SLOVENSKI STANDARD
SIST EN 1041:2008/kFprA1:2013

01-marec-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/FprA1**

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/kFprA1:2013 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

FINAL DRAFT
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ICS 01.110; 11.040.01; 11.120.01

English version

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This draft amendment is submitted to CEN members for unique acceptance procedure. It has been drawn up by the Technical Committee CEN/CLC/TC 3.

This draft amendment A1, if approved, will modify the European Standard EN 1041:2008. If this draft becomes an amendment, CEN and CENELEC 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.

This draft amendment was established by CEN and CENELEC in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN and CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

Warning : This document is not a European Standard. It is distributed for review and comments. It is subject to change without notice and shall not be referred to as a European Standard.

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Foreword

This document (EN 1041:2008/FprA1:2013) 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 document is currently submitted to the Unique Acceptance Procedure.

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.

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

1 Modifications to Clause 2

Delete the following normative reference:

"EN 980, *Symbols for use in the labelling of medical devices*".

Immediately after "EN ISO 3166-1"*, add a new footnote* "[1)]" *and add the related text at the bottom of the page:*

"

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)*.".

2 Modification to 4.2

Replace the 2nd paragraph with the following one:

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

3 Modification to 5.1

Immediately after the line with the number and title of Subclause 5.1, add the following line:

"

5.1.1 Safe and effective use of the device".

Add the following new subclause just before 5.2:

"

5.1.2 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.".

4 Modifications to the Bibliography

Immediately after list entry [6], add the following reference:

"

[7] EN 980, Symbols for use in the labelling of medical devices"*;*

and renumber the following bibliographical entries accordingly.

Immediately after the reference to EN ISO 13485, add the following one:

"

[10] EN ISO 15223-1, *Symbols to be used with medical devices labels, labelling and information to be supplied — Part 1: General requirements*".

Annexes ZA and ZB:

A recent analysis has shown that, in order to cover the essential requirements of the directives, the manufacturer has to go through Annex A of the standard and make sure that the legal requirements are fulfilled. Since the Annex A is an informative annex, it was not included in the current Annexes Z, which now thus appears to be incomplete.

Furthermore, several discrepancies between the content of the Annex A and the requirements of the first Annex of each of the medical devices directives have been noted and need to be remedied. In order to solve these issues, a full revision of the standard will be started directly after publication of this amendment. The standard should, in the meantime, not be used as a means for assuring compliance with requirements of the medical devices directives. Instead the requirements of the directives should be applied directly.