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Cardiovascular implants — Cardiac valve prostheses —

Part 1: General requirements

*Implants cardiovasculaires — Prothèses valvulaires —
Partie 1: Exigences générales*



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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).

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: [Foreword - Supplementary Information](#)

The committee responsible for this document is ISO/TC 150, *Implants for surgery*, Subcommittee SC 2, *Cardiovascular implants and extracorporeal systems*.

This first edition of ISO 5840-1, together with ISO 5840-2 and ISO 5840-3, cancels and replaces ISO 5840:2005, which has been technically revised.

ISO 5840 consists of the following parts, under the general title *Cardiovascular implants — Cardiac valve prostheses*:

- *Part 1: General requirements*
- *Part 2: Surgically implanted heart valve substitutes*
- *Part 3: Heart valve substitutes implanted by transcatheter techniques*

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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, test methods, and/or requirements for test apparatus 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 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. 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.