Mitteaktiivsed kirurgilised implantaadid. Üldnõuded

Non-active surgical implants - General requirements

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 14630:2009 sisaldab Euroopa standardi EN ISO 14630:2009 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 14630:2009 consists of the English text of the European standard EN ISO 14630:2009.
Standard on kinnitatud Eesti Standardikeskuse 30.10.2009 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 30.10.2009 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 13.05.2009.	Date of Availability of the European standard text 13.05.2009.
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.

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EUROPEAN STANDARD

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EN ISO 14630

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Supersedes EN ISO 14630:2008

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 19 April 2009.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN Management Centre has the same status as the official versions.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: Avenue Marnix 17, B-1000 Brussels

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Foreword

The text of ISO 14630:2008 has been prepared by Technical Committee ISO/TC 150 “Implants for surgery” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 14630:2009 by 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 November 2009, and conflicting national standards shall be withdrawn at the latest by March 2010.

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 14630:2008.

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.

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

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

Endorsement notice

The text of ISO 14630:2008 has been approved by CEN as a EN ISO 14630:2009 without any modification.

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 93/42/EEC

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide a means of conforming to Essential Requirements of the New Approach Directive 93/42/EEC on medical devices.

Once this standard is cited in the Official Journal of the European Communities under that Directive and has been implemented as a national standard in at least one Member State, compliance with the clauses of this standard given in table ZA confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

Table ZA — Correspondence between this European Standard and Directive 93/42/EEC

Clause(s)/sub-clause(s) of this EN	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
4	1 - 2 – 3 - 4 – 5- 7. 1	
5	1 - 2 - 3 - 4 - 5 - 7.1 - 7.2 - 7.3 - 7.5 - 7.6 - 8 - 9.1 - 9.2	Part of ER 1 relating to risk of use error is not addressed by this European Standard.
6	1 - 2 - 7.1 - 7.2 - 7.3 - 7.4 - 7.5 - 8.2 - 9.2	
7	1 - 2 - 3 - 4 - 6 -6.a - 7.1 - 7.2 - 7.3 - 7.5 - 7.6 - 8 - 9.1 - 9.2 -	Part of ER 7.1 relating to the results of biophysical or modelling research is not explicitly addressed by this European Standard.
8	1 - 2 - 3 - 5 - 7.1 - 7.2	
9	1 - 2 - 7.2 - 8.1 - 8.3 - 8.4 - 8.5	
10	1 - 2 - 3 - 5 - 7.2 - 8.3 - 8.6	

11	1 - 2 - 8.7 - 13	The part of ER 13.3.a concerning the information on the authorized representative is not addressed in this European Standard ER: 13.3 f) is only partially addressed: Safety issue is addressed, but not the regulatory requirement (consistency around Europe). ER: 13.6.h) relating to single use is not addressed by this European Standard. ER 13.6 q) is not addressed by this European Standard.

WARNING — Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

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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*

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 F2503-05 [1)], 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/.