



ISO 12417-1

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

Second edition
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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.

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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.