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I.S. EN 45502-2-3:2010

Active implantable medical devices -- Part 2-3: Particular requirements for cochlear and auditory brainstem implant systems

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Active implantable medical devices - Part 2-3: Particular requirements for cochlear and auditory brainstem implant systems

Dispositifs médicaux implantables actifs - Partie 2-3: Exigences particulières pour les systèmes d'implant cochléaire et les systèmes d'implant auditif du tronc cérébral

Aktive implantierbare Medizingeräte - Teil 2-3: Besondere Festlegungen für Cochlea-Implantatsysteme und auditorische Hirnstammimplantatsysteme

This European Standard was approved by CEN and CENELEC on 2010-02-01. 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 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 CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

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Foreword

This European Standard was prepared by the CEN/CENELEC Joint Working Group AIMD, Active Implantable Medical Devices. Members of the Joint Working Group were nominated by one of the members of either CEN or CENELEC. The lead has been given to CENELEC.

The text of the draft was submitted to a second formal vote and was approved by CEN and CENELEC as EN 45502-2-3 on 2010-02-01.

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

The following dates were fixed:

- latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2011-02-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 2013-02-01

The requirements of this particular standard supplement or modify those of the General Standard EN 45502-1:1997, *Active implantable medical devices – Part 1: General requirements for safety, marking and information to be provided by the manufacturer*.

This European Standard has been prepared under a mandate 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. See Annexes AA and BB.

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 AA, BB, CC are rationales, providing some further explanation of particular subclauses of this European Standard. All three annexes are informative.

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Introduction

This European Standard specifies particular requirements for those ACTIVE IMPLANTABLE MEDICAL DEVICES that are intended to treat hearing impairment via electrical stimulation (for EXAMPLE COCHLEAR IMPLANT SYSTEMS or AUDITORY BRAINSTEM IMPLANT SYSTEMS), to provide basic assurance of safety for both patients and users.

A COCHLEAR IMPLANT SYSTEM or AUDITORY BRAINSTEM IMPLANT SYSTEM is an ACTIVE IMPLANTABLE MEDICAL DEVICE comprising implantable and NON-IMPLANTABLE PARTS (external parts). The power source may be externally derived or from an internal battery. The IMPLANT SYSTEM is designed to restore hearing via electrical stimulation of the auditory pathways. Externally or internally processed acoustic information is converted to electrical stimulation signals which are delivered via one or more electrodes. The working parameters of the device may be adjusted via a non-implantable accessory.

This European Standard is relevant to all parts of IMPLANT SYSTEMS, including accessories.

The requirements of this European Standard supplement or modify those of EN 45502–1:1997*, Active implantable medical devices – Part 1: General requirements for safety, marking and information to be provided by the manufacturer*, hereinafter referred to as Part 1. The requirements of this European Standard take priority over those of Part 1.

Figures or tables that are additional to those of Part 1 are numbered starting from 101; additional annexes are lettered AA, BB, etc.

1 Scope

This Part 2-3 of EN 45502 specifies requirements that are applicable to those ACTIVE IMPLANTABLE MEDICAL DEVICES that are intended to treat hearing impairment via electrical stimulation of the auditory pathways. Devices which treat hearing impairment via means other than electrical stimulation are not covered by 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 also applicable to NON-IMPLANTABLE PARTS and accessories of the devices (see NOTE 1).

The electrical characteristics of the IMPLANTABLE PART shall be determined by either the appropriate method detailed in this particular standard or by any other method demonstrated to have an accuracy equal to, or better than, the method specified. In the case of dispute, the method detailed in this particular standard shall apply.

NOTE 1 The device that is commonly referred to as an active implantable medical device can 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 part.

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

This clause of Part 1 applies except as follows:

Additional references:

EN ISO 14971 [1)]	2007	Medical devices - Application of risk management to medical devices (ISO 14971:2007)
EN 1593	1999	Non-destructive testing - Leak testing - Bubble emission techniques
EN 13185	2001	Non-destructive testing - Leak testing – Tracer gas method
EN 45502-1	1997	Active implantable medical devices - Part 1: General requirements for safety, marking and information to be provided by the manufacturer
EN 55011 + A2	2007 2007	Industrial, scientific and medical (ISM) radio-frequency equipment - Electromagnetic disturbance characteristics - Limits and methods of measurement (CISPR 11:2003, mod. + A1:2004, mod. + A2:2006)
EN 60068-2-27 [2)]	1993	Basic environmental testing procedures - Part 2: Tests - Test Ea and guidance: Shock (IEC 60068-2-27:1987)
EN 60068-2-31 [3)]	2008	Basic environmental testing procedures - Part 2: Tests - Test Ec: Drop and topple, primarily for equipment-type specimens (IEC 60068-2-31:1969 + A1:1982)

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1) Superseded by EN ISO 14971:2009 "*Medical devices - Application of risk management to medical devices*" (ISO 14971:2007).

2) Will be superseded by EN 60068-2-27:2009 "*Environmental testing - Part 2-27: Tests - Test Ea and guidance: Shock*" (IEC 60068-2-27:2008) at the dow of the latter, i.e. 2012-05-01.