INTERNATIONAL STANDARD

ISO 5840-2

Redline version compares Second edition to First edition

Cardiovascular implants — Cardiac valve prostheses —

Part 2: Surgically implanted heart valve substitutes

Implants cardiovasculaires — Prothèses valvulaires —

Partie 2: Prothèse valvulaires implantées chirurgicalement

Reference number
ISO 5840-2:redline:2021(E)

IMPORTANT

This marked-up version uses the following colour-coding:

Text example 1 — Text has been added (in green)

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 — Graphic figure has been added

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1.x ... — If there are changes in a clause/subclause, the corresponding clause/subclause number is highlighted in yellow in the Table of contents

DISCLAIMER

This marked-up version highlights the main changes in this edition of the document compared with the previous edition. It does not focus on details (e.g. changes in punctuation).

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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~~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~~www.iso.org/patents).

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For an explanation ~~on the~~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 ~~WTO~~World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) ~~see the following URL:~~, see ~~Foreword - Supplementary information~~www.iso.org/iso/foreword.html.

~~The committee responsible for this document is~~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 ~~first~~second edition ~~of ISO 5840-2, together with ISO 5840-1 and~~ cancels and replaces the first edition (ISO 5840-~~3~~2:2015~~, cancels and replaces ISO 5840:2005~~), 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 ~~consists of the following parts, under the general title *Cardiovascular implants — Cardiac valve prostheses:*~~have been updated to current specifications and integrated and harmonized across all of its parts.

~~— *Part 1: General requirements*~~

~~— *Part 2: Surgically implanted heart valve substitutes*~~

~~— *Part 3: Heart valve substitutes implanted by transcatheter techniques*~~

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.

Introduction

This ~~part of ISO 5840~~document has been prepared for surgical heart valve substitutes with emphasis on ~~specifying types of~~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 ~~part of ISO 5840~~document is ~~to be~~ used in conjunction with ISO 5840-1 and ISO 5840-3.

Cardiovascular implants — Cardiac valve prostheses —

Part 2:
Surgically implanted heart valve substitutes

1 Scope

This ~~part of ISO 5840~~document is applicable to heart valve substitutes intended for implantation in human hearts, generally requiring cardiopulmonary bypass and generally with direct visualization. See Annex E for examples of surgical heart valve substitutes and their components.

This ~~part of ISO 5840~~document is applicable to both newly developed and modified surgical heart valve substitutes and to the ~~accessories~~accessory devices, packaging, and labelling required for their implantation and for determining the appropriate size of the surgical heart valve substitute to be implanted.

This ~~part of ISO 5840 outlines~~document establishes an approach for ~~qualifying~~verifying/validating the design and manufacture of a surgical heart valve substitute through risk management. The selection of appropriate qualification tests and methods are derived from the risk assessment. The tests can include those to assess the physical, chemical, biological, and mechanical properties of surgical heart valve substitutes and of their materials and components. The tests can also include those for pre-clinical *in vivo* evaluation and clinical evaluation of the finished surgical heart valve substitute.

This ~~part of ISO 5840 defines~~document defines operational conditions and performance requirements for surgical heart valve substitutes where adequate scientific and/or clinical evidence exists for their justification.

For ~~novel surgical~~some heart valve substitutes (e.g. sutureless), the requirements of both this ~~International Standard~~document and ISO 5840-3:2021 ~~might~~can be relevant and ~~shall be~~are considered as applicable to the specific device design and ~~shall be~~are based on the results of the risk analysis.

~~This part of ISO 5840 excludes heart valve substitutes designed for implantation in artificial hearts or heart assist devices.~~

~~This part of ISO 5840 excludes homografts.~~

2 Normative references

The following documents~~, in whole or in part, are normatively referenced in this document and are indispensable for its application~~ 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:~~2015~~2021, *Cardiovascular implants ~~and extracorporeal systems~~ — Cardiac valve prostheses — Part 1: General requirements*

ISO ~~10993-1~~5840-3, ~~*Biological evaluation of medical devices*~~*Cardiovascular implants — Cardiac valve prostheses — Part ~~1. Evaluation and testing within a risk management process~~3: Heart valve substitutes implanted by transcatheter techniques*

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*