SLOVENSKI STANDARD

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Grafiļ ni simboli za oznaļ evanje medicinskih pripomoļ kov

Graphical symbols for use in the labelling of medical devices

Graphische Symbole zur Kennzeichnung von Medizinprodukten

Symboles graphiques utilisés pour l'étiquetage des dispositifs médicaux

Ta slovenski standard je istoveten z: EN 980:2003

ICS:

01.080.20	Grafiļ ni simboli za posebno opremo	Graphical symbols for use on specific equipment
11.040.01	Medicinska oprema na splošno	Medical equipment in general
11.120.01	Farmacija na splošno	Pharmaceutics in general

SIST EN 980:2003 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

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EN 980

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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.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, Spain, Sweden, Switzerland and United Kingdom.

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

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

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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.

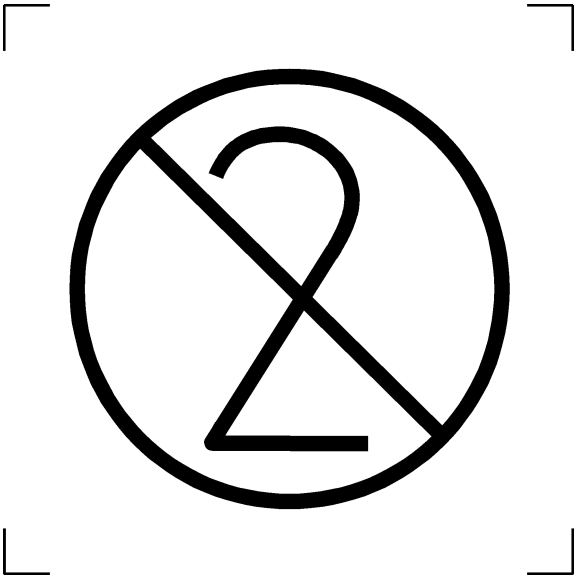
NOTE 3 Colours and minimum dimensions are not specified in this standard.

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"

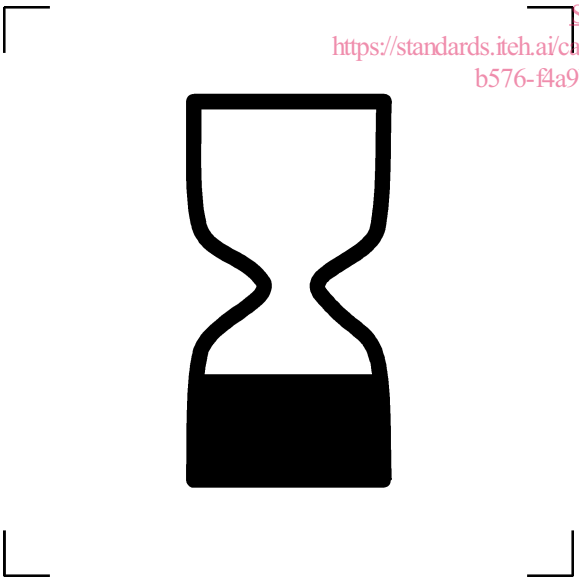


NOTE 1 This symbol is as given in ISO 7000/1051 and as symbol No. 3.2 in ISO 15223.

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.

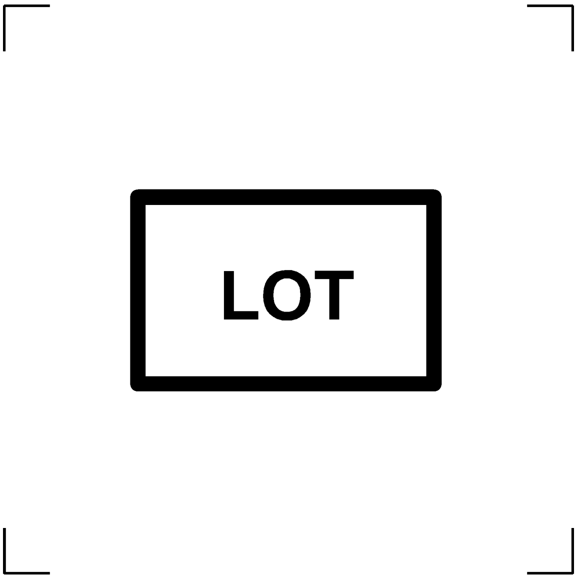
NOTE 3 The symbol is intended to indicate that the device should not be used after the end of the month shown or the day, if applicable.

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.

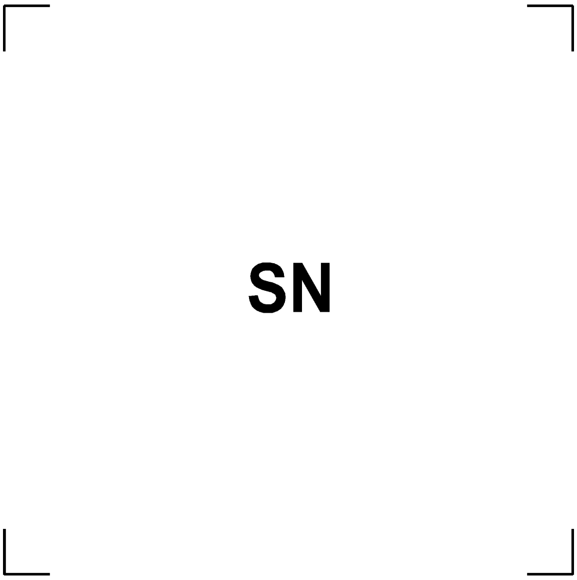
NOTE 1 Synonyms for "batch code" are "lot number", "batch number".

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"



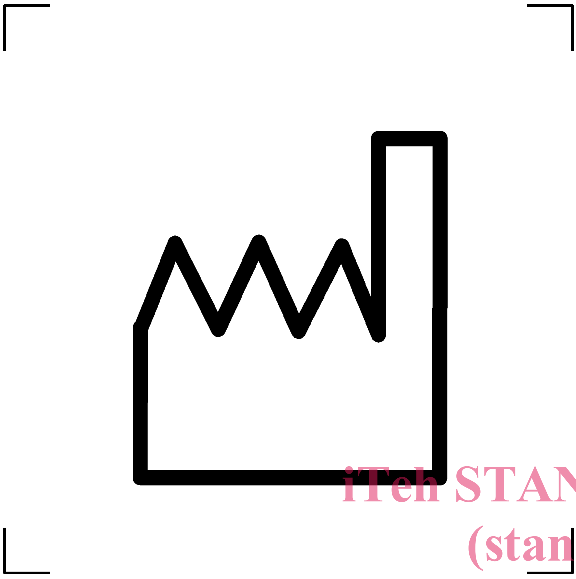
This symbol shall be accompanied by the manufacturer's serial number. The serial number shall be after or below the symbol, adjacent to it.

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).