

# SLOVENSKI STANDARD

## SIST EN 980:2000/A1:2000

01-julij-2000

; fU b]g]a Vc`]'nUcnbU Yj UbY'a YX]Wbg\_] \ 'df]dca c \_cj

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 980:1996/A1:1999

[SIST EN 980:2000/A1:2000](https://standards.iteh.ai/catalog/standards/sist/1c57afc3-7868-44a2-9ddf-6eb44532d3fb/sist-en-980-2000-a1-2000)

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### ICS:

01.080.20	Ō æã} áã à[  áã[ •^à}[ [] i^ { [	Graphical symbols for use on specific equipment
11.040.01	Medicinska oprema na splošno	Medical equipment in general

**SIST EN 980:2000/A1:2000**

**en**

## **iTeh STANDARD PREVIEW (standards.iteh.ai)**

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EUROPEAN STANDARD  
NORME EUROPÉENNE  
EUROPÄISCHE NORM

EN 980:1996/A1

August 1999

ICS 01.080.20; 11.040.01; 11.120.01

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 amendment A1 modifies the European Standard EN 980:1996; it was approved by CEN on 1 August 1999.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

This amendment 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 Central Secretariat 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, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

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

Central Secretariat: rue de Stassart, 36 B-1050 Brussels

## Foreword

This Amendment EN 980:1996/A1:1999 to EN 980:1996 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 Amendment to the European Standard EN 980:1996 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by February 2000, and conflicting national standards shall be withdrawn at the latest by February 2000.

This Amendment to the European Standard EN 980:1996 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).

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, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

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ALMEVOLA AMIANTO  
COPOLIMERO DI ETILENE E AC. STIRONE  
Copolimero di etilene e ac. st. (EAS)  
ANALISI  
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#### 4.6 Symbol for "STERILE"

Change the first sentence to read as follows:

This symbol is for terminally-sterilized medical devices only. Subclause 4.1 (including its associated Note) of EN 556:1994 applies.

#### 4.7 Symbols for "STERILE", including the "METHOD OF STERILIZATION"

Change the first sentence to read as follows:

These symbols are for terminally-sterilized medical devices only. Subclause 4.1 (including its associated Note) of EN 556:1994 applies.

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