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

Contents

Page

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.

3.4
catheter
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
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
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
inscription on a device, package or label

3.10
label
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 whose activity or concentration cannot be disregarded as far as radiation protection is concerned

3.12
sealed source
source containing radioactive substances which is firmly incorporated in solid and effectively inactive materials or is sealed in an inactive container of sufficient strength to prevent, under normal conditions of use, any dispersion of radioactive substances

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

3.14
harm
physical injury or damage to health or property

3.15
hazard
potential source of harm

3.16
unacceptable hazard
hazard whose probability of causing harm is greater than a stated value determined by considering the severity of the harm

3.17
hazard control
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 abbreviated terms

When appropriate, symbols, abbreviated terms and identification colour may be used in the markings and accompanying documents of an active implantable medical device. Symbols, abbreviated terms and identification colour shall conform to published International Standards and conventions (e.g. ISO 15223). Where no standard exists, the symbols, abbreviated terms and identification colour shall be described in the accompanying documentation.

Compliance shall be checked by inspection.

NOTE Symbols for use with particular active implantable medical devices may be specified in subsequent parts of ISO 14708.

5 General requirements for non-implantable parts

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 IEC 60601-1, IEC 60601-1-1, IEC 60601-1-2 and IEC 60601-1-4, unless a requirement in these standards is superseded by a requirement in this part of ISO 14708.

NOTE 1 IEC 60601-1 is applied here as it would be for an electromedical device for which there is no particular standard. Specific sections of IEC 60601-1 are cited in the requirements of this part of ISO 14708 where they address a fundamental principle in ISO/TR 14283.

NOTE 2 Requirements for non-implantable parts of particular active implantable medical devices may be specified in subsequent parts of ISO 14708.

6 Requirements for particular active implantable medical devices

Requirements for particular active implantable medical devices are not detailed in this part of ISO 14708, but they may be specified in subsequent parts of ISO 14708.

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).

The non-reusable pack should be 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 See also 4.

8.1 Any warning notices required by this part of ISO 14708 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

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 manufacturer's name and 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.

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.

9.12 If the device is intended for a special purpose, the sales package shall bear an indication of the special purpose (e.g., “custom-made device” or “exclusively for clinical investigations”).

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: Place the sales packaging 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: Place the package so that the markings under test are uppermost and in a horizontal plane. Dispense 10 ml of water onto the centre of the area. After 1 min, wipe the markings 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 ISO 15223 for recommended symbols).

Compliance shall be checked by inspection.

11.3 The symbol

in accordance with ISO 15223 shall be prominently displayed on the sterile pack.

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.

11.7 The markings on the sterile pack shall identify the contents, unless the sterile pack is transparent and the contents are visible.

Compliance shall be checked by inspection.

11.8 If the intended use of a device enclosed in a sterile pack requires that it be connected to other devices or accessories not included in the sterile pack, the sterile pack shall identify the connector types or configurations, as required by 9.9.