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

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 45502-1:2015 sisaldab Euroopa standardi EN 45502-1:2015 ingliskeelset teksti.	This Estonian standard EVS-EN 45502-1:2015 consists of the English text of the European standard EN 45502-1:2015.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation.
Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 22.05.2015.	Date of Availability of the European standard is 22.05.2015.
Standard on kättesaadav Eesti Standardikeskusest.	The standard is available from the Estonian Centre for Standardisation.

Tagasisidet standardi sisu kohta on võimalik edastada, kasutades EVS-i veebilehel asuvat tagasiside vormi või saates e-kirja meiliaadressile standardiosakond@evs.ee.

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EUROPEAN STANDARD

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EN 45502-1

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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
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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*

3 Terms and definitions

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

3.1
ACTIVE MEDICAL DEVICE
MEDICAL DEVICE relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity

3.2
ACTIVE IMPLANTABLE MEDICAL DEVICE
ACTIVE MEDICAL DEVICE which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure

Note 1 to entry: For purposes of this part of EN 45502, an ACTIVE IMPLANTABLE MEDICAL DEVICE can be a single ACTIVE MEDICAL DEVICE, or a system consisting of a set of components and accessories, including software, which interact to achieve the performance intended by the MANUFACTURER. Not all of these components or accessories may be required to be partially or totally implanted.

3.3
AUTHORIZED REPRESENTATIVE
any natural or legal person established in the European Community who, explicitly designated by the MANUFACTURER, acts and can be addressed by authorities and bodies in the Community instead of the MANUFACTURER with regard to the latter's obligations

3.4
BEGINNING OF SERVICE
BOS
when an individual ACTIVE IMPLANTABLE MEDICAL DEVICE is first released by the MANUFACTURER as fit for placing on the market

3.5
CATHETER
flexible tube allowing access to a point within the body at its distal end through a lumen, often for delivering a substance

Note 1 to entry: A CATHETER CAN be combined with a LEAD.

3.6
CORRECT USE
NORMAL USE without USE ERROR

[SOURCE: EN 62366:2008, 3.7]

3.7
END OF SERVICE
EOS
point at which an individual PROLONGED SERVICE PERIOD has elapsed and performance to design specification cannot be assured