SLOVENSKI STANDARD
SIST EN ISO 5840-1:2021/A1:2025

01-maj-2025

Vsadki (implantati) za srce in ožilje - Proteze za srčno zaklopko - 1. del: Splošne zahteve - Dopolnilo A1 (ISO 5840-1:2021/Amd 1:2025)

Cardiovascular implants - Cardiac valve prostheses - Part 1: General requirements - Amendment 1 (ISO 5840-1:2021/Amd 1:2025)

Herz- und Gefäßimplantate - Herzklappenprothesen - Teil 1: Allgemeine Anforderungen - Änderung 1 (ISO 5840-1:2021/Amd 1:2025)

Implants cardiovasculaires - Prothèses valvulaires - Partie 1: Exigences générales - Amendement 1 (ISO 5840-1:2021/Amd 1:2025)

Ta slovenski standard je istoveten z: **EN ISO 5840-1:2021/A1:2025**

ICS:

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

SIST EN ISO 5840-1:2021/A1:2025 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 5840-1:2021/A1

March 2025

ICS 11.040.40

English Version

Cardiovascular implants - Cardiac valve prostheses - Part 1: General requirements - Amendment 1 (ISO 5840-1:2021/Amd 1:2025)

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This amendment A1 modifies the European Standard EN ISO 5840-1:2021; it was approved by CEN on 12 March 2025.

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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.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
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Ref. No. EN ISO 5840-1:2021/A1:2025 E

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European foreword

This document (EN ISO 5840-1:2021/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 5840-1:2021 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of an identical text or by endorsement, at the latest by September 2025, and conflicting national standards shall be withdrawn at the latest by September 2025.

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Endorsement notice

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