INTERNATIONAL STANDARD

ISO 5840-1

Redline version
compares Second edition to
First edition

Cardiovascular implants — Cardiac valve prostheses —

Part 1: General requirements

Implants cardiovasculaires — Prothèses valvulaires —

Partie 1: Exigences générales

Reference number
ISO 5840-1:redline:2021(E)

IMPORTANT

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

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

~~Text example 2~~ — Text has been deleted (in red)

 — 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).

This marked-up version does not constitute the official ISO document and is not intended to be used for implementation purposes.

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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).

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

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 5840-1, together with ISO 5840-2 and~~ cancels and replaces the first edition (ISO 5840-~~3~~1:2015~~, 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 have been updated to current specifications and integrated and harmonized across all parts.

A list of all parts in the ISO 5840 series ~~consists of the following parts, under the general title~~can be found on the ~~*Cardiovascular implants — Cardiac valve prostheses.*~~ISO website.

~~— *Part 1: General requirements*~~

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

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

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

There is, as yet, no heart valve substitute which can be regarded as ideal.

The ISO 5840 series has been prepared by a group well aware of the issues associated with heart valve substitutes and their development. In several areas, the provisions of the ISO 5840 series deliberately have not been specified to encourage development and innovation. It does specify the types of tests, provides guidance for test methods~~, and/or requirements for test apparatus~~ and test apparatuses and requires documentation of test methods and results. The areas with which the ISO 5840~~-~~ series are concerned are those which ~~will~~ ensure that associated risks to the patient and other users of the device have been adequately mitigated, facilitate quality assurance, aid the clinician in choosing a heart valve substitute, and ensure that the device ~~will be presented at the operating table in~~is presented in a convenient form. Emphasis has been placed on specifying types of *in vitro* testing, ~~on~~ preclinical *in vivo* and clinical evaluations, ~~on~~ reporting of all *in vitro*, preclinical *in vivo*, and clinical evaluations, and ~~on~~ the labelling and packaging of the device. Such a process involving *in vitro*, preclinical *in vivo*, and clinical evaluations is intended to clarify the required procedures prior to market release and to enable prompt identification and management of any subsequent problems.

With regard to *in vitro* testing and reporting, apart from basic material testing for mechanical, physical, chemical, and biocompatibility characteristics, the ISO 5840 series also covers important hydrodynamic and durability characteristics of heart valve substitutes and systems required for their implantation. The ISO 5840 series does not specify exact test methods for hydrodynamic and durability testing, but it offers guidelines for the test apparatus.

The ISO 5840 series is ~~incomplete in several areas. It is~~ intended to be revised, updated, and/or amended as knowledge and techniques in heart valve substitute technology improve.

This document is used in conjunction with ISO 5840-2 and ISO 5840-3.

Cardiovascular implants — Cardiac valve prostheses —

Part 1: General requirements

1 Scope

This ~~part of ISO 5840~~document is applicable to heart valve substitutes intended for ~~human~~ implantation and provides general requirements. Subsequent parts of the ISO 5840 series provide specific requirements.

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

~~This part of~~ ISO 5840-1 outlines an approach for ~~qualifying~~verifying/validating the design and manufacture of a 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 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 part of~~ ISO 5840-1 defines operational conditions for heart valve substitutes.

~~This part of~~ ISO 5840-1 ~~excludes homografts~~furthermore defines terms that are also applicable to ISO 5840-2 and ISO 5840-3.

ISO 5840-1 does not provide requirements specific to homografts, tissue engineered heart valves (e.g. valves intended to regenerate *in vivo*), and heart valve substitutes designed for implantation in circulatory support devices. Some of the provisions of ISO 5840-1 can be applied to valves made from human tissue that is rendered non-viable.

NOTE A rationale for the provisions of ~~this part of~~ ISO 5840-1 is given in Annex A.

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 5840-2, *Cardiovascular implants — Cardiac valve prostheses —Part 2: Surgically implanted heart valve substitutes*

ISO 5840-3, *Cardiovascular implants — Cardiac valve prostheses —Part 3: Heart valve substitutes implanted by transcatheter techniques*

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 11135, *Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 11137 (all parts), *Sterilization of health care products — Radiation*