SVENSK STANDARD
SS-EN ISO 14630:2012

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Icke aktiva kirurgiska implantat – Allmänna krav (ISO 14630:2012)

Non-active surgical implants – General requirements (ISO 14630:2012)

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Europastandarden EN ISO 14630:2012 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN ISO 14630:2012.

Denna standard ersätter SS-EN ISO 14630:2009, utgåva 4.

The European Standard EN ISO 14630:2012 has the status of a Swedish Standard. This document contains the official version of EN ISO 14630:2012.

This standard supersedes the Swedish Standard SS-EN ISO 14630:2009, edition 4.

Upplysningar om sakinnehållet i standarden lämnas av SIS, Swedish Standards Institute, telefon 08-555 520 00. Standarder kan beställas hos SIS Förlag AB som även lämnar allmänna upplysningar om svensk och utländsk standard.

Information about the content of the standard is available from the Swedish Standards Institute (SIS), telephone +46 8 555 520 00. Standards may be ordered from SIS Förlag AB, who can also provide general information about Swedish and foreign standards.

Denna standard är framtagen av kommittén för Implantat, SIS/TK 340/AG i.

Har du synpunkter på innehållet i den här standarden, vill du delta i ett kommande revideringsarbete eller vara med och ta fram andra standarder inom området? Gå in på www.sis.se - där hittar du mer information.

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 14630

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Supersedes EN ISO 14630:2009

English Version

Non-active surgical implants - General requirements (ISO 14630:2012)

Implants chirurgicaux non actifs - Exigences générales (ISO 14630:2012)

Nichtaktive chirurgische Implantate - Allgemeine Anforderungen (ISO 14630:2012)

This European Standard was approved by CEN on 30 November 2012.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: Avenue Marnix 17, B-1000 Brussels

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Foreword

This document (EN ISO 14630:2012) 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 June 2013, and conflicting national standards shall be withdrawn at the latest by June 2013.

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 14630:2009.

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 EU Directive(s).

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

According to the CEN/CENELEC Internal Regulations, the national standards organisations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 14630:2012 has been approved by CEN as a EN ISO 14630:2012 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 for demonstrating compliance with the relevant essential requirements as outlined in the 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 help manufacturers 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, they 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], 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 (see References [5], [6], [7], [8] and [9]) 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 (see References [10], [11], [12] and [13]) 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 specifies 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, might be appropriate to help ensure that 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 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 process*

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

ISO 14160, *Sterilization of health care products — Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives — Requirements for characterization, development, validation and routine control of a sterilization process for medical devices*

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*

ISO 80000 (all parts), *Quantities and units*

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 1 to entry: 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

NOTE 1 to entry: 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.

[SOURCE: ASTM F2503-05, 3.1.7, modified — the second sentence has been converted into a note.]

3.5
magnetic resonance imaging
MRI
imaging technique that uses static and time varying magnetic fields to provide images of tissue by the magnetic resonance of nuclei

[SOURCE: ASTM F2119-07, 2.1.4]

3.6
non-active surgical implant
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

[SOURCE: ISO/IEC Guide 51:1999, 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 To describe the intended performance, it is advisable that particular account be taken of the following, among other things:

— published standards,

— published clinical and scientific literature, and

— validated test results.

5 Design attributes

The design attributes to meet the intended performance shall take into account at least the following:

a) materials and their biocompatibility (see Clause 6);

b) physical, mechanical and chemical properties of materials, including endurance properties and ageing (see Clauses 6 and 7);

c) wear characteristics of materials and the effects of wear and wear products on the implant and the body (see Clauses 6 and 7);

d) degradation characteristics of materials, and the effects of degradation, degradation products and leachables on the implant and the body (see Clauses 6 and 7);

e) the extent and effect of leakage (see Clauses 6 and 7);

f) safety, with respect to viruses and other transmissible agents (unclassified pathogenic entities, prions and similar entities), of animal tissues or derivatives of animal tissue utilized in the implant or during its manufacture (see Clause 6);

g) the effect of manufacturing processes (including sterilization) on material characteristics and performance (see Clauses 6, 7, 8 and 9);

h) possible effects on the implant and its function due to interactions between its constituent materials and between its constituent materials and other materials and substances (see Clauses 6 and 7);

i) interconnections and their effects on the intended performance (see Clause 7);

NOTE It is advisable that the shape, dimensions and tolerances of the interconnections, as well as the potential wear, degradation, corrosion and electrolytic effects, be taken into account.