SVENSK STANDARD
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Aktiva implanterbara medicintekniska produkter – Del 1: Allmänna fordringar för säkerhet och märkning samt för information som lämnas av tillverkaren

Implants for surgery – Active implantable medical devices – Part 1: General requirements for safety, marking and for information to be provided by the manufacturer

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Postadress: SEK, Box 1284, 164 29 Kista
Telefon: 08-444 14 00.
E-post: sek@elstandard.se Internet: www.elstandard.se

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Europastandarden EN 45502-1:2015 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN 45502-1:2015.

Denna standard ersätter SS-EN 45502-1, utgåva 1.

The European Standard EN 45502-1:2015 has the status of a Swedish Standard. This document contains the official English version of EN 45502-1:2015.

This standard supersedes the Swedish Standard SS-EN 45502-1, edition 1.

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Information about the content of the standard is available from the Swedish Standards Institute (SIS), telephone +46 8 555 520 00. Standards may be ordered from SIS Förlag AB, who can also provide general information about Swedish and foreign standards.

Denna standard är framtagen av kommittén för Implantat, SIS/TK 340/AG i.

Har du synpunkter på innehållet i den här standarden, vill du delta i ett kommande revideringsarbete eller vara med och ta fram andra standarder inom området? Gå in på www.sis.se - där hittar du mer information.

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 45502-1

May 2015

ICS 11.040.01

Supersedes EN 45502-1:1997

English Version

Implants for surgery - Active implantable medical devices - Part 1: General requirements for safety, marking and for information to be provided by the manufacturer

Dispositifs médicaux implantables actifs - Partie 1: Règles générales de sécurité, marquage et informations fournies par le fabricant

Aktive implantierbare medizinische Geräte - Teil 1: Allgemeine Festlegungen für die Sicherheit, Aufschriften und vom Hersteller zur Verfügung zu tellende Informationen

This European Standard was approved by CENELEC on 20 April 2015. CEN and CENELEC 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 CEN-CENELEC Management Centre or to any CEN and CENELEC 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 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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European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

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Foreword

This document (EN 45502-1:2015) has been prepared by CEN/CLC/JWG AIMD "CEN/CENELEC Joint Working Group on Active Implantable Medical Devices".

The following dates are fixed:

• latest date by which this document has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2016-04-20
• latest date by which the national standards conflicting with this document have to be withdrawn	(dow)	2018-04-20

This document supersedes EN 45502-1:1997.

EN 45502-1:2015 includes the following significant technical changes with respect to EN 45502-1:1997:

a) update according to the modified AIMD;
b) update of normative references to the “state of the art”;
c) implementation of usability issues;
d) implementation of links to information security;
e) implementation of elements according to EN 14971:2012;
f) improvement of Clause 14 “Protection from unintentional biological effects being caused by the active implantable medical device”;
g) improvement of Clause 20 “Protection of the active implantable medical device from damage caused by external defibrillators”;
h) improvement of Clause 22 “Protection of the active implantable medical device from changes caused by miscellaneous medical treatments” especially for ultrasonic diagnostic devices.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights.

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For the relationship with EU Directive(s) see informative Annex ZZ, which is an integral part of this document.

Introduction

This European Standard specifies general requirements for ACTIVE IMPLANTABLE MEDICAL DEVICES to provide basic assurance of safety for both patients and users.

To minimize the likelihood of a device being misused, this European Standard also details comprehensive requirements for MARKINGS and for other information to be supplied as part of the documentation with any ACTIVE IMPLANTABLE MEDICAL DEVICE.

For particular types of ACTIVE IMPLANTABLE MEDICAL DEVICE, the general requirements can be supplemented or modified by the requirements of other parts of EN 45502. A requirement of a particular part of EN 45502 takes priority over the corresponding requirement of this general part of EN 45502. Where particular parts of EN 45502 exist, this general standard of EN 45502 is not intended to be used alone. Special care is required when applying this general standard part of EN 45502 alone to ACTIVE IMPLANTABLE MEDICAL DEVICES for which no particular part of EN 45502 has yet been published.

1 Scope

This part of EN 45502 specifies requirements that are generally applicable to ACTIVE IMPLANTABLE MEDICAL DEVICES.

NOTE 1 For particular types of ACTIVE IMPLANTABLE MEDICAL DEVICES, these general requirements are supplemented or modified by the requirements of particular standards which form additional parts of this European Standard.

The tests that are specified in EN 45502 are type tests and are to be carried out on samples of an ACTIVE IMPLANTABLE MEDICAL DEVICE to show compliance.

This part of EN 45502 is applicable not only to ACTIVE IMPLANTABLE MEDICAL DEVICES that are electrically powered but also to those powered by other energy sources (for example by gas pressure or by springs).

This part of EN 45502 is also applicable to some non-implantable parts and accessories of the ACTIVE IMPLANTABLE MEDICAL DEVICES.

NOTE 2 The device that is commonly referred to as an ACTIVE IMPLANTABLE MEDICAL DEVICE can be a single device, a combination of devices, or a combination of a device or devices and one or more accessories. Not all of these parts are required to be either partially or totally implantable, but there is a need to specify some requirements of non-implantable parts and accessories if they could affect the safety or performance of the implantable device.

NOTE 3 In this part of EN 45502, terms printed in small capital letters are used as defined in Clause 3. Where a defined term is used as a qualifier in another term, it is not printed in small capital letters unless the concept thus qualified is also defined.

2 Normative references

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.

EN 60068-2-14:2009, *Environmental testing – Part 2 14: Tests – Test N: Change of temperature (IEC 60068-2-14:2009)*

EN 60068-2-27:2009, *Environmental testing – Part 2 27: Tests – Test Ea and guidance: Shock (IEC 60068-2-27:2008)*

EN 60068-2-47:2005, *Environmental testing – Part 2 47: Tests – Mounting of specimens for vibration, impact and similar dynamic tests (IEC 60068-2-47:2005)*

EN 60068-2-64:2008, *Environmental testing – Part 2 64: Tests – Test Fh: Vibration, broadband random and guidance (IEC 60068-2-64:2008)*

EN 60601-1:2006, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005)*

EN 60601-1:2006/A1:2013, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005/A1:2012)*

EN 62304:2006, *Medical devices software – Software life-cycle processes (IEC 62304:2006)*

EN 62366:2008, *Medical devices – Application of usability engineering to medical devices (IEC 62366:2007)*

EN ISO 10993-1:2009, *Biological testing of medical devices – Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2003)*

EN ISO 11607-1:2006, *Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2006)*

EN ISO 14155:2011-10, *Clinical investigation of medical devices for human subjects -- Good clinical practice (ISO 14155:2011)*

EN ISO 14971:2012, *Medical devices – Application of risk management to medical devices (ISO 14971:2007)*

ISO 8601:2004, *Data elements and interchange formats – Information interchange – Representation of dates and times*