



SLOVENSKI STANDARD
SIST EN ISO 5840-2:2021/A1:2025

01-maj-2025

Vsadki (implantati) za srce in ožilje - Proteze za srčno zaklopko - 2. del: Kirurško vsajeni (implantirani) nadomestki srčne zaklopke - Dopolnilo A1 (ISO 5840-2:2021/Amd 1:2025)

Cardiovascular implants - Cardiac valve prostheses - Part 2: Surgically implanted heart valve substitutes - Amendment 1 (ISO 5840-2:2021/Amd 1:2025)

Herz- und Gefäßimplantate - Herzklappenprothesen - Teil 2: Chirurgisch implantierter Herzklappenersatz - Änderung 1 (ISO 5840-2:2021/Amd 1:2025)

Implants cardiovasculaires - Prothèses valvulaires - Partie 2: Prothèse valvulaires implantées chirurgicalement - Amendement 1 (ISO 5840-2:2021/Amd 1:2025)

Ta slovenski standard je istoveten z: EN ISO 5840-2:2021/A1:2025

ICS:

11.040.40	Implantanti za kirurgijo, protetiko in ortetiko	Implants for surgery, prosthetics and orthotics
-----------	---	---

SIST EN ISO 5840-2:2021/A1:2025 **en,fr,de**

ICS 11.040.40

English Version

**Cardiovascular implants - Cardiac valve prostheses - Part
2: Surgically implanted heart valve substitutes -
Amendment 1 (ISO 5840-2:2021/Amd 1:2025)**

Implants cardiovasculaires - Prothèses valvulaires -
Partie 2: Prothèses valvulaires implantées
chirurgicalement - Amendement 1 (ISO 5840-
2:2021/Amd 1:2025)

Herz- und Gefäßimplantate - Herzklappenprothesen -
Teil 2: Chirurgisch implantierter Herzklappenersatz -
Änderung 1 (ISO 5840-2:2021/Amd 1:2025)

This amendment A1 modifies the European Standard EN ISO 5840-2:2021; it was approved by CEN on 12 March 2025.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for inclusion of this amendment into the relevant 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.

This amendment 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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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

EN ISO 5840-2:2021/A1:2025 (E)

Contents	Page
European foreword.....	3

iTeh Standards
(<https://standards.itih.ai>)
Document Preview

[SIST EN ISO 5840-2:2021/A1:2025](https://standards.itih.ai/catalog/standards/sist/640ccc26-b805-4f8d-b3f3-5204d60661e7/sist-en-iso-5840-2-2021-a1-2025)

<https://standards.itih.ai/catalog/standards/sist/640ccc26-b805-4f8d-b3f3-5204d60661e7/sist-en-iso-5840-2-2021-a1-2025>

European foreword

This document (EN ISO 5840-2:2021/A1:2025) 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 Amendment to the European Standard EN ISO 5840-2:2021 shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by September 2025, and conflicting national standards shall be withdrawn at the latest by September 2025.

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.

Any feedback and questions on this document should be directed to the users' national standards body/national committee. A complete listing of these bodies can be found on the CEN website.

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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

Endorsement notice
(<https://standards.iteh.ai>)

The text of ISO 5840-2:2021/Amd 1:2025 has been approved by CEN as EN ISO 5840-2:2021/A1:2025 without any modification.

[SIST EN ISO 5840-2:2021/A1:2025](https://standards.iteh.ai/catalog/standards/sist/640ccc26-b805-4f8d-b3f3-5204d60661e7/sist-en-iso-5840-2-2021-a1-2025)

<https://standards.iteh.ai/catalog/standards/sist/640ccc26-b805-4f8d-b3f3-5204d60661e7/sist-en-iso-5840-2-2021-a1-2025>

