Südame-veresoonkonna implantaadid. Südameklapiproteesid

Cardiovascular implants - Cardiac valve prostheses

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 5840:2009 sisaldab Euroopa standardi EN ISO 5840:2009 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 5840:2009 consists of the English text of the European standard EN ISO 5840:2009.
Standard on kinnitatud Eesti Standardikeskuse 30.11.2009 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 30.11.2009 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

NORME EUROPÉENNE

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EN ISO 5840

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English Version

Cardiovascular implants - Cardiac valve prostheses (ISO 5840:2005)

Implants cardiovasculaires - Prothèses valvulaires (ISO 5840:2005)

Herz- und Gefäßimplantate - Herzklappenprothesen (ISO 5840:2005)

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

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Ref. No. EN ISO 5840:2009: E

Foreword

The text of ISO 5840:2005 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 5840:2009 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 5840:2005.

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.

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 5840:2005 has been approved by CEN as a EN ISO 5840:2009 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
5	1, 2, 3, 6	
6.1	1, 3	
6.2.1 and 6.2.2	3, 4	Procedure for quality system (design input) aiming at supporting general ERs 3 and 4.
6.2.3 with annex P	3, 5, 8.1, 8.3	
6.2.3 with annex Q	13.1, 13.3, 13.4, 13.5, 13.6	The part of ER 13.3 a) relating to authorised representative is not addressed in this European Standard. ER 13.3.f) is only partly addressed in this European Standard: safety issue concerning single use. The part of ER 13.6.h) relating to single use is not addressed in this European Standard. ER 13.6.o) is not addressed in this European Standard. ER 13.6.q) is not addressed in this European Standard.
6.2.3 with annex S	8.1, 8.3, 8.4	
6.3 and 6.4		Elements of procedure for Quality system aiming at supporting all safety and performance ERs
6.5		Elements of procedure for risk management

7.1, 7.2.1		Elements of procedure for quality system aiming at supporting all safety and performance ERs
7.2.2	1, 7.1, 8.2, 9.2, 12.7.1	
7.2.3	3, 4	
7.2.4	3, 4, 9.2, 12.7.1	
7.3	1, 6	Preclinical *in vivo* evaluation also aims at reducing the risks for human subjects undergoing clinical investigations
7.4 with annex R	6.a	

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

Contents

Page

Introduction

There is, as yet, no heart valve substitute that can be regarded as ideal.

This International Standard has been prepared by a group well aware of the problems associated with heart valve substitutes and their development. In several areas, the provisions of this International Standard have been deliberately left open as there has been no wish to inhibit development and innovation. It does specify types of tests, test methods and/or requirements for test apparatus, and requires documentation of test methods and results. The areas with which this International Standard is concerned are those which will ensure that associated risks to the patient and other users of the device have been adequately mitigated, facilitate quality assurance, aid the surgeon in choosing a heart valve substitute, and ensure that the device will be presented at the operating table in a convenient form. Emphasis has been placed on specifying types of *in vitro* testing, on preclinical *in vivo* and clinical evaluations, on reporting of all *in vitro*, preclinical *in vivo* and clinical evaluations and on the labelling and packaging of the device. Such a process involving *in vitro*, preclinical *in vivo* and clinical evaluations is intended to clarify the required procedures prior to market release and to enable prompt identification and management of any subsequent problems.

With regard to *in vitro* testing and reporting, apart from basic material testing for mechanical, physical, chemical and biocompatibility characteristics, this International Standard also covers important hydrodynamic and durability characteristics of heart valve substitutes. The exact test methods for hydrodynamic and durability testing have not been specified, but guidelines for the test apparatus are given.

This International Standard is incomplete in several areas. It is intended to be revised, updated, and/or amended, as knowledge and techniques in heart valve substitute technology improve.

Annexes A to S provide supplementary information, the content of Annexes P to S being necessary for the application of this International Standard.

Cardiovascular implants — Cardiac valve prostheses

1 Scope

1.1 This International Standard is applicable to all devices intended for implantation in human hearts, as a heart valve substitute.

1.2 This International Standard is applicable to both newly developed and modified heart valve substitutes and to the accessory devices, packaging and labelling required for their implantation and for determining the appropriate size of heart valve substitute to be implanted.

1.3 This International Standard outlines an approach for qualifying the design and manufacture of a heart valve substitute through risk management. The selection of appropriate qualification tests and methods are derived from the risk assessment. The tests may include those to assess the physical, chemical, biological and mechanical properties of heart valve substitutes and of their materials and components. The tests may also include those for pre-clinical *in vivo* evaluation and clinical evaluation of the finished heart valve substitute.

1.4 This International Standard imposes design specifications and minimum performance specifications for heart valve substitutes where adequate scientific and/or clinical evidence exists for their justification.

1.5 This International Standard excludes heart valve substitutes designed for implantation in artificial hearts or heart assist devices.

NOTE A rationale for the provisions of this International Standard is given in Annex A.

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 8601:2000, *Data elements and interchange formats — Information interchange — Representation of dates and times*

ISO 10993-1:1997, *Biological evaluation of medical devices — Part 1: Evaluation and testing*

ISO 10993-2:1992, *Biological evaluation of medical devices — Part 2: Animal welfare requirements*

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 11607:2003, *Packaging for terminally sterilized medical devices*

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

ISO 14155-1:2003, *Clinical investigation of medical devices for human subjects — Part 1: General requirements*

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:—[1)], *Non-active surgical implants — General requirements*

ISO 14937:2000, *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*

EN 12442-1, *Animal tissues and their derivatives utilized in the manufacture of medical devices — Part 1: Analysis and management of risk*

EN 12442-2, *Animal tissues and their derivatives utilized in the manufacture of medical devices — Part 2: Controls on sourcing, collection and handling*

EN 12442-3, *Animal tissues and their derivatives utilized in the manufacture of medical devices — Part 3: Validation of the elimination and/or inactivation of viruses and transmissible agents*

Guidelines for reporting morbidity and mortality after cardiac valvular operations, American Association for Thoracic Surgery, European Association for Cardiothoracic Surgery, Society of Thoracic Surgeons, *Annals of Thoracic Surgery*, **62**, pp. 932-935, 1996

3 Terms and definitions

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

3.1
accessories
device-specific tools that are required to assist in the implantation of the heart valve substitute

3.2
actuarial
statistical technique for estimating survival curves prior to the death of the last member of a cohort

NOTE Some examples are the “Kaplan-Meier” technique and the “life-table” technique.

3.3
anticoagulant-related haemorrhage
internal or external bleeding that causes death or stroke, or that requires transfusion, operation or hospitalization

NOTE This definition is restricted to patients who are receiving anticoagulants and/or antiplatelet drugs, and excludes minor bleeding events.

3.4
arterial diastolic pressure
minimum value of the arterial pressure during diastole

3.5
arterial peak systolic pressure
maximum value of the arterial pressure during systole

1) To be published. (Revision of ISO 14630:1997)