ICS 11.040.40 SLOVENSKÁ TECHNICKÁ NORMA Jún 2025

STN	**Srdcovo-cievne implantáty Protézy srdcovej chlopne Časť 2: Chirurgicky implantované náhrady srdcovej chlopne (ISO 5840-2: 2021/Amd 1: 2025) Zmena A1**	**STN EN ISO 5840-2/A1** 85 2922

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

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 05/25

Obsahuje: EN ISO 5840-2:2021/A1:2025, ISO 5840-2:2021/Amd 1:2025

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EUROPEAN STANDARD

NORME EUROPÉENNE

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EN ISO 5840-2:2021/A1

March 2025

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.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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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/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of an identical text or by endorsement, at the latest by September 2025, and conflicting national standards shall be withdrawn at the latest by September 2025.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.

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Endorsement notice

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.

International Standard

ISO 5840-2

Cardiovascular implants — Cardiac valve prostheses —

Part 2: Surgically implanted heart valve substitutes

AMENDMENT 1

Implants cardiovasculaires — Prothèses valvulaires —

Partie 2: Prothèses valvulaires implantées chirurgicalement

AMENDEMENT 1

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Foreword

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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).

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ISO 5840-2:2021/Amd.1:2025(en)

Cardiovascular implants — Cardiac valve prostheses —

Part 2:
Surgically implanted heart valve substitutes

AMENDMENT 1

Clause 2, Normative references

Add the following reference:

ISO/PAS 7020:2023, *Sizing parameters of surgical valve prostheses: Requirements regarding the application of ISO 5840-2*