SLOVENSKI STANDARD
SIST EN 45502-1:2000

01-april-2000

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

Ta slovenski standard je istoveten z: **EN 45502-1:1997**

ICS:

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

SIST EN 45502-1:2000 **en**

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 45502-1

August 1997

ICS 11.040.01

Descriptors: medical equipment, surgical implants, safety requirements, accident prevention, specifications, protection, tests, technical notices, information, packing, sterility, marking

English version

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This European Standard was approved by CENELEC on 11 March 1997 and by CEN on 1997-03-14.

CEN/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 Central Secretariat or to any CEN/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/CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CEN Central Secretariat:
rue de Stassart, 36 B-1050 Brussels

CENELEC Central Secretariat:
rue de Stassart, 35 B-1050 Brussels

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Foreword

This European Standard has been 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.

The text of the draft was submitted to the formal vote and was approved as EN 45502-1 by CENELEC on 1997-03-11 and by CEN on 1997-03-14.

This European Standard has been prepared under a mandate given to CEN and CENELEC by the Commission of the European Communities and the European Free Trade Association, and supports essential requirements of Directive 90/385/EEC.

Although both this 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. Annex B provides references in the other direction, from this European Standard to the Directive. Annex C is a Rationale, providing some further explanation of particular subclauses of this European Standard. All three annexes are informative.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by 1998-03-01, and conflicting national standards shall be withdrawn at the latest by 1998-03-01.

According to the CEN Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

According to the CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom

Introduction

This 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 which are in preparation[†] 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. For particular types of ACTIVE IMPLANTABLE MEDICAL DEVICES, these essential 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 a 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 devices (see note 1).

NOTE 1 The device that is commonly referred to as an ACTIVE IMPLANTABLE MEDICAL DEVICE may in fact 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 2 The terminology used in this European Standard is intended to be consistent with the terminology of Directive 90/385/EEC.

[†] At present (July 1997) particular standards for implantable cardiac pulse generators, implantable cardiac defibrillators, implantable infusion pumps, implantable neurostimulators, and cochlear implants are in preparation.

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

This European Standard incorporates by dated or undated reference provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies.

EN 540	1993	Clinical investigation of medical devices for human subjects
EN 556	1994	Sterilization of medical devices - Requirements for medical devices to be labelled 'sterile'
EN 868-1	1997	Packaging materials for sterilization of wrapped goods Part 1: General requirements and requirements for the validation of packaging for terminally-sterilized devices.
EN 980	1996	Terminology, symbols and information provided with medical devices - Graphical symbols for use in the labelling of medical devices
EN 60068-2-32	1993	Environmental testing Part 2: Tests - Test Ed: Free fall (IEC 60068-2-32:1975 + A2:1990)
EN 60068-2-47	1993	Environmental testing Part 2: Tests Mounting of components, equipment and other articles for dynamic tests including shock (Ea), bump (Eb), vibration (Fc and Fd) and steady state acceleration (Ga) and guidance (IEC 68-2-47:1982)
EN 60601-1	1990	Medical electrical equipment Part 1: General requirements for safety (IEC 601-1:1988)
EN 60601-1-1	1993	Medical electrical equipment Part 1: General requirements for safety 1. Collateral Standard: Safety requirements for medical electrical systems (IEC 601-1-1:1992)
EN 60601-1-2	1993	Medical electrical equipment Part 1: General requirements for safety 2. Collateral standard: Electromagnetic compatibility - Requirements and tests (IEC 601-1-2:1992)

EN 60601-1-4	1996	Medical electrical equipment Part 1: General requirements for safety 4. Collateral standard: ¨Programmable electrical medical systems (IEC 601-1-4:1996)
EN 60601-2-27	1994	Medical electrical equipment Part 2: Particular requirements for the safety of electrocardiographic monitoring equipment (IEC 601-2-27:1994)
EN 60801-2	1993	Electromagnetic compatibility for industrial process measurement and control equipment Part 2: Electrostatic discharge requirements (IEC 801-2:1991)
HD 323.2.14	1987	Environmental testing Part 2: Tests - Test N: Change of temperature (IEC 68-2-14:1984 + A1:1986)
HD 323.2.36	1988	Environmental testing Part 2: Tests - Test Fdb: Random vibration wide band - Reproducibility medium (IEC 68-2-36:1973 + A1:1983)
ISO 8601	1988	Data elements and interchange formats - Information interchange - Representation of dates and times

3 Definitions

For the purposes of this Part of EN 45502, the following definitions apply.

3.1 medical device: An article, whether used alone or in combination, together with any accessories or software for its proper functioning, intended by the manufacturer to be used for human beings in the:

- diagnosis, prevention, monitoring, treatment or alleviation of disease or injury;
- investigation, replacement or modification of the anatomy or of a physiological process;
- control of conception

and which does not achieve its principal intended action by pharmacological, chemical, immunological or metabolic means but which may be assisted in its function by such means.

3.2 active medical device: A 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: An 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 standard an ACTIVE IMPLANTABLE MEDICAL DEVICE may be a single ACTIVE MEDICAL DEVICE, or a system consisting of a set of components and accessories 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:** A 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.

3.5 **lead:** A 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:** A 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:** An inscription on a device, package, or LABEL.

3.10 **label:** An area bearing a MARKING, affixed to a device or package but not an integral part of the device or package.

3.11 **radioactive substance:** Any substance that contains one or more nuclides, the activity or concentration of which cannot be disregarded as far as radiation protection is concerned.

[Based on 80/836/Euratom]

3.12 **sealed source:** A source containing RADIOACTIVE SUBSTANCES firmly incorporated in solid and effectively inactive materials, or sealed in an inactive container of sufficient strength to prevent, under normal conditions of use, any dispersion of RADIOACTIVE SUBSTANCES.

[Based on 80/836/Euratom]

3.13 **medicinal substance:** Substance which, when used separately, is intended for the treatment or prevention of disease in human beings, or which may be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings.

[Based on Article 1 of Directive 65/65/EEC]

3.14 **harm:** Physical injury or damage to health or property.

3.15 hazard: A potential source of HARM.

3.16 unacceptable hazard: HAZARD where the probability of it causing HARM is greater than a stated value determined by considering the severity of the HARM.

3.17 hazard control: A design feature of an ACTIVE IMPLANTABLE MEDICAL DEVICE intended to ensure that it does not cause an UNACCEPTABLE HAZARD.

3.18 portable (equipment): (Equipment) intended to be moved from one location to another while being used or between periods of use while being carried by one or more persons.

3.19 hand held (equipment): (Equipment) intended to be supported by the hand during normal use.

4 Symbols and abbreviations (optional)

NOTE Requirements may be included in this clause in subsequent Parts of EN 45502. There are no requirements specified in this Part of EN 45502. However this does not preclude the use of symbols defined in other standards nor special symbols defined in the accompanying documentation.

5 General requirements for non-implantable parts

5.1 The non-implantable part of an ACTIVE IMPLANTABLE MEDICAL DEVICE which is connected to or equipped with a power source shall comply with the requirements of EN 60601-1, EN 60601-1-1, EN 60601-1-2 and EN 60601-1-4, unless a requirement in these standards is superseded by a requirement in this Part of EN 45502.

5.2 (Vacant)

NOTE Requirements may be included in this clause in subsequent Parts of EN 45502.

6 (Vacant)

NOTE Requirements may be included in this clause in subsequent Parts of EN 45502. There are no requirements specified in this Part of EN 45502.

7 General arrangement of the packaging

7.1 Implantable parts of ACTIVE IMPLANTABLE MEDICAL DEVICES shall be supplied in A NON-REUSABLE PACK (see 14.1).

NOTE The NON-REUSABLE PACK is designed to be sealed yet allow its contents to be sterilized by the manufacturer.

Compliance shall be checked by inspection.

7.2 The NON-REUSABLE PACK shall be enclosed in the SALES PACKAGING.

Compliance shall be checked by inspection.

8 General markings for active implantable medical devices

NOTE Any MARKING required by this Part of EN 45502, in either figures or letters, may be expressed using appropriate symbols specified in relevant European Standards, e.g. EN 980. (See also clauses 9, 11 and 13.)

8.1 Any warning notices required by this European Standard shall be prominently displayed.

Compliance shall be checked by inspection.

8.2 Implanted parts of devices and components of those parts shall be identified in such a way as to allow any necessary measure to be taken following the discovery of a possible HAZARD in connection with any implanted part.

Compliance shall be checked by review of the manufacturer's explanation of the relationship between the identity of the ACTIVE IMPLANTABLE MEDICAL DEVICE and the identities of its component parts.

9 Markings on the sales packaging

NOTE The SALES PACKAGING may be required to carry other regulatory markings, such as the CE mark of conformity and identification of the notified body authorizing the mark.

9.1 If the SALES PACKAGING contains any RADIOACTIVE SUBSTANCE, it shall have MARKINGS that state the type and activity of the RADIOACTIVE SUBSTANCE.

Compliance shall be checked by inspection.

9.2 The SALES PACKAGING shall bear the name and address of the manufacturer, the address including at least the city and the country.

Compliance shall be checked by inspection.

9.3 The SALES PACKAGING shall bear a description of the device (e.g. cardiac pulse generator), the model designation of the device and, if applicable, the batch number or the serial number of the device.

Compliance shall be checked by inspection.

9.4 The SALES PACKAGING of implantable parts of an ACTIVE IMPLANTABLE MEDICAL DEVICE shall bear any additional information and relevant characteristics, as necessary, to identify the device.

Compliance shall be checked by inspection.

9.5 The SALES PACKAGING of implantable parts of an ACTIVE IMPLANTABLE MEDICAL DEVICE shall bear a statement that the contents of the package have been sterilized.

Compliance shall be checked by inspection.

9.6 The SALES PACKAGING of implantable parts of an ACTIVE IMPLANTABLE MEDICAL DEVICE shall bear the year and month of manufacture, expressed in numerals as specified by ISO 8601 : 1988.

Compliance shall be checked by inspection.

9.7 The SALES PACKAGING of implantable parts of an ACTIVE IMPLANTABLE MEDICAL DEVICE shall bear the 'use before' date, expressed as year and month.

Compliance shall be checked by inspection.

9.8 The markings on the SALES PACKAGING of implantable parts of an ACTIVE IMPLANTABLE MEDICAL DEVICE shall identify the accessories within the packaging or, if there is insufficient space on the SALES PACKAGING, the contents shall be identified within the SALES PACKAGING.

Compliance shall be checked by inspection.

9.9 If the intended use of an implantable part of an ACTIVE IMPLANTABLE MEDICAL DEVICE enclosed within the SALES PACKAGING requires that it be connected to another device or accessory not included in the pack, the SALES PACKAGING shall identify the connector types or configurations required.

Compliance shall be checked by inspection.

9.10 The SALES PACKAGING of implantable parts of an ACTIVE IMPLANTABLE MEDICAL DEVICE shall carry a clear description of the intended use of the device, if this is not obvious from the device description as required by 9.3 and 9.4.

Compliance shall be checked by inspection.

9.11 The SALES PACKAGING shall bear information about any exceptional environmental or handling constraints (for example, protection from impact, vibration, temperature, pressure, or humidity) necessary to allow the devices to be correctly handled and stored (see clause 10).

Compliance shall be checked by inspection.

10 Construction of the sales packaging

10.1 The SALES PACKAGING of an ACTIVE IMPLANTABLE MEDICAL DEVICE shall be constructed to protect the device and to withstand the HAZARDS of dropping (shock), stacking (compression), vibration and temperature that occur during storage or handling as specified by the manufacturer.

Compliance shall be confirmed by inspection and review of records provided by the manufacturer.

10.2 The SALES PACKAGING of an ACTIVE IMPLANTABLE MEDICAL DEVICE shall be sufficiently protected against the effects of humidity during storage or handling to prevent visible deterioration of the packaging, MARKINGS, LABELS or accompanying documentation.

Test: The SALES PACKAGING shall be placed in a test chamber for two days. The temperature of the test chamber shall be stabilized at 30 °C ± 2 °C. The relative humidity in the test chamber shall be 93 % ± 3 %.

Compliance shall be confirmed by examination of the manufacturer's records.

10.3 The markings on the SALES PACKAGING of an ACTIVE IMPLANTABLE MEDICAL DEVICE shall be indelible.

Test: The package shall be placed so that the MARKINGS under test are uppermost and in a horizontal plane. Ten millilitres of water shall be dispensed onto the centre of the area. After one minute, the MARKINGS shall be wiped clear of surface water using a wet, soft cloth.

Compliance shall be confirmed if, after performing the procedure above, all MARKINGS remain clearly legible. If the MARKINGS are on a LABEL, the adhesive fixing the LABEL shall not have loosened and the LABEL shall not have become curled at any edge.

10.4 The SALES PACKAGING shall ensure association between the ACTIVE IMPLANTABLE MEDICAL DEVICE and the accompanying documentary information that defines the purposes and functions of the device and the conditions qualified and specified for its implantation.

Compliance shall be checked by inspection.

11 Markings on the sterile pack

11.1 The STERILE PACK shall bear the name or trade name of the manufacturer, and the address (city and country) of manufacture.

Compliance shall be checked by inspection.

11.2 The STERILE PACK shall bear a statement that the package and its contents have been sterilized and indicate the method of sterilization used (see EN 556 and EN 980).

Compliance shall be checked by inspection.

11.3 The symbol

STERILE

shall be prominently displayed on the STERILE PACK (see EN 980).

Compliance shall be checked by inspection.

11.4 The STERILE PACK shall bear the year and month when the packaged device was manufactured, as required by 9.6.

Compliance shall be checked by inspection.

11.5 The STERILE PACK shall bear the 'use before' date, as required by 9.7.

Compliance shall be checked by inspection.

11.6 The STERILE PACK shall bear a description of the device, as required by 9.3.

Compliance shall be checked by inspection.