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# Cardiovascular implants and extracorporeal systems — Vascular device-drug combination products — Part 1: General requirements

*Implants cardiovasculaires et circuits extra-corporels — Produits de  
combinaison médicament-dispositif vasculaire —*

*Partie 1: Exigences générales*



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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  
www.iso.org

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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](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 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*.

ISO 12417 consists of the following parts under the general title, *Cardiovascular implants and extracorporeal systems — Vascular device-drug combination products*:

- *Part 1: General requirements*
- *Part 2: Local regulatory guidance*

## Introduction

This part of ISO 12417 was prepared in order to provide minimum requirements for vascular device-drug combination products (VDDCPs).

Only issues related to vascular devices combined with drug(s), wherein the drug serves an ancillary function of the VDDCP are covered by this part of ISO 12417.

It was impossible, when writing this part of ISO 12417, to take into consideration all future and emerging technologies. VDDCPs using such technologies will need to be evaluated following the basic requirements of this International Standard. Testing beyond the scope of this part of ISO 12417 might also be necessary to characterize these device systems. Consideration shall be given to the failure modes of the VDDCP and their effects on the performance in deciding what testing will be appropriate.

For issues related to the primary mode of action (PMOA) of the vascular VDDCP, the reader might find it useful to consider a number of other International Standards (see Bibliography).