



SLOVENSKI STANDARD SIST EN ISO 5840:2009

01-julij-2009

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SIST EN ISO 5840:2006

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

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

Implants cardiovasculaires - Prothèses valvulaires (ISO 5840:2005)

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Ta slovenski standard je istoveten z: EN ISO 5840:2009

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ICS:

11.040.40	Implantanti za kirurgijo, protetiko in ortetiko	Implants for surgery, prosthetics and orthotics
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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 5840

May 2009

ICS 11.040.40

Supersedes EN ISO 5840:2005

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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COMITÉ EUROPÉEN DE NORMALISATION
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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of an identical text or by endorsement, at the latest by November 2009, and conflicting national standards shall be withdrawn at the latest by March 2010.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.

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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 <i>in vivo</i> 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.

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INTERNATIONAL STANDARD

**ISO
5840**

Fourth edition
2005-03-01

Cardiovascular implants — Cardiac valve prostheses

Implants cardiovasculaires — Prothèses valvulaires

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Reference number
ISO 5840:2005(E)

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 5840 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 2, *Cardiovascular implants and extracorporeal systems*.

This fourth edition cancels and replaces the third edition (ISO 5840:1996), which has been technically revised to include risk management.

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ISO 5840:2005(E)**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*