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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

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Foreword

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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).

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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*.

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

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 Technical Report.

Although this document attempts to represent the state-of-the-art regarding regulatory requirements for pre/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.

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NOTE For issues related to the primary mode of action of the vascular device, the reader might find it useful to consider a number of other International Standards (see Bibliography).