SLOVENSKI STANDARD
SIST EN ISO 12417-1:2024

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Nadomešča:
SIST EN ISO 12417-1:2015

Vsadki (implantati) za srce in ožilje ter zunajtelesni pretočni sistemi - Žilni medicinski kombinirani proizvodi/zdravila - 1. del: Splošne zahteve (ISO 12417-1:2024)

Cardiovascular implants and extracorporeal systems - Vascular device-drug combination products - Part 1: General requirements (ISO 12417-1:2024)

Kardiovaskuläre Implantate und extrakorporale Systeme - Vaskuläre Medizinprodukt-Arzneimittel-Kombinationsprodukte - Teil 1: Allgemeine Anforderungen (ISO 12417-1:2024)

Implants cardiovasculaires et circuits extra-corporels - Produits de combinaison médicament-dispositif vasculaire - Partie 1: Exigences générales (ISO 12417-1:2024)

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11.040.40	Implantanti za kirurgijo, protetiko in ortetiko	Implants for surgery, prosthetics and orthotics

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EUROPEAN STANDARD

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English Version

Cardiovascular implants and extracorporeal systems - Vascular device-drug combination products - Part 1: General requirements (ISO 12417-1:2024)

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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European foreword

This document (EN ISO 12417-1:2024) has been prepared by Technical Committee ISO/TC 150 "Implants for surgery" in collaboration with Technical Committee CEN/TC 285 “Non-active surgical implants” the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by August 2024, and conflicting national standards shall be withdrawn at the latest by August 2024.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

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Endorsement notice

The text of ISO 12417-1:2024 has been approved by CEN as EN ISO 12417-1:2024 without any modification.

International Standard

ISO 12417-1

Second edition
2024-02

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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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 document 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).

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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,* in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 285, *Non-active surgical implants,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 12417-1:2015), which has been technically revised.

The main changes are as follows:

— the text regarding ethylene oxide sterilization limits has been revised,

— references have been updated, and

— terms and definitions have been revised.

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

Vascular device-drug combination products (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.

Many vascular device-drug combination products have been shown to be safe and effective in clinical use. This revision is not intended to require additional evaluation of these products as the testing would not provide useful information regarding the expected clinical performance of the product. Manufacturers can rely on historical data gathered in the previous edition of this document (i.e. ISO 12417-1:2015). Similarly, for product modifications or changes in intended clinical use, this edition of this document (i.e. ISO 12417-1:202X) is not intended to require additional evaluation of any aspects of the product that are not expected to change clinical performance.

When developing this document, it was impossible to consider all future and emerging technologies. VDDCPs using such technologies need to be evaluated following the basic requirements of this document. Testing beyond the scope of this document can also be necessary to characterize these future and emerging device systems.

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

Part 1: General requirements

1 Scope

This document specifies requirements for vascular device-drug combination products (VDDCPs).

With regard to safety, this document outlines requirements for intended performance, design attributes, materials, design evaluation, manufacturing, sterilization, packaging and information supplied by the manufacturer.

For implanted products, this document is intended to be used as a supplement to ISO 14630, which specifies general requirements for the performance of non-active surgical implants. This document is intended to be used as a supplement to relevant device-specific standards, such as the ISO 25539 series specifying requirements for endovascular devices. Requirements listed in this document also address VDDCPs that are not permanent implants.

NOTE 1 Due to variations in the design of combination products covered by this document 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 document can be necessary.

This document applies to delivery systems or parts of the delivery system that are an integral component of the vascular device and that are drug-covered (e.g. drug-covered balloon catheters and drug-covered guidewires).

This document does not apply to devices whose PMOA provide a conduit for delivery of a drug (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).

This document does not apply to procedures and devices used prior to and following the introduction of the VDDCP (e.g. balloon angioplasty devices) that do not affect the drug-related aspects of the device.

This document does not provide a comprehensive pharmacological evaluation of VDDCPs.

NOTE 2 Some information about the requirements of certain national and regional authorities is given in Annex B.

The connection of absorbable components of VDDCPs (e.g. coatings) with drug-related aspects of the device are addressed in this document. This document does not provide an exhaustive list of the degradation and other time-dependent aspects of absorbable implants and coatings.

NOTE 3 For more information on absorbable coatings, refer to ISO/TS 17137 and ASTM F3036-13.

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

This document 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 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 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 — Part 2: Animal welfare requirements*

ISO 10993-7, *Biological evaluation of medical devices — Part 7: 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 14971:2019, *Medical devices — Application of risk management to medical devices*

ISO 15223-1, *Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements*

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

3 Terms and definitions

For the purposes of this document, the terms and definitions provided in 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 (e.g. minimizing vascular restenosis)

3.2
batch
quantity of *vascular device-drug combination product* (3.27) 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