PD ISO/TR 12417-2:2022



BSI Standards Publication

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

Part 2: Local regulatory information

bsi.

National foreword

This Published Document is the UK implementation of ISO/TR 12417-2:2022. It supersedes PD ISO/TR 12417-2:2017, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee CH/150/2, Cardiovascular implants.

A list of organizations represented on this committee can be obtained on request to its committee manager.

Contractual and legal considerations

This publication has been prepared in good faith, however no representation, warranty, assurance or undertaking (express or implied) is or will be made, and no responsibility or liability is or will be accepted by BSI in relation to the adequacy, accuracy, completeness or reasonableness of this publication. All and any such responsibility and liability is expressly disclaimed to the full extent permitted by the law.

This publication is provided as is, and is to be used at the recipient's own risk.

The recipient is advised to consider seeking professional guidance with respect to its use of this publication.

This publication is not intended to constitute a contract. Users are responsible for its correct application.

This publication is not to be regarded as a British Standard.

© The British Standards Institution 2022
Published by BSI Standards Limited 2022

ISBN 978 0 539 18471 6

ICS 11.040.40

Compliance with a Published Document cannot confer immunity from legal obligations.

This Published Document was published under the authority of the Standards Policy and Strategy Committee on 31 July 2022.

Amendments/corrigenda issued since publication

Date	Text affected

PD ISO/TR 12417-2:2022

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)

© ISO 2022



COPYRIGHT PROTECTED DOCUMENT

© ISO 2022

All rights reserved. Unless otherwise specified, or required in the context of its implementation, 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
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

© ISO 2022 – All rights reserved

Contents

Page

Foreword ..... **v**
Introduction ..... **vi**
1 Scope **1**
2 Normative references **1**
3 Terms and definitions **1**
4 Information on device- and drug-related aspects — Applicable documents for local guidance **4**
4.1 General 4
4.2 Australia 4
4.2.1 General 4
4.2.2 Australia: Managing changes 5
4.2.3 Australia: Clinical evaluation requirements 5
4.2.4 Australia: Audit requirements 5
4.3 Brazil 5
4.3.1 Brazil: Managing changes 5
4.3.2 Brazil: Clinical evaluation requirements 6
4.3.3 Brazil: Audit requirements 6
4.4 Canada 6
4.4.1 Canada: Managing changes 6
4.4.2 Canada: Clinical evaluation requirements 6
4.4.3 Canada: Audit requirements 6
4.5 European Union (EU) 6
4.5.1 EU: Managing changes 6
4.5.2 EU: Material inclusion and labelling requirements 7
4.5.3 EU: Clinical evaluation requirements 7
4.5.4 EU: Audit requirements 7
4.6 India 7
4.6.1 India: Managing changes 7
4.6.2 India: Clinical evaluation requirements 8
4.6.3 India: Audit requirements 8
4.7 Japan 8
4.7.1 Japan: Managing changes 8
4.7.2 Japan: Clinical evaluation requirements 8
4.7.3 Japan: Audit requirements 8
4.8 People's Republic of China (PRC) 8
4.8.1 PRC: Managing changes 8
4.8.2 PRC: Clinical evaluation requirements 9
4.8.3 PRC: Audit requirements 10
4.9 Russia 10
4.9.1 Russia: Managing changes 10
4.9.2 Russia: Clinical evaluation requirements 10
4.9.3 Russia: Audit requirements 10
4.10 United States of America (USA) 10
4.10.1 USA: Managing changes 10
4.10.2 USA: Clinical evaluation requirements 11
4.10.3 USA: Audit requirements 11
5 Managing changes that can impact the DCP **12**
5.1 General 12
5.2 Change evaluation 12
5.2.1 Identify changes 12
5.2.2 Risk evaluation 13
5.2.3 Guidance for change evaluation 13

© ISO 2022 – All rights reserved

5.2.4 Pre-market 14
5.3 Interactions with region-specific regulatory authorities — Post-commercialization 14

Bibliography **22**

© ISO 2022 – All rights reserved

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.

© ISO 2022 – All rights reserved

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.

© ISO 2022 – All rights reserved

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

© ISO 2022 – All rights reserved