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Cardiovascular implants - Cardiac valve prostheses - Part 2: Surgically implanted heart valve substitutes (ISO 5840-2:2021)

Herz- und Gefäßimplantate - Herzklappenprothesen - Teil 2: Chirurgisch implantierter Herzklappenersatz (ISO 5840-2:2021)

Implants cardiovasculaires - Prothèses valvulaires - Partie 2: Prothèse valvulaires implantées chirurgicalement (ISO 5840-2:2021)

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ICS:

11.040.40	Implantanti za kirurgijo, protetiko in ortetiko	Implants for surgery, prosthetics and orthotics
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Cardiovascular implants - Cardiac valve prostheses - Part 2: Surgically implanted heart valve substitutes (ISO 5840-2:2021)

Implants cardiovasculaires - Prothèses valvulaires -
Partie 2: Prothèse valvulaires implantées
chirurgicalement (ISO 5840-2:2021)

Herz- und Gefäßimplantate - Herzklappenprothesen -
Teil 2: Chirurgisch implantierter Herzklappenersatz
(ISO 5840-2:2021)

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CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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European foreword

This document (EN ISO 5840-2:2021) 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of an identical text or by endorsement, at the latest by August 2021, and conflicting national standards shall be withdrawn at the latest by August 2021.

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

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INTERNATIONAL
STANDARD

ISO
5840-2

Second edition
2021-01

**Cardiovascular implants — Cardiac
valve prostheses —**

**Part 2:
Surgically implanted heart valve
substitutes**

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Implants cardiovasculaires — Prothèses valvulaires —
(standards.iteh.ai) **Partie 2: Prothèse valvulaires implantées chirurgicalement**

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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 of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 2, *Cardiovascular implants and extracorporeal systems*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 285, *Non-active surgical implants*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 5840-2:2015), which has been technically revised.

The main changes compared to the previous edition are as follows: the engineering and clinical requirements in the ISO 5840 series have been updated to current specifications and integrated and harmonized across all of its parts.

A list of all parts in the ISO 5840 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

ISO 5840-2:2021(E)**Introduction**

This document has been prepared for surgical heart valve substitutes with emphasis on providing guidance for *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 document is used in conjunction with ISO 5840-1 and ISO 5840-3.

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Cardiovascular implants — Cardiac valve prostheses —

Part 2: Surgically implanted heart valve substitutes

1 Scope

This document is applicable to heart valve substitutes intended for implantation in human hearts, generally requiring cardiopulmonary bypass and generally with direct visualization. See [Annex E](#) for examples of surgical heart valve substitutes and their components.

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

This document establishes an approach for verifying/validating 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 can include those to assess the physical, chemical, biological, and mechanical properties of surgical heart valve substitutes and of their materials and components. The tests can also include those for pre-clinical *in vivo* evaluation and clinical evaluation of the finished surgical heart valve substitute.

This document defines operational conditions and performance requirements for surgical heart valve substitutes where adequate scientific and/or clinical evidence exists for their justification.

For some heart valve substitutes (e.g. sutureless), the requirements of both this document and ISO 5840-3:2021 can be relevant and are considered as applicable to the specific device design and are based on the results of the risk analysis.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 5840-1:2021, *Cardiovascular implants — Cardiac valve prostheses — Part 1: General requirements*

ISO 5840-3, *Cardiovascular implants — Cardiac valve prostheses — Part 3: Heart valve substitutes implanted by transcatheter techniques*

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

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 5840-1:2021 and the following apply.

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ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <http://www.electropedia.org/>

3.1
acute assessment
intra-procedural and immediate post-procedural results used to assess *in vivo* safety and performance

Note 1 to entry: All animals entered into acute short-term assessment shall remain under general anaesthesia for the duration of the study.

3.2
chronic assessment
long-term results following the procedure used to assess chronic *in vivo* safety and performance after the animal has recovered from anaesthesia

Note 1 to entry: The endpoints and durations of these studies should be determined by risk analysis.

3.3
component-joining material
material such as a suture, adhesive, or welding compound used to assemble the components of a heart valve system

[SOURCE: ISO 5840-1:2021, 3.31]

3.4
external sewing ring diameter
ESRD

outside diameter in millimetres of the sewing ring at the largest point

Note 1 to entry: See [Figure 1](https://standards.iteh.ai/catalog/standards/sist/e8494045-5276-4e42-a8f9-22715d808966/sist-en-iso-5840-2-2021).

Note 2 to entry: See also [3.5](#), [3.7](#) and [3.8](#).

3.5
prosthesis minimum internal diameter
<flexible surgical heart valve> numerical indication of the minimum diameter within a fully assembled flexible surgical heart valve substitute and which is measured with a standard validated procedure, taking the entire flow channel into consideration

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

Note 2 to entry: See also [3.2](#) and [3.4](#).

3.6
prosthesis minimum internal diameter
<rigid surgical heart valve> measurement of the prosthesis minimum internal housing diameter

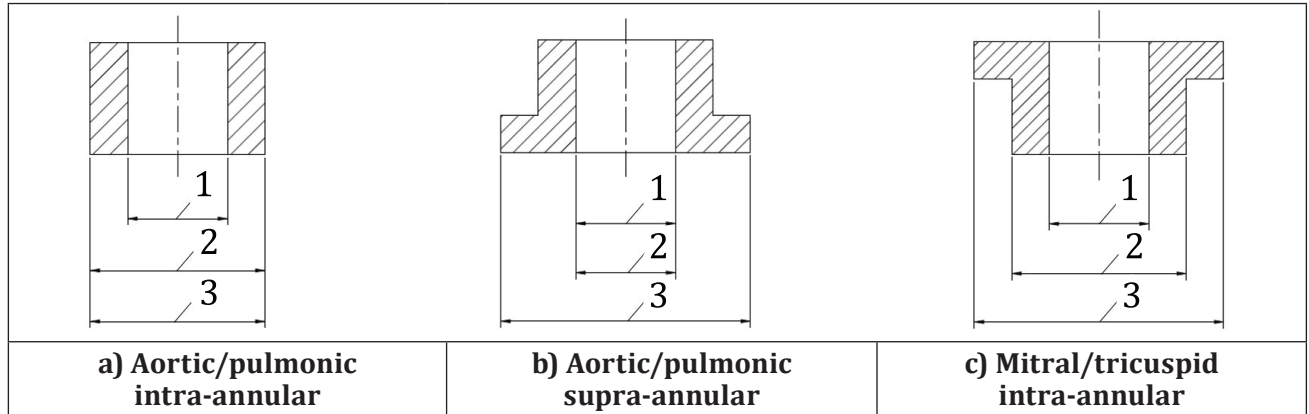
Note 1 to entry: See [Figure 1](#).

Note 2 to entry: See also [3.2](#) and [3.4](#).

3.7
intra-annular
wholly or partially within the patient's annulus

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

Note 2 to entry: See also [3.4](#), [3.5](#) and [3.8](#).

**Key**

- 1 prosthesis minimum internal diameter
- 2 patient annulus diameter
- 3 external sewing ring diameter

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

3.8**supra-annulus**

region wholly above the patient's annulus

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

Note 2 to entry: See also [3.4](#), [3.5](#), and [3.7](#). [SIST EN ISO 5840-2:2021](https://standards.iteh.ai/catalog/standards/sist/e8494045-5276-4e42-a8f9-22715d808966/sist-en-iso-5840-2-2021)
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3.9**patient annulus diameter****PAD**

diameter in millimetres of the smallest flow area within the patient's valve annulus

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

3.10**valve size****designated valve size**

manufacturer's designation of a surgical heart valve substitute which indicates the intended patient annulus diameter

Note 1 to entry: The valve size is equivalent to the *PAD* ([3.9](#)).

Note 2 to entry: This takes into consideration the manufacturer's recommended implant position relative to the annulus and the suture technique.

4 Abbreviations

For the purposes of this document, the following abbreviations apply.

- AE adverse event
- CIP clinical investigation plan
- CRF case report form