Südame-veresoonkonna implantaadid. Soonesisesed vahendid. Osa1: Soonesisesed proteesid

Cardiovascular implants - Endovascular devices - Part 1: Endovascular prostheses

EESTI STANDARDIKESKUS
ESTONIAN CENTRE FOR STANDARDISATION

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 25539-1:2009 sisaldab Euroopa standardi EN ISO 25539-1:2009 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 25539-1:2009 consists of the English text of the European standard EN ISO 25539-1:2009.
Standard on kinnitatud Eesti Standardikeskuse 31.08.2009 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 31.08.2009 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 06.05.2009.	Date of Availability of the European standard text 06.05.2009.
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.

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English Version

Cardiovascular implants - Endovascular devices - Part 1: Endovascular prostheses (ISO 25539-1:2003 including Amd 1:2005)

Implants cardiovasculaires - Dispositifs endovasculaires - Partie 1: Prothèses endovasculaires (ISO 25539-1:2003, Amd 1:2005 inclus)

Kardiovaskuläre Implantate - Endovaskuläre Implantate - Teil 1: Endovaskuläre Prothesen (ISO 25539-1:2003, einschließlich Amd 1:2005)

This European Standard was approved by CEN on 19 April 2009.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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Ref. No. EN ISO 25539-1:2009: E

Foreword

The text of ISO 25539-1:2003, including Amd 1:2005 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 25539-1:2009 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of an identical text or by endorsement, at the latest by November 2009, and conflicting national standards shall be withdrawn at the latest by March 2010.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 25539-1:2008.

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 EU Directive.

For relationship with EU 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 25539-1:2003, including Amd 1:2005 has been approved by CEN as a EN ISO 25539-1:2009 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 - 7.1	
5	1 - 2 - 3 - 4 - 5 - 7.1 - 7.2 - 7.3 - 7.5 - 7.6 - 8 - 9.1 - 9.2	
6	1 - 2 - 7.1 - 7.2 - 7.3 - 7.4 - 7.5 - 7.6 - 8.2 - 9.2	ER 7.4 includes a mandatory consultation of regulatory authorities in relation to medicinal substances that is not addressed in this European Standard.
7	1 - 2 - 3 - 4 - 6 - 6a. - 7.1 - 7.2 - 7.3 - 7.5 - 7.6 - 8 - 9.1 - 9.2	
8	1 - 2 - 3 - 5 - 7.1 - 7.2	
9	1 - 2 - 7.2 - 8.1 - 8.2 - 8.3 - 8.4	
10.1	1 - 2 - 3 - 5 - 7.2 - 7.3 - 7.4 - 7.6 - 8.3 - 8.4	ER 7.4 includes a mandatory consultation of regulatory authorities in relation to medicinal substances that is not addressed in this European Standard.

10.2 - 10.3	1 - 2 - 8.7 - 9.1 - 13	The part of ER 13.3.a concerning the information of the authorized representative is not addressed in this European Standard. Part of ER 13.3 f relating to single use is not addressed in this European Standard. Part of ER 13.6 h) relating to single use is not addressed in 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 part of ISO 25539 has been prepared in order to provide minimum requirements for endovascular prostheses and the methods of test that will enable their evaluation. It is the first part of a proposed three-part International Standard. ISO/TS 15539, from which this part of ISO 25539 is derived, serves as a rationale for the requirements. The Technical Specification was developed by first identifying the design requirements for endovascular implants and listing the potential implant and clinical failure modes. Tests were then identified to address each of the failure modes. The requirements provided in this part of ISO 25539 are based on that assessment.

Due to the variations in the design of implants covered by this part of ISO 25539 and in some cases due to the relatively recent development of some of these implants, acceptable standardized *in vitro* tests and clinical results are not always available. As further scientific and clinical data become available, appropriate revision of this part of ISO 25539 will be undertaken.

Cardiovascular implants — Endovascular devices —

Part 1: Endovascular prostheses

1 Scope

1.1 This part of ISO 25539 specifies requirements for endovascular prostheses, based upon current medical knowledge. With regard to safety, it gives requirements for intended performance, design attributes, materials, design evaluation, manufacturing, sterilization packaging and information supplied by the manufacturer. It should be considered as a supplement to ISO 14630, which specifies general requirements for the performance of non-active surgical implants.

1.2 This part of ISO 25539 is applicable to endovascular prostheses used to treat arterial aneurysms, arterial stenoses, or other appropriate vascular abnormalities.

1.3 This part of ISO 25539 is applicable to delivery systems if they comprise an integral component of the deployment of the endovascular prostheses.

1.4 This part of ISO 25539 is not applicable to vascular occluders, with the exception of contra-lateral iliac occluders when used as an integral part of an aorto-uni-iliac device. See ISO 14630 for excluded products.

1.5 This part of ISO 25539 is not applicable to procedures and devices used prior to the introduction of the endovascular system (defined in 3.6), such as balloon angioplasty devices.

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 7198:1998, *Cardiovascular implants — Tubular vascular prostheses*

ISO 11134:1994, *Sterilization of health care products — Requirements for validation and routine control — Industrial moist heat sterilization*

ISO 11135:1994, *Medical devices — Validation and routine control of ethylene oxide sterilization*

ISO 11137:1995, *Sterilization of health care products — Requirements for validation and routine control — Radiation sterilization*

ISO 10993 (all parts), *Biological evaluation of medical devices*

ISO 11607:1997, *Packaging for terminally sterilized medical devices*

ISO 13485, *Medical devices — Quality management systems — Requirements for regulatory purposes*

ISO 13488:1996, *Quality systems — Medical devices — Particular requirements for the application of ISO 9002*

ISO 14155 (all parts), *Clinical investigation of medical devices for human subjects*

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

ISO 14630:1997, *Non-active surgical implants — General requirements*

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 14971:2000, *Medical devices — Application of risk management to medical devices*