



SLOVENSKI STANDARD
SIST EN ISO 5840-1:2021/oprA1:2024
01-april-2024

Vsadki (implantati) za srce in ožilje - Proteze za srčno zaklopko - 1. del: Splošne zahteve - Dopolnilo A1 (ISO 5840-1:2021/DAM 1:2024)

Cardiovascular implants - Cardiac valve prostheses - Part 1: General requirements - Amendment 1 (ISO 5840-1:2021/DAM 1:2024)

Herz- und Gefäßimplantate - Herzklappenprothesen - Teil 1: Allgemeine Anforderungen - Änderung 1 (ISO 5840-1:2021/DAM 1:2024)

Implants cardiovasculaires - Prothèses valvulaires - Partie 1: Exigences générales - Amendement 1 (ISO 5840-1:2021/DAM 1:2024)

Ta slovenski standard je istoveten z: EN ISO 5840-1:2021/prA1

SIST EN ISO 5840-1:2021/oprA1:2024

ICS:

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

SIST EN ISO 5840-1:2021/oprA1:2024 en,fr,de



DRAFT Amendment

ISO 5840-1:2021/ DAM 1

Cardiovascular implants — Cardiac valve prostheses —

Part 1: General requirements

AMENDMENT 1

Implants cardiovasculaires — Prothèses valvulaires —

Partie 1: Exigences générales

AMENDEMENT 1

ICS: 11.040.40

ISO/TC 150/SC 2

Secretariat: ANSI

Voting begins on:
2024-02-07

Voting terminates on:
2024-05-01

iTeh Standards
(<https://standards.iteh.ai>)
Document Preview

[SIST EN ISO 5840-1:2021/oprA1:2024](https://standards.iteh.ai/catalog/standards/sist/95699575-ce53-4f74-aa3a-bae0be1ac762/sist-en-iso-5840-1-2021-opra1-2024)

<https://standards.iteh.ai/catalog/standards/sist/95699575-ce53-4f74-aa3a-bae0be1ac762/sist-en-iso-5840-1-2021-opra1-2024>

This document is circulated as received from the committee secretariat.

ISO/CEN PARALLEL PROCESSING

THIS DOCUMENT IS A DRAFT CIRCULATED FOR COMMENTS AND APPROVAL. IT IS THEREFORE SUBJECT TO CHANGE AND MAY NOT BE REFERRED TO AS AN INTERNATIONAL STANDARD UNTIL PUBLISHED AS SUCH.

IN ADDITION TO THEIR EVALUATION AS BEING ACCEPTABLE FOR INDUSTRIAL, TECHNOLOGICAL, COMMERCIAL AND USER PURPOSES, DRAFT INTERNATIONAL STANDARDS MAY ON OCCASION HAVE TO BE CONSIDERED IN THE LIGHT OF THEIR POTENTIAL TO BECOME STANDARDS TO WHICH REFERENCE MAY BE MADE IN NATIONAL REGULATIONS.

RECIPIENTS OF THIS DRAFT ARE INVITED TO SUBMIT, WITH THEIR COMMENTS, NOTIFICATION OF ANY RELEVANT PATENT RIGHTS OF WHICH THEY ARE AWARE AND TO PROVIDE SUPPORTING DOCUMENTATION.

ISO 5840-1:2021/DAM 1:2024(en)

iTeh Standards (<https://standards.iteh.ai>) Document Preview

[SIST EN ISO 5840-1:2021/oprA1:2024](https://standards.iteh.ai/catalog/standards/sist/95699575-ce53-4f74-aa3a-bae0be1ac762/sist-en-iso-5840-1-2021-opra1-2024)

<https://standards.iteh.ai/catalog/standards/sist/95699575-ce53-4f74-aa3a-bae0be1ac762/sist-en-iso-5840-1-2021-opra1-2024>



COPYRIGHT PROTECTED DOCUMENT

© ISO 2024

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

© ISO 2024 – All rights reserved

ISO 5840-1:2021/DAM 1:2023(en)

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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by ISO/TC 150, Implants for surgery, Subcommittee 2, Cardiovascular implants and extracorporeal system.

The main changes are as follows:

- Corrections and clarifications to ISO 5840-1:2021

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

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

