SLOVENSKI STANDARD
oSIST prEN 45502-1:2010

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Aktivni medicinski pripomočki za vsaditev - 1. del: Splošne zahteve za varnost, označevanje in informacije, ki jih priskrbi proizvajalec

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

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

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

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ICS:

11.040.40	Implantanti za kirurgijo, protetiko in ortetiko	Implants for surgery, prosthetics and orthotics

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English version

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This draft European Standard is submitted to CENELEC members for CENELEC enquiry. Deadline for CENELEC: 2010-12-17.

It has been drawn up by CEN/CLC/JWG AIMD.

If this draft becomes a European Standard, 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.

This draft European Standard was established by CENELEC in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the Central Secretariat 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.

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CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

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Foreword

This draft European Standard was prepared by the CEN/CENELEC Joint Working Group on Active Implantable Medical Devices (CEN/CLC/JWG AIMD). Members of the Joint Working Group were nominated by one of the members of either CEN or CENELEC. It is submitted to CENELEC enquiry.

This document will supersede EN 45502-1:1997.

This draft European Standard has been prepared under Mandate M/432 given to CEN and CENELEC by the European Commission and the European Free Trade Association and covers essential requirements of EC Directive 90/385/EEC.

Although both this European Standard and the Directive deal with the same range of products, the structure and purpose of the two documents are different. Annex A of this European Standard correlates the requirements of the Directive with the subclauses of this Standard.

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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 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 are supplemented or modified by the requirements of particular standards as separate parts of EN 45502. A requirement of such a particular standard takes priority over the corresponding requirement of this general standard. Where particular standards exist, this general standard should not be used alone. Special care is required when applying this general standard alone to ACTIVE IMPLANTABLE MEDICAL DEVICES for which no particular standard has yet been published.

1 Scope

This Part 1 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 1 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 1 of EN 45502 is also applicable to some non-implantable parts and accessories of the ACTIVE IMPLANTABLE MEDICAL DEVICES.

NOTE 2 The terminology used in this European Standard is intended to be consistent with the terminology of Directive 90/385/EEC.

NOTE 3 In this European Standard, 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 referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 556-1:2001, *Sterilization of medical devices – Requirements for medical devices to be labelled 'STERILE' – Part 1: Requirements for terminally sterilized devices*

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 + corr. Mar. 2010, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance* (IEC 60601-1:2005)

EN 60601-1-2:2007 + corr. Mar. 2010, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests* (IEC 60601-1-2:2007, mod.)

EN 62304:2006 + corr. Nov. 2008, *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 10993-1:2009)

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

EN ISO 14155-1:2009, *Clinical investigation of medical devices for human subjects – Part 1: General requirements* (ISO 14155-1:2003)

EN ISO 14155-2:2009, *Clinical investigation of medical devices for human subjects – Part 2: Clinical investigation plans* (ISO 14155-2:2003)

EN ISO 14971:2009, *Medical devices – Application of risk management to medical devices* (ISO 14971:2007, Corrected version 2007-10-01)

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
MEDICAL DEVICE
any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, 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

3.2
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

3.3
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 For purposes of this Part 1 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.

3.4
CATHETER
flexible tube allowing access to a point within the body at its distal end through a lumen, often for delivering a substance

NOTE A CATHETER may be combined with a LEAD.

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1) Superseded by EN ISO 11607-1:2009, *Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems* (ISO 11607-1:2006).

3.5
LEAD
flexible tube enclosing one or more insulated electrical conductors, intended to transfer electrical energy along its length

NOTE A LEAD may be combined with a CATHETER.

3.6
NON-REUSABLE PACK
single use pack designed to allow the contents to be sterilized and to maintain that sterility

3.7
STERILE PACK
NON-REUSABLE PACK in which the contents have been sterilized

3.8
SALES PACKAGING
packaging that protects and identifies the ACTIVE IMPLANTABLE MEDICAL DEVICE during storage and handling by the purchaser

NOTE The SALES PACKAGING may be enclosed in further packaging, for example, a 'shipping package', for delivery.

3.9
MARKING
inscription on a device, package, or LABEL

3.10
LABEL
area bearing a MARKING, affixed to an ACTIVE IMPLANTABLE MEDICAL DEVICE or package but not an integral part of the ACTIVE IMPLANTABLE MEDICAL DEVICE or package

3.11
RADIOACTIVE SUBSTANCE
any substance that contains one or more radionuclides the activity or concentration of which cannot be disregarded as far as radiation protection is concerned

[Based on 96/29/Euratom]

3.12
SEALED SOURCE
source containing RADIOACTIVE SUBSTANCES whose structure is such as to prevent, under normal conditions of use, any dispersion of the radioactive substances into the environment

[Based on 96/29/Euratom]

3.13
MANUFACTURER
natural or legal person with responsibility for the design, manufacture, packaging and labelling of an ACTIVE IMPLANTABLE MEDICAL DEVICE before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party

NOTE This definition also applies to the natural or legal person who assembles, packages, processes, fully refurbishes and/or labels one or more ready-made products and/or assigns to them their intended purpose as an ACTIVE IMPLANTABLE MEDICAL DEVICE with a view to their being placed on the market under his own name. This definition also applies to the manufacturer of non implantable parts and accessories of the ACTICE IMPLANABLE MEDICAL DEVICE.

3.14
MEDICINAL SUBSTANCE
any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis

[Based on Article 1 of Directive 2001/83/EC]

3.15
MEDICINAL SUBSTANCE DERIVED FROM HUMAN BLOOD OR HUMAN PLASMA
MEDICINAL SUBSTANCES based on blood constituents which are prepared industrially by public or private establishments, such MEDICINAL SUBSTANCES including, in particular, albumin, coagulating factors and immunoglobulins of human origin

3.16
HARM
physical injury or damage to health of people, or damage to property or the environment

[EN ISO 14971:2009, definition 2.2]

3.17
HAZARD
potential source of HARM

[EN ISO 14971:2009, definition 2.3]

3.18
RESIDUAL RISK
RISK remaining after RISK CONTROL measures have been taken

[EN ISO 14971:2009, definition 2.15]

3.19
RISK
combination of the probability of occurrence of HARM and the severity of that HARM

[EN ISO 14971:2009, definition 2.16]

3.20
RISK ANALYSIS
systematic use of available information to identify HAZARDS and to estimate the RISK

NOTE RISK ANALYSIS includes examination of different sequences of events that can produce hazardous situations and HARM. See Annex E [of EN ISO 14971:2009].

[EN ISO 14971:2009, definition 2.17]

3.21
RISK ASSESSMENT
overall process comprising a RISK ANALYSIS and a RISK EVALUATION

[EN ISO 14971:2009, definition 2.18]

3.22
RISK CONTROL
process in which decisions are made and measures implemented by which RISKS are reduced to, or maintained within, specified levels

[EN ISO 14971:2009, definition 2.19]

3.23
RISK EVALUATION
process of comparing the estimated RISK against given RISK criteria to determine the acceptability of the RISK

[EN ISO 14971:2009, definition 2.21]

3.24
RISK MANAGEMENT
systematic application of management policies, procedures and practices to the tasks of analysing, evaluating, controlling and monitoring RISK

[EN ISO 14971:2009, definition 2.22]

3.25
RISK MANAGEMENT FILE
set of RECORDS and other documents that are produced by RISK MANAGEMENT

[EN ISO 14971:2009, definition 2.23]

3.26
PORTABLE
term referring to part of an ACTIVE IMPLANTABLE MEDICAL DEVICE intended to be moved from one location to another while being carried by one or more persons

[EN 60601-1:2006, definition 3.85 modified]

3.27
HAND HELD
term referring to part of an ACTIVE IMPLANTABLE MEDICAL DEVICE intended to be supported by the hand during NORMAL USE

[EN 60601-1:2006, definition 3.37 modified]

3.28
CORRECT USE
normal use without use error

[EN 62366:2008, definition 3.7]

3.29
NORMAL USE
operation, including routine inspection and adjustments by any USER, and stand-by, according to the instructions for use or in accordance with generally accepted practice for those MEDICAL DEVICES provided without instructions for use

[EN 60601-1:2006, definition 3.71, modified]

NOTE 1 USE ERROR can occur in NORMAL USE.

NOTE 2 MEDICAL DEVICES that can be used safely without instructions for use are exempted from having instructions for use by some authorities with jurisdiction.

3.30
USE ERROR
act or omission of an act that results in a different ACTIVE IMPLANTABLE MEDICAL DEVICE response than intended by the MANUFACTURER or expected by the USER

NOTE 1 USE ERROR includes slips, lapses, and mistakes.

NOTE 2 An unexpected physiological response of the patient is not in itself considered USE ERROR.

[EN 62366:2008, definition 3.21, modified]

3.31
BEGINNING OF SERVICE
BOS
when an individual ACTIVE IMPLANTABLE MEDICAL DEVICE is first released by the manufacturer as fit for placing on the market

3.32
END OF SERVICE
EOS
when the PROLONGED SERVICE PERIOD has elapsed and performance to design specification cannot be assured

3.33
PROLONGED SERVICE PERIOD
PSP
period during which the ACTIVE IMPLANTABLE MEDICAL DEVICE continues to function as defined by the MANUFACTURER to prolong basic bradyarrhythmia pacing beyond the RECOMMENDED REPLACEMENT TIME

3.34
RECOMMENDED REPLACEMENT TIME
RRT
when the POWER SOURCE INDICATOR reaches the value set by the MANUFACTURER of the ACTIVE IMPLANTABLE MEDICAL DEVICE for its recommended replacement

NOTE This indicates entry into the PROLONGED SERVICE PERIOD

3.35
AUTHORIZED REPRESENTATIVE
means any natural or legal person established in the European Community who, explicitly designated by the MANUFACTURER, acts and may be addressed by authorities and bodies in the Community instead of the MANUFACTURER with regard to the latter's obligations

4 Symbols and abbreviations (optional)

When appropriate, symbols, abbreviated terms and identification colour may be used in the MARKINGS and accompanying documentation of an ACTIVE IMPLANTABLE MEDICAL DEVICE. Symbols, abbreviated terms and identification colour shall conform to harmonized standards (e.g. EN 980). Where no harmonized standard exists, the symbols, abbreviated terms and identification colour shall be described in the accompanying documentation.

Compliance shall be checked by inspection.

NOTE Symbols for use with particular ACTIVE IMPLANTABLE MEDICAL DEVICES can be specified in subsequent parts of EN 45502.

5 General requirements for ACTIVE IMPLANTABLE MEDICAL DEVICES

5.1 General requirements for software

Software of an ACTIVE IMPLANTABLE MEDICAL DEVICE or software that falls within the definition of an ACTIVE IMPLANTABLE MEDICAL DEVICE shall be designed and validated according to software life cycle process activities compliant with EN 62304.

Compliance is determined by inspection and assessment as required by EN 62304:2006, 1.4.