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Icke aktiva kirurgiska implantat – Allmänna krav (ISO 14630:2008)

Non-active surgical implants – General requirements (ISO 14630:2008)

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Denna standard ersätter SS-EN ISO 14630:2005.

The European Standard EN ISO 14630:2008 has the status of a Swedish Standard. This document contains the official English version of EN ISO 14630:2008.

This standard supersedes the Swedish Standard SS-EN ISO 14630:2005.

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EUROPEAN STANDARD

EN ISO 14630

NORME EUROPÉENNE

EUROPÄISCHE NORM

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Supersedes EN ISO 14630:2005

English Version

Non-active surgical implants - General requirements (ISO 14630:2008)

Implants chirurgicaux non actifs - Exigences générales
(ISO 14630:2008)

Nichtaktive chirurgische Implantate - Allgemeine
Anforderungen (ISO 14630:2008)

This European Standard was approved by CEN on 12 January 2008.

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Contents

Page

Foreword.....	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	2
4 Intended performance	3
5 Design attributes.....	4
6 Materials	5
7 Design evaluation	5
7.1 General.....	5
7.2 Pre-clinical evaluation	5
7.3 Clinical evaluation	6
7.4 Post-market surveillance	6
8 Manufacture.....	6
9 Sterilization.....	6
9.1 General.....	6
9.2 Products supplied sterile.....	6
9.3 Sterilization by the user	7
9.4 Sterilization residuals.....	7
10 Packaging	7
10.1 Protection from damage in storage and transport.....	7
10.2 Maintenance of sterility in transit.....	8
11 Information supplied by the manufacturer	8
11.1 General.....	8
11.2 Labelling	9
11.3 Instructions for use	9
11.4 Restrictions on combinations	11
11.5 Marking on implants	11
11.6 Marking for special purposes.....	11
Annex A (informative) Correspondence between this International Standard and ISO/TR 14283:2004.....	12
Annex ZA (informative)	13
Bibliography	14

Foreword

This document (EN ISO 14630:2008) has been prepared by Technical Committee ISO/TC 150 "Implants for surgery" in collaboration with Technical Committee CEN/TC 285 "Non-active surgical implants" the secretariat of which is held by DIN.

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of an identical text or by endorsement, at the latest by July 2008, and conflicting national standards shall be withdrawn at the latest by July 2008.

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

This document supersedes EN ISO 14630:2005.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EC Directive(s).

For relationship with EC Directive(s), see informative Annex ZA, which is an integral part of this document.

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Endorsement notice

The text of ISO 14630:2008 has been approved by CEN as a EN ISO 14630:2008 without any modification.

Introduction

This International Standard provides a method of addressing the fundamental principles outlined in ISO/TR 14283, as they apply to non-active surgical implants. It also provides a method to demonstrate compliance with the relevant essential requirements as outlined in general terms in Annex 1 of the European Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, as they apply to non-active surgical implants, hereafter referred to as implants. It might also assist manufacturers to comply with the requirements of other regulatory bodies.

There are three levels of standards dealing with non-active surgical implants and related instrumentation. For the implants themselves these are as follows, with level 1 being the highest:

- level 1: general requirements for non-active surgical implants;
- level 2: particular requirements for families of non-active surgical implants;
- level 3: specific requirements for types of non-active surgical implants.

Level 1 standards, such as this International Standard and reference [4] in the Bibliography, contain requirements that apply to all non-active surgical implants. They also anticipate that there are additional requirements in the level 2 and level 3 standards.

Level 2 standards (e.g. references [5] – [9] in the Bibliography) apply to a more restricted set or family of non-active surgical implants, such as those designed for use in neurosurgery, cardiovascular surgery, or joint replacement.

Level 3 standards (e.g. references [10] – [13] in the Bibliography) apply to specific types of implants within a family of non-active surgical implants, such as hip joints or arterial stents.

To address all requirements for a specific implant, it is advisable that the standard of the lowest available level be consulted first.

NOTE The requirements in this International Standard correspond to international consensus. Individual or national standards or regulatory bodies can prescribe other requirements.

Non-active surgical implants — General requirements

1 Scope

This International Standard specifies general requirements for non-active surgical implants, hereafter referred to as implants. This International Standard is not applicable to dental implants, dental restorative materials, transendodontic and transradicular implants, intra-ocular lenses and implants utilizing viable animal tissue.

With regard to safety, this International Standard gives requirements for intended performance, design attributes, materials, design evaluation, manufacture, sterilization, packaging and information supplied by the manufacturer, and tests to demonstrate compliance with these requirements. Additional tests are given or referred to in level 2 and level 3 standards.

NOTE This International Standard does not require that the manufacturer have a quality management system in place. However, the application of a quality management system, such as that described in ISO 13485, could be appropriate to help ensure the implant achieves its intended performance.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 31 (all parts), *Quantities and units*

ISO 8601, *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 system*

ISO 10993-7, *Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals*

ISO 11135-1, *Sterilization of health care products — Ethylene oxide — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 11137-1, *Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 11137-2, *Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose*

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

ISO 13408-1, *Aseptic processing of health care products — Part 1: General requirements*

ISO 14155-1, *Clinical investigation of medical devices for human subjects — Part 1: General requirements*

ISO 14155-2, *Clinical investigation of medical devices for human subjects — Part 2: Clinical investigation plans*

SS-EN ISO 14630:2008 (E)

ISO 14160, *Sterilization of single-use medical devices incorporating materials of animal origin — Validation and routine control of sterilization by liquid chemical sterilants*

ISO 14937, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*

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

ISO 17664, *Sterilization of medical devices — Information to be provided by the manufacturer for the processing of resterilizable medical devices*

ISO 17665-1, *Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 22442-1, *Medical devices utilizing animal tissues and their derivatives — Part 1: Application of risk management*

ISO 22442-2, *Medical devices utilizing animal tissues and their derivatives — Part 2: Controls on sourcing, collection and handling*

ISO 22442-3, *Medical devices utilizing animal tissues and their derivatives — Part 3: Validation of the elimination and/or inactivation of viruses and transmissible spongiform encephalopathy (TSE) agents*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1

coating

layer of material covering or partially covering a surface of an implant

3.2

implantable state

condition of an implant prepared for implantation into a human subject

3.3

leakage

unintended movement of fluid, including body fluids, into or out of an implant

NOTE An unintended diffusion phenomenon is an example of leakage for the purposes of this International Standard.

3.4

magnetic resonance environment

MR environment

volume within the 0,50 mT [5 gauss (G)] line of a magnetic resonance imaging (MRI) system, which includes the entire three-dimensional volume surrounding the magnetic resonance imaging scanner

[ASTM F2503-05¹⁾, definition 3.1.7]

NOTE For cases where the 0,50 mT line is contained within the Faraday shielded volume, the entire room is considered the MR environment. For cases where the 0,50 mT line is outside the Faraday shielded volume (e.g. in the adjacent room or area), it is advisable that the entire adjacent room or area be considered part of the MR environment.

1) Definitions for magnetic resonance environment and magnetic resonance imaging are reproduced from ASTM F2503-05 and ASTM F2119-01 respectively, copyright ASTM. Reproduced with permission of ASTM International, <http://www.astm.org/>.

3.5

magnetic resonance imaging

MRI

diagnostic imaging technique that uses static and time varying magnetic fields to provide images of tissue by the magnetic resonance of nuclei

[ASTM F2119-01 ¹⁾, definition 2.1.4]

3.6

non-active surgical implant

surgical implant, the operation of which does not depend on a source of electrical energy or any source of power other than that directly generated by the human body or gravity

3.7

safety

freedom from unacceptable risk

[ISO/IEC Guide 51:1999, definition 3.1]

3.8

surgical implant

device that is intended to be totally introduced into the human body, or to replace an epithelial surface or the surface of the eye, by means of surgical intervention and that is intended to remain in place after the procedure, or any medical device that is intended to be partially introduced into the human body by means of surgical intervention and that is intended to remain in place after the procedure for at least 30 days

4 Intended performance

The intended performance of an implant shall be described and documented by addressing the following, with particular regard to safety:

- a) intended purpose(s);
- b) functional characteristics;
- c) intended conditions of use;
- d) intended lifetime.

NOTE For this purpose, it is advisable that particular account be taken of

- published standards,
- published clinical and scientific literature, and
- validated test results.