ICS 11.040.40 SLOVENSKÁ TECHNICKÁ NORMA Jún 2025

STN	**Srdcovo-cievne implantáty Protézy srdcovej chlopne Časť 3: Náhrady srdcovej chlopne implantované minimálne invazívnymi technikami (ISO 5840-3: 2021/Amd 1: 2025) Zmena A1**	**STN EN ISO 5840-3/A1** 85 2922

Cardiovascular implants - Cardiac valve prostheses - Part 3: Heart valve substitutes implanted by transcatheter techniques (ISO 5840-3:2021)

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 5840-3:2021/A1:2025, ISO 5840-3:2021/Amd 1:2025

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EUROPEAN STANDARD

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EN ISO 5840-3:2021/A1

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English Version

Cardiovascular implants - Cardiac valve prostheses - Part 3: Heart valve substitutes implanted by transcatheter techniques - Amendment 1 (ISO 5840-3:2021/Amd 1:2025)

Implants cardiovasculaires - Prothèses valvulaires - Partie 3: Valves cardiaques de substitution implantées par des techniques transcathéter - Amendement 1 (ISO 5840-3:2021/Amd 1:2025)

Herz- und Gefäßimplantate - Herzklappenprothesen - Teil 3: Durch Minimal-Invasive Methoden Implantierter Herzklappenersatz - Änderung 1 (ISO 5840-3:2021/Amd 1:2025)

This amendment A1 modifies the European Standard EN ISO 5840-3:2021; 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 5840-3:2021/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 5840-3:2021 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of an identical text or by endorsement, at the latest by September 2025, and conflicting national standards shall be withdrawn at the latest by September 2025.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 5840-3:2021/Amd 1:2025 has been approved by CEN as EN ISO 5840-3:2021/A1:2025 without any modification.

International Standard

ISO 5840-3

Cardiovascular implants — Cardiac valve prostheses —

Part 3: Heart valve substitutes implanted by transcatheter techniques

AMENDMENT 1

Implants cardiovasculaires — Prothèses valvulaires —

Partie 3: Valves cardiaques de substitution implantées par des techniques transcathéter

AMENDEMENT 1

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Foreword

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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 document 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).

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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).

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

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ISO 5840-3:2021/Amd.1:2025(en)

Cardiovascular implants — Cardiac valve prostheses —

Part 3: Heart valve substitutes implanted by transcatheter techniques

AMENDMENT 1

Clause 1, Scope

Replace the second paragraph with the following:

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

6.3.2.3

Replace the entire subclause with the following text.

The intended performance of the transcatheter heart valve substitute shall include, but not be limited to the following:

a) the ability to be consistently, accurately and safely loaded onto the delivery system;

b) the ability to be consistently, accurately and safely deployed;

c) the ability to be safely retrieved and/or repositioned (if applicable);

d) the ability to maintain structural and functional integrity throughout the anticipated lifetime of the device;

e) the ability to conform or interact with anatomical structures within the implant site (e.g. in the aortic position, there is potential for interaction with the coronary ostia, the anterior mitral leaflet and the conduction system; in the mitral position, there is potential for interaction with the aortic root, LA, LAA, LVOT and the subvalvular apparatus);

f) the ability to conform or interact with previously implanted device (e.g. surgical valve, annuloplasty ring, transcatheter valve, valve docking device), if applicable;

g) the ability to allow forward flow with an acceptably small mean pressure difference in all anticipated configurations;

h) the ability to prevent retrograde flow with acceptably small regurgitation, including paravalvular leakage;

i) the ability to resist migration and embolization;

j) the ability to avoid haemolysis;

k) the ability to resist thrombus formation;

l) biocompatibility;

m) the ability to maintain its functionality and sterility for a reasonable shelf life prior to implantation;

n) reproducibility of function.

7.2.4, fifth paragraph

Add the following text to the end of the paragraph:

The values in Table 1 and Table 2 are applicable to new or modified heart valve substitutes which have not been clinically proven.

C.2.2.1

Replace this subclause with the following:

Each pressure measurement (e.g. ventricular pressure, aortic pressure) should have an upper frequency limit (–3 dB cut-off) of at least 30 Hz and a measurement accuracy of at least ±0,26 kPa (±2 mmHg). The flow meter should have an upper frequency limit (–3 dB cut-off) of at least 30 Hz.

C.2.4.2

Replace the entire subclause with the following text.

C.2.4.2 This test fixture is not expected to be used for periodic hydrodynamic performance testing conducted during AWT or with steady flow testing.

Annex C, Table C.4

Replace the entire table with the following:

Beat rate cycles/min	**Systolic duration** %	**Cardiac output** l/min	**Differential pressure across closed valve[a]**
45	30	5	Hypotensive, normotensive, severe hypertensive
70	35	5	Hypotensive, normotensive, severe hypertensive
120	50	5	Hypotensive, normotensive, severe hypertensive
[a] Refers to the mean differential pressure across the closed valve.			

C.2.7

Replace the list item g) with the following:

g) regurgitant volume, including the closing volume and leakage volume (see ISO 5840-1:2021, Figure 2), expressed in millilitres and as a percentage of forward flow volume; and the corresponding differential pressure across closed valve (i.e. mean back pressure).

Clause G.5

Replace the first paragraph with the following:

Each adverse device effect (ADE) shall be defined and categorized as either a serious adverse device effect (SADE) or non-serious ADE in accordance with ISO 14155. SADE are further categorised as anticipated or unanticipated.

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Price based on 3 pages