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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

Implants chirurgicaux — Dispositifs médicaux implantables actifs —

Partie 1: Exigences générales pour la sécurité, le marquage et pour les informations à fournir par le fabricant

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 150, *Implants for surgery*, Subcommittee SC 6, *Active implants*.

This second edition cancels and replaces the first edition (ISO 14708-1:2000), which has been technically revised.

ISO 14708 consists of the following parts, under the general title *Implants for surgery — Active implantable medical devices*:

— *Part 1: General requirements for safety, marking and for information to be provided by the manufacturer*

— *Part 2: Cardiac pacemakers*

— *Part 3: Implantable neurostimulators*

— *Part 4: Implantable infusion pumps*

— *Part 5: Circulatory support devices*

— *Part 6: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (including implantable defibrillators)*

— *Part 7: Particular requirements for cochlear implant systems*

NOTE The attention of Member Bodies is drawn to the fact that equipment manufacturers and testing organizations might need a transitional period following publication of a new, amended, or revised ISO publication in which to make products in accordance with the new requirements and to equip them for conducting new or revised tests. It is the recommendation of the committee that the content of this publication not be adopted for mandatory implementation nationally earlier than three years from the date of publication.

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Introduction

This part of ISO 14708 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 part of ISO 14708 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 ISO 14708. A requirement of a particular part of ISO 14708 takes priority over the corresponding requirement of this general part of ISO 14708. Where particular parts of ISO 14708 exist, this general part of ISO 14708 is not intended to be used alone. Special care is required when applying this general part of ISO 14708 alone to ACTIVE IMPLANTABLE MEDICAL DEVICES for which no particular International Standard has yet been published.

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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

1 Scope

This part of ISO 14708 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 parts of ISO 14708.

The tests that are specified in ISO 14708 are type tests and are to be carried out on samples of an ACTIVE IMPLANTABLE MEDICAL DEVICE to show compliance.

This part of ISO 14708 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 ISO 14708 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 ISO 14708, 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.

NOTE 4 The terminology used in this part of ISO 14708 is intended to be consistent with the terminology of ISO/TR 14283:2004.

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.

ISO 8601:2004, *Data elements and interchange formats — Information interchange — Representation of dates and times*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 14155, *Clinical investigation of medical devices for human subjects — Good clinical practice*

ISO 14971:2007, *Medical devices — Application of risk management to medical devices*

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IEC 60068-2-14:2009, *Environmental testing — Part 2-14: Tests — Test N: Change of temperature*

IEC 60068-2-27:2008, *Environmental testing — Part 2-27: Tests — Test Ea and guidance: Shock*

IEC 60068-2-47:2005, *Environmental testing — Part 2-47: Tests — Mounting of specimens for vibration, impact and similar dynamic tests*

IEC 60068-2-64:2008, *Environmental testing — Part 2-64: Tests — Test Fh: Vibration, broadband random and guidance*

IEC 60601-1:2005 + A1:2012, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 62304:2006, *Medical device software — Software life cycle processes*

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 the purposes of this part of ISO 14708, 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 who, explicitly designated by the MANUFACTURER, acts and can be addressed by authorities and bodies instead of the MANUFACTURER with regard to the latter's obligations

3.4
beginning of service
BOS
point at which 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: IEC 62366:2007, 3.7]

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