INTERNATIONAL STANDARD

ISO 14708-1

First edition
2000-11-15

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

Reference number
ISO 14708-1:2000(E)

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 734 10 79
E-mail copyright@iso.ch
Web www.iso.ch

Printed in Switzerland

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this part of ISO 14708 may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

International Standard ISO 14708-1 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*.

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*

Additional parts are under discussion in TC 150.

Annexes A, B and C of this part of ISO 14708 are for information only.

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.

This part of ISO 14708 is based on the fundamental principles in ISO/TR 14283, which closely parallel the essential requirements of the European Directives applicable to medical devices.

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 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 ISO 14708. Special care is required in applying this part of ISO 14708 to active implantable medical devices where no particular standard exists.

The tests that are specified in this part of ISO 14708 are type tests intended to be carried out on samples of a device to show compliance, and are not intended to be used for the routine testing of manufactured products.

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 gas pressure or springs).

This part of ISO 14708 is also applicable to some non-implantable parts and accessories of the devices (see 3.3).

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this part of ISO 14708. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this part of ISO 14708 are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

ISO 8601:1988, *Data elements and interchange formats — Information interchange — Representation of dates and times*.

ISO 11607:1997, *Packaging for terminally sterilized medical devices.*

ISO 14155:1996, *Clinical investigation of medical devices*.

ISO 15223:2000, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied*.

IEC 60068-2-14:1986, *Environmental testing — Part 2: Tests. Test N: Change of temperature*.

IEC 60068-2-32:1990, *Environmental testing — Part 2: Tests. Test Ed: Free fall (Procedure 1)*.

IEC 60068-2-47:1999, *Environmental testing — Part 2-47: Test methods — Mounting of components, equipment and other articles for vibration, impact and similar dynamic tests.*

IEC 60068-2-64:1993, *Environmental testing — Part 2: Test methods — Test Fh: Vibration, broad-band random (digital control) and guidance.*

IEC 60601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety. Amendment 1:1991 and Amendment 2:1995.*

IEC 60601-1-1:1992, *Medical electrical equipment — Part 1: General requirements for safety — 1. Collateral standard: Safety requirements for medical electrical systems.*

IEC 60601-1-2:1993, *Medical electrical equipment — Part 1: General requirements for safety — 2. Collateral standard: Electromagnetic compatibility – Requirements and tests.*

IEC 60601-1-4:1996, *Medical electrical equipment — Part 1: General requirements for safety — 4. Collateral standard: Programmable electrical medical systems.*

IEC 60601-2-27:1994, *Medical electrical equipment — Part 2: Particular requirements for the safety of electrocardiographic monitoring equipment*.

IEC 61000-4-2:1995, *Electromagnetic compatibility (EMC) — Part 4: Testing and measurement techniques — Section 2: Electrostatic discharge immunity test. Basic EMC Publication.*

3 Terms and definitions

For the purposes of this part of ISO 14708, the following terms and definitions apply.

3.1
medical device
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
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 in place after the procedure

NOTE For purposes of this part of ISO 14708, 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, 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.