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Cardiovascular implants and extracorporeal systems — Centrifugal blood pumps

*Implants cardiovasculaires et systèmes extracorporels — Pompes
sanguines centrifuges*



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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 World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

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

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Introduction

This document is intended to ensure that devices designed to provide continuous flow of blood in support of, or as a substitution for, the normal pumping function of the heart have been adequately tested for both their safety and function, and that extracorporeal device characteristics are appropriately disclosed when labelling the device.

This document therefore contains procedures to be used for evaluation of extracorporeal centrifugal blood pumps. Test procedures for determination of the hydraulic performance, blood cell damage and other performance characteristics are described, although limits for these characteristics are not specified. Ready identification of the performance characteristics should, however, assist the user in the selection of a centrifugal blood pump that will suit the needs of the patient.

This document also includes minimum reporting requirements, which will allow the user to compare performance characteristics of centrifugal blood pumps of different designs in a standard way.

This document makes reference to other International Standards in which methods for determination of characteristics common to medical devices can be found.

Requirements for animal and clinical studies have not been included in this document. Such studies may be part of a manufacturer's quality system.

This document contains only those requirements that are specific to centrifugal blood pumps. Non-specific requirements are covered by references to other International Standards listed in [Clause 2](#).