



Sisaldab värvilisi lehekülgi  
Colour inside

**KARDIO-VASKULAARSED IMPLANTAADID.  
SÜDAMEKLAPI PROTEESID. OSA 3: KATEETRI KAUDU  
IMPLANTEERITAVAD ASENDUSKLAPID**

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

**EESTI STANDARDI EESSÕNA****NATIONAL FOREWORD**

See Eesti standard EVS-EN ISO 5840-3:2021+A1:2025 sisaldab Euroopa standardi EN ISO 5840-3:2021 ja selle muudatuse A1:2025 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 5840-3:2021+A1:2025 consists of the English text of the European standard EN ISO 5840-3:2021 and its amendment A1:2025.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas.  Euroopa standardimisorganisatsioonid on teinud Euroopa standardi rahvuslikele liikmetele kättesaadavaks 03.02.2021, muudatus A1 19.03.2025.	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.  Date of Availability of the European standard is 03.02.2021, for A1 19.03.2025.
Muudatusega A1 lisatud või muudetud teksti algus ja lõpp on tekstis tähistatud sümbolitega $\boxed{A1}$ $\langle A1 \rangle$ .  Standard on kättesaadav Eesti Standardimis- ja Akrediteerimiskeskusest.	The start and finish of text introduced or altered by amendment A1 is indicated in the text by tags $\boxed{A1}$ $\langle A1 \rangle$ .  The standard is available from the Estonian Centre for Standardisation and Accreditation.

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ICS 11.040.40

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EUROPEAN STANDARD

**EN ISO 5840-3 + A1**

NORME EUROPÉENNE

EUROPÄISCHE NORM

February 2021, March 2025

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Supersedes EN ISO 5840-3:2013

English Version

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

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

Herz- und Gefäßimplantate - Herzklappenprothesen -  
Teil 3: Durch minimal-invasive Methoden  
implantierter Herzklappenersatz (ISO 5840-3:2021 +  
ISO 5840-3:2021/Amd 1:2025)

This European Standard was approved by CEN on 22 September 2020. Amendment A1 was approved by CEN on 12 March 2025.

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COMITÉ EUROPÉEN DE NORMALISATION  
EUROPÄISCHES KOMITEE FÜR NORMUNG

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

## European foreword

This document (EN ISO 5840-3:2021) 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 European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by August 2021, and conflicting national standards shall be withdrawn at the latest by August 2021.

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This document supersedes EN ISO 5840-3:2013.

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## Endorsement notice

The text of ISO 5840-3:2021 has been approved by CEN as EN ISO 5840-3:2021 without any modification.

## **A1** Amendment A1 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.

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## Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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 documents 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](http://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).

This second edition cancels and replaces the first edition (ISO 5840-3:2013), which has been technically revised.

The main changes compared to the previous edition are as follows: the engineering and clinical requirements in the ISO 5840 series have been updated to current specifications and integrated and harmonized across all parts.

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

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## **A1** Amendment A1 Foreword

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## Introduction

This document has been prepared for transcatheter heart valve substitutes with emphasis on providing guidance for *in vitro* testing, preclinical *in vivo* and clinical evaluations, reporting of all *in vitro*, preclinical *in vivo*, and clinical evaluations and labelling and packaging of the device. This process is intended to clarify the required procedures prior to market release and to enable prompt identification and management of any subsequent issues.

This document is used in conjunction with ISO 5840-1 and ISO 5840-2.

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# Cardiovascular implants — Cardiac valve prostheses —

## Part 3:

## Heart valve substitutes implanted by transcatheter techniques

### 1 Scope

This document is applicable to all devices intended for implantation as a transcatheter heart valve substitute.

**A1)** 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. **A1)**

This document establishes an approach for verifying/validating the design and manufacture of a transcatheter heart valve substitute through risk management. The selection of appropriate verification/validation tests and methods are to be derived from the risk assessment. The tests can include those to assess the physical, chemical, biological and mechanical properties of heart valve substitutes and of their materials and components. The tests can also include those for preclinical *in vivo* evaluation and clinical evaluation of the finished heart valve substitute.

This document defines operational conditions and performance requirements for transcatheter heart valve substitutes where adequate scientific and/or clinical evidence exists for their justification.

This document includes considerations for implantation of a transcatheter heart valve substitute inside a pre-existing prosthetic device (e.g. valve-in-valve and valve-in-ring configurations).

### 2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 5840-1:2021, *Cardiovascular implants — Cardiac valve prostheses — Part 1: General requirements*

ISO 10993-2, *Biological evaluation of medical devices — Part 2: Animal welfare requirements*

ISO 14155, *Clinical investigation of medical devices for human subjects — Good clinical practice*

ISO 14630, *Non-active surgical implants — General requirements*

ISO 14971, *Medical devices — Application of risk management to medical devices*

IEC 62366 (all parts), *Medical devices — Application of usability engineering to medical devices*