INTERNATIONAL STANDARD

ISO 12417-1

First edition
2015-10-01

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

Reference number
ISO 12417-1:2015(E)

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

Contents

Page

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).

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).

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).

Cardiovascular implants and extracorporeal systems — Vascular device-drug combination products —

Part 1: General requirements

1 Scope

This part of ISO 12417 specifies requirements for vascular device-drug combination products (VDDCPs) based upon current technical and medical knowledge. VDDCPs are medical devices with various clinical indications for use in the human vascular blood system. A VDDCP incorporates, as an integral part, substance(s) which, if used separately, can be considered to be a medicinal substance or product (drug substance, drug product) but the action of the medicinal substance is ancillary to that of the device and supports the primary mode of action (PMOA) of the device. With regard to safety, this part of ISO 12417 outlines requirements for intended performance, design attributes, materials, design evaluation, manufacturing, sterilization, packaging, and information supplied by the manufacturer. For implanted products, this International Standard should be considered as a supplement to ISO 14630, which specifies general requirements for the performance of non-active surgical implants. This International Standard should also be considered as a supplement to relevant device-specific standards, such as the ISO 25539-series specifying requirements for endovascular devices. Requirements listed in this part of ISO 12417 also address VDDCPs that are not permanent implants.

NOTE Due to variations in the design of combination products covered by this part of ISO 12417 and due to the relatively recent development of some of these combination products, acceptable standardized *in vitro* test results and clinical study results are not always available. As further scientific and clinical data become available, appropriate revision of this part of ISO 12417 might be necessary.

Delivery systems or parts of the delivery system are included in the scope of this part of ISO 12417, if they comprise an integral component of the vascular device and if they are drug-covered (e.g. drug-covered balloon catheters and drug-covered guidewires).

Devices whose PMOA is to provide a conduit for delivery of a drug, are excluded from the scope of this part of ISO 12417 (e.g. infusion catheters), unless they contain a drug component that is intended to have an ancillary action to the device part (e.g. antimicrobial coated infusion catheter).

Procedures and devices used prior to and following the introduction of the VDDCP (e.g. balloon angioplasty devices) are excluded from the scope of this part of ISO 12417 if they do not affect the drug-related aspects of the device.

This part of ISO 12417 is not comprehensive with respect to the pharmacological evaluation of VDDCPs. Some information on the requirements of different national and regional authorities is given in Annex B.

Absorbable components of VDDCPs (e.g. coatings) are addressed by this part of ISO 12417 in their connection with drug-related aspects of the device. Degradation and other time-dependent aspects of absorbable implants and coatings are not completely addressed by this part of ISO 12417.

NOTE See also ISO/TS 17137 and ASTM F3036-13.

This part of ISO 12417 does not address issues associated with viable or non-viable biological materials such as tissues, cells, or proteins.

This part of ISO 12417 does not address issues associated with active surgical implants (i.e. implants that require power not generated by the human body or gravity).

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

ISO 10993-2, *Biological evaluation of medical devices — Animal welfare requirements*

ISO 10993-7, *Biological evaluation of medical devices — Ethylene oxide sterilization residuals*

ISO 11070, *Sterile single-use intravascular introducers, dilators and guidewires*

ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 14155, *Clinical investigation of medical devices for human subjects — Good clinical practice*

ISO 14630:2012, *Non-active surgical implants — General requirements*

ISO 14937, *Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices*

ISO 14971:2007, *Medical devices — Application of risk management to medical devices*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 25539-2, *Cardiovascular implants — Endovascular devices — Part 2: Vascular stents*

NOTE See the Bibliography for additional device-specific and regional information about standards and guidance documents.

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 14630 and the following apply.

NOTE Potential clinical events are defined in Annex A.

3.1
active pharmaceutical ingredient
API
drug
pharmacologically active (drug or medicinal) substance used as a raw material, which is coated on, bound to or incorporated into the device to achieve an ancillary device function (e.g. minimizing vascular restenosis)

3.2
batch
quantity of VDDCP at the final stage or pre-final stage of manufacture which has undergone the same manufacturing cycle, using the same components (e.g. same coating solution, same device size), and meets the same specifications

3.3
change
alteration to an activity or to the VDDCP to improve or maintain the composition or performance of a VDDCP

