

<b>STN</b>	<b>Srdcovo-cievne implantáty Protézy srdcovej chlopne Časť 1: Všeobecné požiadavky (ISO 5840-1: 2021/Amd 1: 2025) Zmena A1</b>	<b>STN EN ISO 5840-1/A1</b>  85 2922
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Cardiovascular implants - Cardiac valve prostheses - Part 1: General requirements (ISO 5840-1:2021)

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 5840-1:2021/A1:2025, ISO 5840-1:2021/Amd 1:2025

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Úrad pre normalizáciu, metrológiu a skúšobníctvo Slovenskej republiky, 2025

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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)**

Implants cardiovasculaires - Prothèses valvulaires -  
Partie 1: Exigences générales - Amendement 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)

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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**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of an identical text or by endorsement, at the latest by September 2025, and conflicting national standards shall be withdrawn at the latest by September 2025.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.



# International Standard

**ISO 5840-1**

## Cardiovascular implants — Cardiac valve prostheses —

### Part 1: General requirements

#### AMENDMENT 1

*Implants cardiovasculaires — Prothèses valvulaires —*

*Partie 1: Exigences générales*

*AMENDEMENT 1*

**Second edition  
2021-01**

**AMENDMENT 1  
2025-03**

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



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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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