

SLOVENSKI STANDARD

SIST EN ISO 5840-2:2015

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Nadomešča:

SIST EN ISO 5840:2009

Vsadki (implantati) za srce in ožilje - Proteze za srčno zaklopko - 2. del: Kirurško vsajeni (implantirani) nadomestki srčne zaklopke (ISO 5840-2:2015)

Cardiovascular implants - Cardiac valve prostheses - Part 2: Surgically implanted heart valve substitutes (ISO 5840-2:2015)

Herz- und Gefäßimplantate - Herzklappenprothesen - Teil 2: Chirurgisch implantierter Herzklappenersatz (ISO 5840-2:2015)

Implants cardiovasculaires - Prothèses valvulaires - Partie 2: Prothèse valvulaires implantées chirurgicalement (ISO 5840-2:2015)

Ta slovenski standard je istoveten z: EN ISO 5840-2:2015

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 5840-2

September 2015

ICS 11.040.40

Supersedes EN ISO 5840:2009

English Version

**Cardiovascular implants - Cardiac valve prostheses - Part
2: Surgically implanted heart valve substitutes (ISO 5840-
2:2015)**

Implants cardiovasculaires - Prothèses valvulaires -
Partie 2: Prothèse valvulaires implantées
chirurgicalement (ISO 5840-2:2015)

Herz- und Gefäßimplantate - Herzklappenprothesen -
Teil 2: Chirurgisch implantierter Herzklappenersatz
(ISO 5840-2:2015)

This European Standard was approved by CEN on 24 July 2015.

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.

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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

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

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European foreword

This document (EN ISO 5840-2:2015) 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 March 2016, and conflicting national standards shall be withdrawn at the latest by September 2018.

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 5840:2009.

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 organizations 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 5840-2:2015 has been approved by CEN as EN ISO 5840-2:2015 without any modification.

Annex ZA (informative)

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

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 on medical devices

Clause(s)/sub-clause(s) of this European Standard	Essential Requirements (ERs) of Directive 93/42/EEC	Qualifying remarks/Notes
Clause 5, 6.1, 6.2.1, 6.2.2, 6.4	7.1	
6.2, 6.2.3, 6.4, 7.2.2.2	7.2	
6.2, 6.4	7.3	
6.2, 6.4, 6.5, 7.2.2.2	7.5	
6.2.2, 6.4, 6.5	7.6	
6.2, 6.4, 6.5	8.1	
6.5, 7.2.2.2	8.2	
6.2.3	8.3	
6.2.3	8.4	
6.4	8.5	
6.2.3	8.6	
6.2.3	8.7	
6.3, 6.2.3	9.1	
6.2.1, 6.2.2, 6.4, 6.5	9.2	
6.2.3, 6.3	13	

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

INTERNATIONAL STANDARD

**ISO
5840-2**

First edition
2015-09-15

Cardiovascular implants — Cardiac valve prostheses —

Part 2: Surgically implanted heart valve substitutes

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*Implants cardiovasculaires — Prothèses valvulaires —
Partie 2: Prothèse valvulaires implantées chirurgicalement*

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ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: [Foreword - Supplementary information](http://www.iso.org/foreword)

The committee responsible for this document is ISO/TC 150, *Implants for surgery*, Subcommittee SC 2, *Cardiovascular implants and extracorporeal systems*.

This first edition of ISO 5840-2, together with ISO 5840-1 and ISO 5840-3, cancels and replaces ISO 5840:2005, which has been technically revised.

ISO 5840 consists of the following parts, under the general title *Cardiovascular implants — Cardiac valve prostheses*:

- *Part 1: General requirements*
- *Part 2: Surgically implanted heart valve substitutes*
- *Part 3: Heart valve substitutes implanted by transcatheter techniques*

ISO 5840-2:2015(E)

Introduction

This part of ISO 5840 has been prepared for surgical heart valve substitutes with emphasis on specifying types of *in vitro* testing, preclinical *in vivo* and clinical evaluations, reporting of all *in vitro*, preclinical *in vivo*, and clinical evaluations and labelling and packaging of the device. This process is intended to clarify the required procedures prior to market release and to enable prompt identification and management of any subsequent issues.

This part of ISO 5840 is to be used in conjunction with ISO 5840-1.

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Cardiovascular implants — Cardiac valve prostheses —

Part 2: Surgically implanted heart valve substitutes

1 Scope

This part of ISO 5840 is applicable to heart valve substitutes intended for implantation in human hearts, generally requiring cardiopulmonary bypass and generally with direct visualization.

This part of ISO 5840 is applicable to both newly developed and modified surgical heart valve substitutes and to the accessories, packaging, and labelling required for their implantation and for determining the appropriate size of the surgical heart valve substitute to be implanted.

This part of ISO 5840 outlines an approach for qualifying the design and manufacture of a surgical 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 surgical 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 surgical heart valve substitute.

This part of ISO 5840 defines performance requirements for surgical heart valve substitutes where adequate scientific and/or clinical evidence exists for their justification.

For novel surgical heart valve substitutes, e.g. sutureless, the requirements of both this International Standard and ISO 5840-3 might be relevant and shall be considered as applicable to the specific device design and shall be based on the results of the risk analysis.

This part of ISO 5840 excludes heart valve substitutes designed for implantation in artificial hearts or heart assist devices.

This part of ISO 5840 excludes homografts.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 5840-1:2015, *Cardiovascular implants and extracorporeal systems — Cardiac valve prostheses — Part 1: General requirements*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

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

ISO 14155, *Clinical investigation of medical devices for human subjects — Good clinical practice*

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

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

ISO 16061, *Instrumentation for use in association with non-active surgical implants — General requirements*

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ISO/IEC 17025:2005, *General requirements for the competence of testing and calibration laboratories*

ISO 22442 (all parts), *Medical devices utilizing animal tissues and their derivatives*

ASTM F2052, *Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment*

ASTM F2119, *Standard Test Method for Evaluation of MR Image Artifacts from Passive Implants*

ASTM F2182, *Standard Test Method for Measurement of Radio Frequency Induced Heating On or Near Passive Implants During Magnetic Resonance Imaging*

ASTM F2213, *Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment*

ASTM F2503, *Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment*

3 Terms and definitions

For the purposes of this document, the following terms and definitions given in ISO 5840-1 and the following apply.

**3.1
cycle rate**

number of complete cycles per unit of time, usually expressed as cycles per minute (cycles/min)

**3.2
internal orifice diameter**

numerical indication of the minimum diameter within a surgical heart valve substitute through which blood flows

Note 1 to entry: See [Figure 1](#).

**3.3
intra-annular sewing ring**

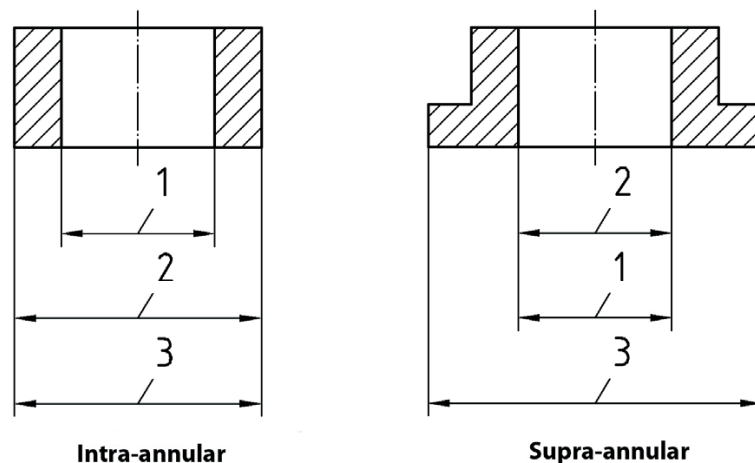
sewing ring designed to secure the surgical heart valve wholly or mostly within the patient's tissue annulus

Note 1 to entry: See [Figure 1](#).

Note 2 to entry: See also [3.2](#), [3.10](#), and [3.12](#).

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Key

- 1 internal orifice diameter
- 2 tissue annulus diameter
- 3 external sewing ring diameter

Figure 1 — Designation of dimensions of surgical heart valve substitute sewing ring configurations

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3.4

major bleeding

any episode of major internal or external bleeding that causes death, hospitalization, or permanent injury (e.g. vision loss) or necessitates transfusion

3.5

major paravalvular leak

paravalvular leakage leading to death or re-intervention, or causing heart failure requiring additional medication, or causing moderate or severe regurgitation or prosthesis 'rocking' on investigation even in the apparent absence of symptoms, or causing hemolytic anemia

3.6

nonstructural valve dysfunction

abnormality extrinsic to the heart valve substitute that results in stenosis, regurgitation, and/or haemolytic anemia

3.7

prosthetic valve endocarditis

any infection involving a valve in which an operation has been performed, based on reoperation, autopsy or the Duke Criteria for Endocarditis

Note 1 to entry: See Reference [16].

3.8

structural valve deterioration

change in the function of a heart valve substitute resulting from an intrinsic abnormality that causes stenosis or regurgitation

Note 1 to entry: This definition excludes infection or thrombosis of the heart valve substitute. It includes intrinsic changes such as wear, fatigue failure, stress fracture, occluder escape, suture line disruption of components of the prosthesis, calcification, cavitation erosion, leaflet tear, and stent creep.