80416. Where the presentation is symbolic (see 3.2), alphanumeric characters shall not be part of the symbol. Alphanumeric characters may be used when appropriate and relevant in an iconic symbol (see 3.3).

4.1.4 Any symbol proposed for adoption into this European Standard shall be applicable to a range of devices, at least comprising one category of the Global Medical Device Nomenclature (see EN ISO 15225).

4.1.5 When a symbol is presented for adoption, the following details are required:

— a brief, unique title sufficient only to identify the symbol;

— conditions of use for the symbol and identity of proposed audience;

— information on any existing or proposed related symbols;

— information on any validation or evaluation of the symbol in use;

— a graphic file (bitmap, JPEG, TIF or similar) with a print-out of the file.

4.2 Requirements for usage

4.2.1 Symbols contained in Clause 5 may be used without explanation in the information supplied by the manufacturer.

4.2.2 The meaning of symbols contained in Clause 6 shall be explained in the information supplied by the manufacturer.

4.2.3 Symbols shown in 5.2 to 5.26 and 6.2 to 6.4 are used to convey the information described in the headings and notes of those sub-clauses.

NOTE 1 Other symbols can be used to convey different information. Many other standards specify symbols for particular purposes and/or for particular kinds of device. The Bibliography lists some of these standards.

NOTE 2 ISO and IEC jointly maintain an on-line database of graphical symbols for use on equipment that contains the complete set of graphical symbols included in ISO 7000, IEC 60417-1 and IEC 60417-2. 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 access this database is available through the ISO Store, the IEC Web Store or by contacting your local national standards body.

4.2.4 Symbols presented in this standard shall be reproduced as illustrated with the exception of 5.5 and 5.10, which may be reproduced with or without the enclosure.

NOTE Future editions of this standard may remove this exception for 5.5 and 5.10 and an enclosure may be required as defined in ISO 7000:2004 and ISO 15223-1:2007.

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4.2.5 All symbols and information intended for visual recognition 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 Colours and minimum dimensions are not specified in this standard.

4.2.6 Guidance on the appropriate use of the general prohibition symbol is given in Annex B.

5 Symbols already in use

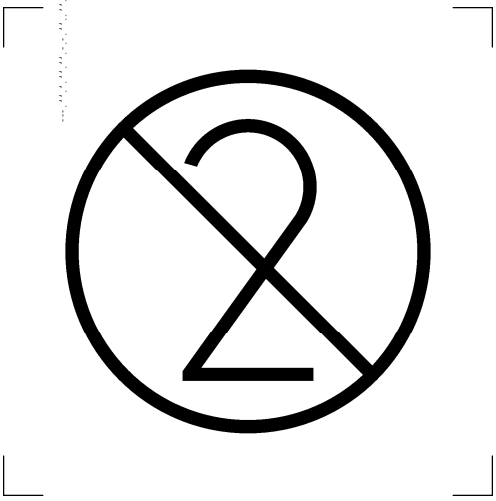
5.1 General

This Clause contains symbols that are already in use, and are deemed to be suitable without need for further explanation.

NOTE Symbols used with medical devices for use by other than healthcare professionals can require additional explanations.

Annexes ZA, ZB and ZC can be used to determine the symbols that address essential requirements of Council Directives 93/42/EEC, 90/385/EEC and 98/79/EC respectively.

5.2 Symbol for "DO NOT REUSE"



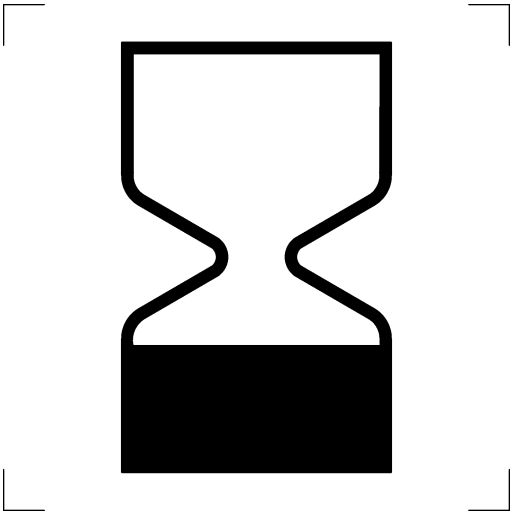
NOTE 1 Synonyms for "Do not reuse" are "single use", "Use only once".

NOTE 2 This symbol corresponds to that given in ISO 7000-1051 and to symbol number 5.2 in ISO 15223-1:2007

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5.3 Symbol for "USE BY"



This symbol shall be accompanied by a date to indicate that the device should not be used after the end of the year, month or day shown. The date shall be expressed as given 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 could be a year, year and month, or year, month, and day, as required by the relevant Directive. The date shall be located adjacent to the symbol (see A.1).

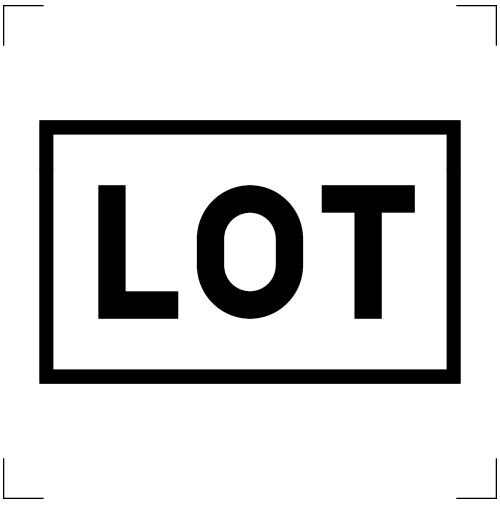
NOTE 1 For example, June 2007 becomes 2007-06.

NOTE 2 The relative sizes of the symbol and the date are not specified.

NOTE 3 This symbol can be used to identify the time limit for implanting an active implantable device safely as required by Directive 90/385/EEC.

NOTE 4 This symbol corresponds to that given in ISO 7000-2607 and to symbol No. 5.12 in ISO 15223-1:2007.

5.4 Symbol for "BATCH CODE"



This symbol shall be accompanied by the manufacturer's batch code. The batch code shall be adjacent to the symbol (see A.2).

NOTE 1 The relative size of the symbol and the size of the batch code are not specified.

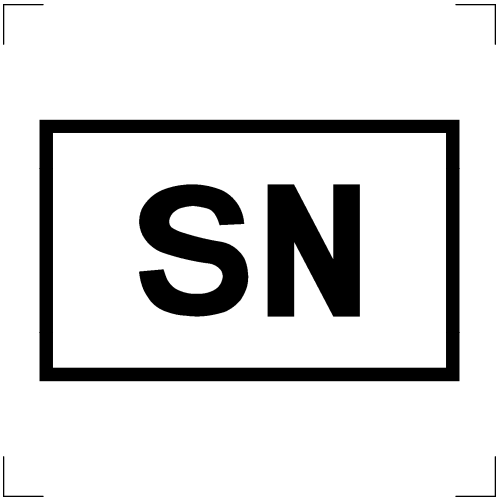
NOTE 2 Synonyms for "batch code" are "lot number", "batch number".

NOTE 3 This symbol corresponds to that given in ISO 7000-2492 and to symbol number 5.14 in ISO 15223-1:2007.

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5.5 Symbol for "SERIAL NUMBER"

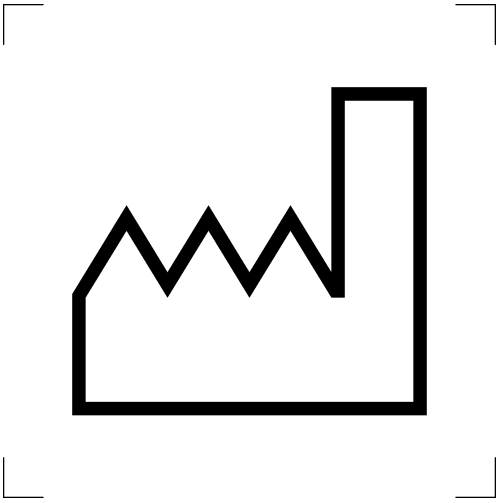


This symbol shall be accompanied by the manufacturer's serial number. The serial number shall be after or below the symbol, adjacent to it (see A.3).

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

NOTE 2 This symbol corresponds to that given in ISO 7000-2498 and to symbol number 5.16 in ISO 15223-1:2007.

5.6 Symbol for "DATE OF MANUFACTURE"



This symbol shall be accompanied by a date to indicate the date of manufacture, expressed as given 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 could be a year, year and month, or year, month, and day, as required by the relevant Directive. The date shall be located adjacent to the symbol (see A.4).

NOTE 1 The relative sizes of the symbol and 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 manufacturer can be combined in one symbol (see A.7).

NOTE 3 This symbol can 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 Directive.

NOTE 4 This symbol corresponds to that given in ISO 7000-2497 and to symbol number 5.13 in ISO 15223-1:2007.

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