TECHNICAL REPORT

ISO/TR 12417-2

Second edition
2022-07

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

Part 2: Local regulatory information

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

Partie 2: Directives règlementaires locales

Reference number
ISO/TR 12417-2:2022(E)

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Published in Switzerland

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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).

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 of the voluntary nature of standards, 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 www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 2, *Cardiovascular implants and extracorporeal systems*.

This second edition cancels and replaces the first edition (ISO/TR 12417-2:2017), which has been technically revised.

The main changes are: editorial changes have been made regarding the use of requirements, recommendations, permissions and possibilities.

A list of all parts in the ISO 12417 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

This document was prepared in order to provide local regulatory information for vascular device-drug combination products (VDDCPs).

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 in final formulation separately, can be considered to be a medicinal product (drug product) but the action of the medicinal substance is ancillary to that of the device and supports the primary mode of action of the device.

Only regulatory issues related to drug(s) combined with the vascular device based on the ancillary function of the VDDCP are covered by this document.

Although this document attempts to represent the state-of-the-art regarding regulatory requirements for pre and post-approval changes, these requirements are evolving and as such, it is strongly suggested that the applicant consult with the regulatory authority under which whose jurisdiction the VDDCP falls. This is most easily done by accessing the local authorities' current webpage.

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

NOTE 1 For issues related to the primary mode of action of the vascular device, the reader can find it useful to consider a number of other International Standards given in the Bibliography.

NOTE 2 Potential clinical events are defined in ISO 12417-1:2015, Annex A.

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

Part 2: Local regulatory information

1 Scope

This document provides region-specific information for:

— local submissions and approvals for vascular device-drug combination products (VDDCPs) in countries and regions around the world;

— changes related to the drug-containing part and how they are evaluated by different local regions.

For implanted products, this document is considered as a supplement to ISO 14630, which specifies general requirements for the performance of non-active surgical implants.

This document is considered also as a supplement to ISO 12417-1, and any relevant device-specific standards, such as the ISO 25539 series specifying requirements for endovascular devices. This document also addresses VDDCPs that are not necessarily permanent implants.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 12417-1, *Cardiovascular implants and extracorporeal systems — Vascular device-drug combination products — Part 1: General requirements*

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

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 12417-1, ISO 14630 and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
active pharmaceutical ingredient
API
drug substance
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, such as minimizing vascular restenosis