Irish Standard
I.S. EN 1041:2008+A1:2013

Information supplied by the manufacturer of medical devices

I.S. EN 1041:2008+A1:2013

Incorporating amendments/corrigenda/National Annexes issued since publication:

The National Standards Authority of Ireland (NSAI) produces the following categories of formal documents:

I.S. xxx: Irish Standard – national specification based on the consensus of an expert panel and subject to public consultation.

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SWiFT xxx: A rapidly developed recommendatory document based on the consensus of the participants of an NSAI workshop.

This document replaces:
EN 1041:2008

This document is based on:	*Published:*
EN 1041:2008+A1:2013	7 October, 2013
EN 1041:2008	6 August, 2008

This document was published under the authority of the NSAI and comes into effect on:
7 October, 2013

ICS number:
01.110
11.040.01
11.120.01

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I.S. EN 1041:2008+A1:2013

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

Information supplied by the manufacturer of medical devices

Informations fournies par le fabricant de dispositifs médicaux

Bereitstellung von Informationen durch den Hersteller von Medizinprodukten

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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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 and CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN and CENELEC members are the national standards bodies and national electrotechnical committees of 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 United Kingdom.

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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]

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