SLOVENSKI STANDARD
SIST EN 45502-1:2015

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

Implants for surgery - Active implantable medical devices - Part 1: General requirements for safety, marking and for 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 tellende 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

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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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
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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

3.8
HAND HELD
part of an ACTIVE IMPLANTABLE MEDICAL DEVICE intended to be supported by the hand during NORMAL USE

[SOURCE: EN 60601-1:2006 + A1:2013, 3.37, modified — 'Electrical equipment' replaced by 'part of an ACTIVE IMPLANTABLE MEDICAL DEVICE'.]

3.9
HARM
physical injury or damage to health of people, or damage to property or the environment

[SOURCE: EN ISO 14971:2012, 2.2]

3.10
HAZARD
potential source of HARM

[SOURCE: EN ISO 14971:2012, 2.3]

3.11
INFORMATION SECURITY
protection of information and information systems from unauthorized access, use, disclosure, disruption, modification, or destruction in order to provide confidentiality, integrity, and availability

[SOURCE: FIPS PUB 199]

3.12
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

3.13
LEAD
flexible tube enclosing one or more insulated electrical conductors, intended to transfer electrical energy along its length

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

3.14
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 1 to entry: 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 ACTIVE IMPLANTABLE MEDICAL DEVICE.

3.15
MARKING
inscription on a device, package, or LABEL

3.16
MEDICAL DEVICE
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

3.17
MEDICINAL SUBSTANCE
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

Note 1 to entry: Based on Article 1 of European Union Directive 2001/83/EC.

3.18
MEDICINAL SUBSTANCE DERIVED FROM HUMAN BLOOD OR HUMAN PLASMA

MEDICINAL SUBSTANCE based on blood constituents which are prepared industrially by public or private establishments, such MEDICINAL SUBSTANCE including, in particular, albumin, coagulating factors and immunoglobulins of human origin

3.19
NON-REUSABLE PACK
single use pack designed to allow the contents to be sterilized and to maintain that sterility

3.20
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

Note 1 to entry: USE ERROR can occur in NORMAL USE.

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

[SOURCE: EN 60601-1:2006 + A1:2013, 3.71, modified — 'Operator' replaced by 'user' and 'or in accordance with generally accepted practice for those MEDICAL DEVICES provided without instructions for use' added to the end of the definition.]

3.21
PORTABLE
part of an ACTIVE IMPLANTABLE MEDICAL DEVICE intended to be moved from one location to another while being carried by one or more persons

[SOURCE: EN 60601-1:2006 + A1:2013, 3.85, modified — 'Transportable equipment' replaced by 'part of an ACTIVE IMPLANTABLE MEDICAL DEVICE'.]

3.22
PROCESS
set of inter-related or interacting resources and activities which transform inputs into outputs

[SOURCE: EN ISO 14971:2012, 2.130]

3.23
PROLONGED SERVICE PERIOD
PSP
period during which the ACTIVE IMPLANTABLE MEDICAL DEVICE continues to function as defined by the MANUFACTURER beyond the RECOMMENDED REPLACEMENT TIME

3.24
RADIOACTIVE SUBSTANCE
substance that contains one or more radionuclides the activity or concentration of which cannot be disregarded as far as radiation protection is concerned

Note 1 to entry: Based on European Council Directive 96/29/Euratom.

3.25
RECOMMENDED REPLACEMENT TIME
RRT
point at which the power source indicator reaches the value set by the MANUFACTURER of the ACTIVE IMPLANTABLE MEDICAL DEVICE for its recommended replacement

Note 1 to entry: This indicates entry into the PROLONGED SERVICE PERIOD.

3.26
RESIDUAL RISK
RISK remaining after RISK CONTROL measures have been taken

[SOURCE: EN ISO 14971:2012, 2.15]

3.27
RISK
combination of the probability of occurrence of HARM and the severity of that HARM

[SOURCE: EN ISO 14971:2012, 2.16]

3.28
RISK ANALYSIS
systematic use of available information to identify HAZARDS and to estimate the RISK

Note 1 to entry: RISK ANALYSIS includes examination of different sequences of events that can produce hazardous situations and HARM. See Annex E of EN ISO 14971:2012.

[SOURCE: EN ISO 14971:2012, 2.17]

3.29
RISK ASSESSMENT
overall PROCESS comprising a RISK ANALYSIS and a RISK EVALUATION

[SOURCE: EN ISO 14971:2012, 2.18]

3.30
RISK CONTROL
PROCESS in which decisions are made and measures implemented by which RISKS are reduced to, or maintained within, specified levels

[SOURCE: EN ISO 14971:2012, 2.19]

3.31
RISK EVALUATION
PROCESS of comparing the estimated RISK against given RISK criteria to determine the acceptability of the RISK

[SOURCE: EN ISO 14971:2012, 2.21]

3.32
RISK MANAGEMENT
systematic application of management policies, procedures and practices to the tasks of analysing, evaluating, controlling and monitoring RISK

[SOURCE: EN ISO 14971:2012, 2.22]

3.33
RISK MANAGEMENT FILE
set of records and other documents that are produced by RISK MANAGEMENT

[SOURCE: EN ISO 14971:2012, 2.23]

3.34
SALES PACKAGING
packaging that protects and identifies the ACTIVE IMPLANTABLE MEDICAL DEVICE during storage and handling by the purchaser

Note 1 to entry: The SALES PACKAGING may be enclosed in further packaging, for example, a 'shipping package', for delivery.

3.35
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

Note 1 to entry: Based on European Council Directive 96/29/Euratom.

3.36
STERILE PACK
NON-REUSABLE PACK in which the contents have been sterilized

3.37
USABILITY
characteristic of the user interface that establishes effectiveness, efficiency, ease of user learning and user satisfaction

[SOURCE: EN 62366:2008, 3.17]

3.38
USABILITY ENGINEERING
application of knowledge about human behaviour, abilities, limitations, and other characteristics related to the design of tools, devices, systems, tasks, jobs, and environments to achieve adequate USABILITY

[SOURCE: EN 62366:2008, 3.18]

3.39
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 to entry: USE ERROR includes slips, lapses, and mistakes.

Note 2 to entry: An unexpected physiological response of the patient is not in itself considered USE ERROR.

[SOURCE: EN 62366:2008, 3.21, modified — 'MEDICAL DEVICE' replaced by 'ACTIVE IMPLANTABLE MEDICAL DEVICE'.]

3.40
VALIDATION
confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled

[SOURCE: EN 62366:2008, 3.26]

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 ISO 15223-1). Where no harmonized standard exists, the symbols, abbreviated terms and identification colour shall be described in the accompanying documentation.

Compliance is 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 non-implantable parts

The non-implantable part of an ACTIVE IMPLANTABLE MEDICAL DEVICE which is connected to or equipped with an electrical power source shall comply with the appropriate requirements of EN 60601-1:2006 and its A1:2013, as determined in the RISK ANALYSIS, unless a requirement in that standard is superseded by a requirement in this or other parts of EN 45502.

NOTE Other subclauses in this standard require compliance with some subclauses of EN 60601-1:2006 and its A1:2013 even for non-implantable parts that are not electrically powered.

Compliance is checked by assessment of the test report and the RISK ANALYSIS provided by the MANUFACTURER.

5.2 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 according to software life cycle process activities compliant with EN 62304:2006 and shall be validated.

Compliance is checked by assessment of the software life cycle PROCESS in accordance with EN 62304:2006, 1.4 and assessment of the VALIDATION report provided by the MANUFACTURER.

5.3 USABILITY of non-implantable parts

5.3.1 USABILITY of non-implantable parts of an ACTIVE IMPLANTABLE MEDICAL DEVICE connected to or equipped with an electrical power source

The MANUFACTURER shall address in a USABILITY ENGINEERING PROCESS the RISK of poor USABILITY, including those associated with identification, MARKING and documents

Compliance is checked by assessment of the MANUFACTURER'S documentations that the acceptance criteria of the USABILITY VALIDATION plan have been met (see EN 62366:2008, 5.9).

5.3.2 USABILITY of non-implantable parts of an ACTIVE IMPLANTABLE MEDICAL DEVICE not connected to or equipped with an electrical power source

The non-implantable part of an ACTIVE IMPLANTABLE MEDICAL DEVICE shall provide adequate USABILITY such that the RISKS resulting from CORRECT USE and USE ERRORS are acceptable.

Compliance is checked by assessment of the MANUFACTURER'S documentations that the acceptance criteria of the USABILITY VALIDATION plan have been met (see EN 62366:2008, 5.9).

5.4 Data security and protection from HARM caused by unauthorized information tampering

When communication with the implantable part of an ACTIVE IMPLANTABLE MEDICAL DEVICE through wireless communication channels is provided, the MANUFACTURER shall evaluate INFORMATION SECURITY through the RISK MANAGEMENT PROCESS, and apply the appropriate RISK CONTROL measures to protect the patient from HARM.

Compliance is checked by the inspection of the RISK MANAGEMENT FILE.

5.5 General requirements for RISK MANAGEMENT

5.5.1 RISK MANAGEMENT policy

The MANUFACTURER shall define and document a policy for determining acceptable RISK and the acceptability of the RESIDUAL RISK(S) as required in EN ISO 14971.

Compliance is checked by inspection of the MANUFACTURER'S policy for determining criteria for RISK acceptability.

5.5.2 RISK MANAGEMENT FILE

The MANUFACTURER shall establish and maintain a RISK MANAGEMENT FILE complying with those requirements of EN ISO 14971 necessary to satisfy the requirements of this part of EN 45502.

Compliance is checked by confirming the existence of an index containing references or pointers to the RISK MANAGEMENT documentation required by this standard.

5.5.3 RISK MANAGEMENT PLAN

The MANUFACTURER shall establish and maintain a RISK MANAGEMENT PLAN complying with the relevant requirements of EN ISO 14971:2012 except those related to collection and review of production and post-production information. The RISK MANAGEMENT PLAN shall be part of the RISK MANAGEMENT FILE.

Compliance is checked by inspection of the RISK MANAGEMENT PLAN.