SLOVENSKI STANDARD
SIST EN 1041:2000

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Informacije, ki jih proizvajalec priloži medicinskim pripomočkom

Information supplied by the manufacturer with medical devices

Bereitstellung von Informationen durch den Hersteller eines Medizinprodukts

Informations fournies par le fabricant avec les dispositifs médicaux

Ta slovenski standard je istoveten z: **EN 1041:1998**

ICS:

01.110	Tehnična dokumentacija za izdelke	Technical product documentation
11.040.01	Medicinska oprema na splošno	Medical equipment in general

SIST EN 1041:2000 **en**

EUROPEAN STANDARD
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Descriptors: medical equipment, information, manufacturers, vocabulary, symbols

English version

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This European Standard was approved by CEN on 18 January 1998.

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 Central Secretariat 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 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.

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

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

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Contents

Foreword

This European Standard 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of an identical text or by endorsement, at the latest by August 1998, and conflicting national standards shall be withdrawn at the latest by August 1998.

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 Directives.

For relationship with EU Directives, see informative Annex ZA and ZB, which are integral parts of this standard.

This standard is intended to complement the specific requirements of the EU Directives on medical devices relating to the information supplied by the manufacturer for different categories of medical devices.

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.

Introduction

This standard is applicable to medical devices generally, but it should be noted that other European standards may specify additional information requirements for particular types of medical devices.

The requirements of this standard are given in clause 4. Additional information and guidance are given in the annexes.

Annex A gives a short bibliography of documents related to information including labelling supplied by the manufacturer. Annexes B and C reproduce, for convenience of use, the relevant text of the EU Directives relating to active implantable medical devices, and to medical devices, respectively. Guidance is given in Annexes B and C to assist manufacturers to achieve compliance with the requirements of those texts.

For ease of use, a two column system of presentation has been adopted for annexes B and C. The first column reproduces verbatim the information requirements as given in Annex I of the Council Directives concerning medical devices. The second column contains, where appropriate, further guidance for manufacturers as to ways in which compliance with the particular information requirements of the Directives may be achieved. This guidance is not to be considered as the obligatory or only way of achieving compliance with the requirements of the Directive; alternative ways may be acceptable.

In order to facilitate the presentation of information and to reduce the need for translation into numerous languages, consideration should always be given to using appropriate symbols.

1 Scope

This standard specifies requirements on information to be supplied by a manufacturer for different categories of medical devices, as required by the relevant EU Directives. It does not specify the language to be used for such information. It is intended to complement the specific requirements of the EU Directives on medical devices in the context of specifying means by which certain requirements can be met. If these means are followed by a manufacturer, they will provide presumption of conformity with the relevant essential requirements regarding information to be supplied.

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.

ISO 31 (all parts)	Quantities and units
EN 28601	Data elements and interchange formats - Information interchange - Representation of dates and times (ISO 8601, 1st edition 1988 and technical corrigendum 1:1991)

3 Definitions

For the purposes of this standard, the following definitions apply:

3.1 batch; lot: A defined quantity of starting material, packaging material or product processed in one process or series of processes.

3.2 batch code; lot number; batch number; lot code: A distinctive combination of numbers and/or letters which specifically identifies a batch.

NOTE : This definition is as given for batch or lot number in the Rules governing Medicinal Products in the European Community, Volume IV. Guide to Good Manufacturing Practice for Medicinal Products.

3.3 information supplied by the manufacturer with the medical device: All written, printed or graphic matter

a) on a medical device or any of its containers or wrappers, or

b) accompanying a medical device

relating to the identification, technical description and use of the medical device, but excluding shipping documentation and promotional material.

The information comprises the details on the label and the data in the instructions for use. The instructions for use may be included on the label.

3.4 medical device: Any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means. [EN 46001]

NOTE : This definition is as given in the Council Directive concerning medical devices (93/42/EEC), Article 1, paragraph 2 (a).

4 Requirements for information to be supplied by the manufacturer

NOTE : The medical devices Directives stipulate the legal requirements for information supplied by the manufacturer. These are reproduced verbatim in the informative Annex B for active implantable devices and informative Annex C for medical devices. Due consideration should be given to the guidance in these Annexes.

Product related standards may require additional information to be supplied. Product area standards may also require additional information, e.g. clause 6 of the various Parts of EN 60601 to medical electrical equipment.

4.1 Requirements

4.1.1 Information supplied by the manufacturer and intended for direct 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 1 : The information presented should be understandable by the intended user and/or other persons, where appropriate.

NOTE 2 : If there is insufficient space on the container or the device, the relevant information may be given on an insert, accompanying document or on the next layer of packaging, as applicable.

The recognition of certain marking on small or specialized devices may require the use of methods other than visual, for example, electronic.

4.1.2 Any symbols used in the information supplied by the manufacturer with the medical devices shall either:

a) conform to those specified in harmonized standards, or

b) in areas for which no harmonized standards exist, have their meanings explained in the information supplied by the manufacturer with the device.

NOTE : Examples of harmonized standards are EN 980 and EN 60601.

4.1.3 Any identification colours used in the information supplied by the manufacturer with the medical devices shall either:

a) conform to those specified in relevant harmonized standards, e.g. Medical gas cylinders,or

b) where no harmonized standard exists, be described together with their meanings in the information supplied by the manufacturer with the device.

NOTE : Reference to standards which include colour coding is given in Annex A.

4.1.4 The information supplied by the manufacturer shall not be presented in such a manner that it obscures other essential information.

NOTE : The information supplied by the manufacturer should not be presented in such a manner that it may be confused with other essential information.

4.1.5 Any units of measurement shall be expressed in SI units as specified in ISO 31, or other legal units.

NOTE 1 : Attention is drawn to Council Directive 80/181/EEC as amended, see Annex A, and to ISO 1000 which gives further guidance on the application of SI units.

NOTE 2 : This requirement does not preclude the additional use of other units as allowed by harmonized standards.

4.1.6 As far as practicable and appropriate, the information needed to use the device safely shall be set out on the device itself and/or on the packaging for each unit, or, where appropriate, on the sales packaging. If individual packaging of each unit is not practicable, the information shall be set out in the leaflet supplied with one or more devices.

4.1.7 User adjustable controls shall have their function clearly specified.

4.1.8 Any detachable component, intended by the manufacturer to be used separately from the original device, shall be identified by its batch code, or by other appropriate means.

4.1.9 The address of the manufacturer shall be provided in sufficient detail to enable contact to be established.

NOTE : Specific legal requirements apply to devices imported into the European Union, see Annex C, 13.3 a).

4.1.10 Any date shall be expressed in the format YYYY-MM-DD, or YYYY-MM, or YYYY, in accorrdance with EN 28601.

NOTE : The choice of format will be determined by the requirements of the relevant Directive(s) and the specific nature of the device itself.

Annex A (informative)

Bibliography

EN 556	Sterilization of medical devices - Requirements for medical devices to be labelled "Sterile"
EN 980	Graphical symbols for use in the labelling of medical devices
EN 1089-3	Transportable gas cylinders - Cylinder identification - Part 3: Colour coding
prEN 1733	Suction catheters for use in the respiratory tract
EN 20780	Packaging - Pictorial marking for handling of goods (ISO 780:1985)
EN ISO 9001	Quality systems - Model for quality assurance in design/development, production, installation and servicing (ISO 9001:1994)
EN ISO 9002	Quality systems - Model for quality assurance in production, installation and servicing (ISO 9002:1994)
EN ISO 9004-1	Quality management and quality system elements - Part 1: Guidelines (ISO 9004-1:1994)
EN 45502-1	Active implantable medical devices - Part 1: General requirements for safety, marking and information to be provided by the manufacturer
EN 46001	Quality systems -Medical devices - Particular requirements for the application of EN ISO 9001
EN 46002	Quality systems - Medical devices - Particular requirements for the application of EN ISO 9002
EN 60601	Medical electrical equipment
EN ISO 6009	Hypodermic needles for single use - Colour coding for identification (ISO 6009:1992)
ISO 1000	SI units and recommendations for the use of their multiples and of certain other units
ISO 7000	Graphical symbols for use on equipment - Index and synopsis
IEC 1258	Guidelines for the development and use of medical electrical equipment educational materials
93/42/EEC	Council Directive concerning medical devices. Council of European Communities
90/385/EEC	Council Directive on the approximation of the laws of the Member States relating to active implantable medical devices. Council of European Communities

80/181/EEC	Council Directive on the approximation of the laws of the Member States relating to units of measurement. Council of European Communities
89/336/EEC	Council Directive on the approximation of the laws of the Member States relating to electromagnetic compatibility. Council of European Communities
	Rules Governing Medicinal Products in the EEC, Volume IV, GMP for Medicinal Products Council of European Communities
93/465/EEC	Council Decision on CE-Mark. Council of European Communities
89/618/EURATOM	Council Directive on informing the general public about health protection measures to be applied and steps to be taken in the event of a radiological emergency. Council of European Communities