Mitteaktiivsed kirurgilised implantaadid. Üldnõuded

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

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 14630:2012 sisaldab Euroopa standardi EN ISO 14630:2012 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 14630:2012 consists of the English text of the European standard EN ISO 14630:2012.
Standard on kinnitatud Eesti Standardikeskuse 31.12.2012 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 31.12.2012 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 01.12.2012.	Date of Availability of the European standard text 01.12.2012.
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.

ICS 11.040.40

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 14630

December 2012

ICS 11.040.40

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.

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-CENELEC 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-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of 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 United Kingdom.

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

Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN ISO 14630:2012: E

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.

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 Union 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.1 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.1 — Correspondence between this European Standard and Directive 93/42/EEC

Clause(s)/sub-clause(s) of this European Standard	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
4	1, 2nd indent	
4, 5, 8 and 10	5	
7.1 and 7.2	6a	
5 a), 5 l), 6 a) and 6 b)	7.1, 1st indent	
5 a), 6 a) and 6 b)	7.1, 2nd indent	
7.2 c)	7.1, 3rd indent	
5 f), 5 r), 7, 8 and 10	7.2	
5 h) and 6	7.3	
6	7.4	
5 d), 5 e) and 6	7.5	
5 b), 5 f), 5 m) and 6	7.6	
5 q), 6, 8, 9.1 and 10.1	8.1	
6	8.2	
10.2	8.3	
9.2	8.4	
5 g), 8 and 9.3	8.5	
9.1 and 10.1	8.6	
11.2 f) and 11.3 j)	8.7	
5 i), 5 j) and 11.4	9.1	
5 b), 5 k), 6 and 7.1	9.2, 1st indent	
5 n), 6 and 7.1	9.2, 2nd indent	
5 n)	9.2, 3rd indent	
5 c), 5 d) and 6	9.2, 4th indent	
11.1, 11.2, 11.3 b), g), h) and 11.5	13.1	

Clause(s)/sub-clause(s) of this European Standard	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
11.1	13.2	
11.2 b)	13.3 a)	
11.2 c) and 11.2 d)	13.3 b)	
11.2 e)	13.3 c)	
11.2 c)	13.3 d)	
11.2 g)	13.3 e)	
11.2 h)	13.3 f)	
11.6	13.3 g)	
11.6	13.3 h)	
10.1 and 11.2 j)	13.3 i)	
11.2 j)	13.3 j)	
11.2 k)	13.3 k)	
11.2 e)	13.3 m)	
11.2 d) and 11.3 d)	13.4	
4 and 11.2 c)	13.5	
11.3 b), c), d), i), m), n) and 11.6	13.6 a)	
11.3 e)	13.6 b)	
11.3 f) and 11.4	13.6 c)	
11.3 h)	13.3 d)	
11.3 g) and o)	13.6 e)	
11.3 q), r) and t), Indent 5	13.6 f)	
9.3.2, 10.2 and 11.3 l)	13.6 g)	
9.3 and 11.2 k)	13.6 i)	
11.3 a)	13.6 j)	
11.3 b) and t), Indent 3	13.6 k)	
11.3 t), Indents 1, 2 and 4	13.6 l)	
11.3 t), Indent 6	13.6 m)	
11.3 s)	13.6 n)	
11.3 u)	13.6 q)	

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

Contents

Page

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*

