

---

---

**Cardiovascular implants and  
extracorporeal systems — Centrifugal  
blood pumps**

*Implants cardiovasculaires et systèmes extracorporels — Pompes  
sanguines centrifuges*

Sample Document

get full document from [standards.iteh.ai](https://standards.iteh.ai)



Reference number  
ISO 18242:2016(E)

© ISO 2016

# Sample Document

get full document from [standards.iteh.ai](https://standards.iteh.ai)



## **COPYRIGHT PROTECTED DOCUMENT**

© ISO 2016, Published in Switzerland

All rights reserved. Unless otherwise specified, 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  
Ch. de Blandonnet 8 • CP 401  
CH-1214 Vernier, Geneva, Switzerland  
Tel. +41 22 749 01 11  
Fax +41 22 749 09 47  
[copyright@iso.org](mailto:copyright@iso.org)  
[www.iso.org](http://www.iso.org)

# Contents

Page

|                                                                            |           |
|----------------------------------------------------------------------------|-----------|
| <b>Foreword</b>                                                            | <b>iv</b> |
| <b>Introduction</b>                                                        | <b>v</b>  |
| <b>1 Scope</b>                                                             | <b>1</b>  |
| <b>2 Normative references</b>                                              | <b>1</b>  |
| <b>3 Terms and definitions</b>                                             | <b>1</b>  |
| <b>4 Requirements</b>                                                      | <b>3</b>  |
| 4.1 Biological characteristics                                             | 3         |
| 4.1.1 Sterility and non-pyrogenicity                                       | 3         |
| 4.1.2 Biocompatibility                                                     | 3         |
| 4.2 Physical characteristics                                               | 3         |
| 4.2.1 Blood pathway integrity                                              | 3         |
| 4.2.2 Prime volume                                                         | 3         |
| 4.2.3 Connector integrity                                                  | 3         |
| 4.3 Performance characteristics                                            | 3         |
| 4.3.1 Hydraulic performance                                                | 3         |
| 4.3.2 Blood cell damage                                                    | 3         |
| 4.3.3 Bearing durability                                                   | 4         |
| 4.3.4 Shelf life                                                           | 4         |
| <b>5 Tests and measurements to determine compliance with this document</b> | <b>4</b>  |
| 5.1 General                                                                | 4         |
| 5.1.1 Tests and measurements                                               | 4         |
| 5.1.2 Operating variables                                                  | 4         |
| 5.1.3 Temperature                                                          | 4         |
| 5.1.4 Relationship between variables                                       | 4         |
| 5.1.5 Procedures                                                           | 5         |
| 5.1.6 Driver/console                                                       | 5         |
| 5.2 Biological characteristics                                             | 5         |
| 5.2.1 Sterility and non-pyrogenicity                                       | 5         |
| 5.2.2 Biocompatibility                                                     | 5         |
| 5.3 Physical characteristics                                               | 5         |
| 5.3.1 Blood pathway integrity                                              | 5         |
| 5.3.2 Prime volume                                                         | 5         |
| 5.3.3 Connectors                                                           | 5         |
| 5.4 Performance characteristics                                            | 6         |
| 5.4.1 Hydraulic performance                                                | 6         |
| 5.4.2 Blood cell damage                                                    | 6         |
| 5.4.3 Bearing wear                                                         | 7         |
| 5.4.4 Shelf life                                                           | 7         |
| <b>6 Information supplied by the manufacturer</b>                          | <b>7</b>  |
| 6.1 Information on the device                                              | 7         |
| 6.2 Information on the packaging                                           | 8         |
| 6.2.1 Unit container                                                       | 8         |
| 6.2.2 Shipping container                                                   | 8         |
| 6.3 Information in the accompanying documents                              | 8         |
| 6.4 Information in the accompanying documents in a prominent form          | 9         |
| <b>7 Packaging</b>                                                         | <b>9</b>  |
| <b>Bibliography</b>                                                        | <b>10</b> |

## 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](http://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](http://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 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](http://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*.

get full document from [standards.iteh.ai](http://standards.iteh.ai)

## 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](#).

# Sample Document

get full document from [standards.iteh.ai](https://standards.iteh.ai)