SLOVENSKI STANDARD
SIST EN 1041:2008+A1:2013

01-december-2013

Informacije, ki jih proizvajalec priloži medicinskim pripomočkom

Information supplied by the manufacturer of medical devices

Bereitstellung von Informationen durch den Hersteller von Medizinprodukten

Informations fournies par le fabricant de dispositifs médicaux

Ta slovenski standard je istoveten z: **EN 1041:2008+A1:2013**

ICS:

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

SIST EN 1041:2008+A1:2013 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 1041:2008+A1

September 2013

ICS 01.110; 11.040.01; 11.120.01

Supersedes EN 1041:2008

English version

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This European Standard was approved by CEN on 4 July 2008 and includes Amendment 1 approved by CEN on 11 July 2013.

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Contents

Page

Foreword

This document (EN 1041:2008+A1:2013) has been prepared by Technical Committee CEN/CLC/TC 3 “Quality management and corresponding general aspects for medical devices”, the secretariat of which is held by NEN.

This European Standard ⟨A1⟩ *deleted text* ⟨A1⟩ shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by March 2014 and conflicting national standards shall be withdrawn at the latest by March 2014.

⟨A1⟩ 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. ⟨A1⟩

This document includes Amendment 1 approved by CEN on 11 July 2013.

This document supersedes ⟨A1⟩ EN 1041:2008 ⟨A1⟩.

The start and finish of text introduced or altered by amendment is indicated in the text by tags ⟨A1⟩ ⟨A1⟩.

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 Directives 93/42/EEC and 90/385/EEC, as amended, with the exception of 3.3 and Annex B.

Annex A provides practical guidance about the implementation of the essential requirements of the applicable Directives.

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

According to the CEN/CENELEC Internal Regulations, the national standards organisations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Introduction

The first edition of this standard was drafted in a period when the Active Implantable Medical Device Directive (AIMDD) (90/385/EEC) and the Medical Device Directive (MDD) (93/42/EEC) were relatively new and the In Vitro Diagnostic Medical Device Directive (IVDD) (98/79/EEC) was not in existence. In addition, at the time the previous edition of this standard was adopted, the established method of providing information on, with, or otherwise in association with a device was by hard copy. Predominantly, this was printed copy on substrates such as paper, card, or plastic.

Since the time of approval of the first edition of this standard on 18 January 1998, the MDD and AIMDD have been amended. In addition, other methods of provision of information have become freely available and widely used.

The intention of this second edition is to make available guidance for manufacturers of medical devices that is appropriate regardless of the means used to disseminate that information as well as to update the requirements to reflect the changes to Directives 90/385/EEC and 93/42/EEC. In this standard, Directives 90/385/EEC and 93/42/EEC refer to the versions amended in 2007. The guidance reflects the desire to take into account different methods of provision of information, and it is intended that it should, as far as possible, be suitable for future methods of provision of information.

The requirements and guidance will provide manufacturers with appropriate means to ensure that their provision of information is relevant to all intended recipients and is in compliance with the Essential Requirements of the Directives. The requirements may also provide means by which compliance can be tested by regulatory and inspection agencies.

The possibility of providing information by alternative means is foreseen in Directives 93/42/EEC and 90/385/EEC. Annex B provides guidance on alternative labelling.

1 Scope

This [A1] European Standard [A1] specifies requirements for information to be supplied by a manufacturer for medical devices regulated by Council Directive 90/385/EEC relating to active implantable medical devices and Council Directive 93/42/EEC concerning medical devices. It does not specify the language to be used for such information, nor does it specify the means by which the information is to be supplied. It is also intended to complement the specific requirements of the cited EU Directives on medical devices by providing guidance on means by which certain requirements can be met. If a manufacturer follows these means, they will provide a presumption of conformity with the relevant Essential Requirements regarding information to be supplied.

This standard does not cover requirements for provision of information for in vitro diagnostic medical devices, which are covered by other labelling standards (see Bibliography).

NOTE When national transpositions of the Directives specify the means by which information shall be supplied, this standard does not provide derogation from these requirements for that country.

2 Normative references

[A1] The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies. [A1]

[A1] *deleted text* [A1]

EN ISO 3166-1,[A1] [1] [A1] *Codes for the representation of names of countries and their subdivisions — Part 1: Country codes (ISO 3166-1:2006)*

ISO 639-1, *Codes for the representation of names of languages — Part 1: Alpha-2 Code*

ISO 1000, *SI units and recommendations for the use of their multiples and of certain other units*

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

CEN/TR 15133, *Nomenclature — Collective terms and codes for groups of medical devices*

3 Terms and definitions

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

3.1
batch; lot
defined amount of material or a number of devices, including finished product and accessories, that is processed in one process or a series of related processes

NOTE The defined amount of material or number of devices will normally be associated with a unique statement of conformity to a defined quality specification.

[A1]

1) EN ISO 3166-1 is currently impacted by the corrigendum EN ISO 3166-1:2006/AC:2008, *Codes for the representation of names of countries and their subdivisions — Part 1: Country codes (ISO 3166-1:2006/Cor 1:2007)*. [A1]

3.2
batch code; lot number; batch number; lot code
unique identifier associated with a single batch or lot (see 3.1)

3.3
alternative labelling
any form of electronically accessible information supplied by the manufacturer (see 3.4) related to a medical device such as CD/DVD-ROM, Internet or other mode

3.4
information supplied by the manufacturer
all material, however provided, relating to the identification, technical description and use of a medical device that is intended to ensure the safe, effective and compliant use of the device

NOTE Shipping documents and promotional material are excluded from this definition when identification, technical description and use of a medical device are not intended to ensure the safe, effective and compliant use of the device.

3.5
medical device
any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and 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

[Council Directive concerning medical devices (93/42/EEC), Article 1, paragraph 2 (a)]

3.6
user
any person, legal or natural, for whom the information supplied (see 3.4) is intended

4 Requirements

4.1 General

Product information and labelling shall be part of risk management procedures.

NOTE 1 Due consideration should be given to the guidance provided in Annex A.

NOTE 2 Product-related standards may require additional information to be supplied.

4.2 Units, symbols and colours

Units used shall be SI units as specified in ISO 1000 or any other legal units.

[A1] Symbols and safety-related identification colours shall be explained in the information supplied unless they are taken from harmonised standards. [A1]

4.3 Language and country identifiers

If the manufacturer decides to identify the language used in the information provided, for example to indicate to users the appropriate language in a multilingual document, this shall be done using the language codes given in ISO 639-1 and/or the plain text of the language (e.g. “English”).

If the manufacturer decides to identify the country in the information provided, for example to indicate to users the appropriate customer service contact details for their country, this shall be done using the country codes given in EN ISO 3166-1 and/or the plain name of the country (e.g. “France”).

4.4 Dates

Any human-readable date shall be expressed in the format YYYY-MM-DD, YYYY-MM or YYYY, in accordance with ISO 8601.

NOTE The choice of format will be determined by the requirements of the relevant Directives and the specific nature of the devices concerned.

4.5 Device nomenclature

4.5.1 Identifiers of nomenclature

When it is required to include the identification of the generic device group or the device category in the information supplied with the device, this may be done using a nomenclature that is in compliance with EN ISO 15225.

NOTE For details of nomenclatures claimed to be in compliance with EN ISO 15225, see the Bibliography.

4.5.2 Device common terms

When it is appropriate to identify collective terms for medical devices in the information supplied, for example common technology or common materials of construction, this shall be done using the terms and codes set out in CEN/TR 15133.

4.5.3 Batch code; lot number; batch number; lot code

These shall consist of alphanumeric characters but may also be presented by other means, for example by using machine-readable codes.

5 Requirements for provision of information

5.1 General

5.1.1 [A1) Safe and effective use of the device (A1]

Any means of provision of information with medical devices shall take into account the intended users, the conditions of use and any issues specific to individual device types that are necessary for the safe and effective use of the device. This shall apply regardless of whether the specific requirements listed below apply to the device.

The appropriate way of providing information shall be based on a risk assessment and in line with the training, experience and education of the intended users.

5.1.2 [A1) Address required under medical devices directives

All medical devices which are placed on the market and put into service within the Community, shall contain the name or trade name and address of the manufacturer in the information supplied by the manufacturer. When the

manufacturer does not have a registered place of business in the Community, the information shall contain in addition the name and address of the authorised representative.

For devices covered by the MDD, the name or the trade name and address of the manufacturer shall appear on the label and in the instruction for use if provided with the device. When the manufacturer does not have a registered place of business in the Community, the label, or the outer packaging, or instructions for use shall contain, in addition, the name and address of the authorised representative.

For devices covered by the AIMDD, the name and address of the manufacturer shall appear on the sterile pack and the sales packaging and in the instruction for use. When the manufacturer does not have a registered place of business in the Community, the sales packaging and the instructions for use shall contain, in addition, the name and address of the authorised representative.

The address to be used shall be the same as the address of the manufacturer and/or the authorised representative as their registered place of business. The address shall be the same as the address used on the declaration of conformity, in relevant certificates and in the European database for medical devices.

The full address used shall contain the following elements insofar as they are available in the address system of the country where the relevant entity (manufacturer or authorised representative) is registered:

— street/road;

— number/house/floor;

— postal code;

— city;

— state/region; and

— country.

The information regarding street/road and number/house/floor may be omitted if a postal code dedicated to the manufacturer (corporate postal code) or authorised representative is used which fully replaces the indication of street/road and number/house/floor, and is not a PO box number. 〈A1▌

5.2 Specific requirements

5.2.1 Applicability

These specific requirements shall be applicable to all devices to the extent that they are applicable to the specific device type concerned and to the means of provision of the relevant information. For example, the requirement to allow for a “use by” date is not applicable to devices that do not bear a “use by” date.

5.2.2 Accessibility

The information presented with a device shall be accessible to intended users taking into account their age, education, knowledge and training.

When appropriate, a specific means of provision may be restricted to users to whom it is particularly applicable.

NOTE This requirement may result in more than one means of provision being necessary.

5.2.3 Legibility

Information intended for visual recognition shall be easily legible when viewed using normal vision, corrected if necessary, taking into account the specific size and conditions of use of the particular device.

5.2.4 Availability

Information shall be available as long as reasonably necessary, taking the lifetime of the device into consideration.

5.2.5 Security

As far as practicably possible, the medium of information provision shall be protected from corruption, degradation and deliberate change by those other than the manufacturer, whether malicious or not.

If the user can readily identify faulty information, for example by virtue of damaged labels, advice on the action to take shall be provided.

Where the damage to information is not readily apparent and/or the consequences of damage are not obvious, guidance shall be provided on how to maintain the security of the information and limit any adverse consequences.

NOTE When appropriate and relevant, manufacturers should consider if there are any preventative measures that can be taken to maintain information security in relation to customer service.

5.2.6 Changes to information provided

Any changes to information provided for existing users shall be clearly communicated if they are important for patient safety.

6 Documentation

Documentation relating to information provided shall be maintained in the technical documentation(s) relating to the device(s) that are the subject of the information. This may take the form of a specific section holding all the documentation or, alternatively, references to parts of a larger document where the information may be found, such as a quality manual.