NATIONAL STANDARD OF THE

PEOPLE'S REPUBLIC OF CHINA

GB/T 39381.1-2020

Cardiovascular implants - Vascular device-drug combination products - Part 1: General requirements

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Foreword

GB/T 39381 Cardiovascular Implants - Vascular Device-Drug Combination Products consists of the following 2 parts:

--- Part 1: General Requirements;

--- Part 2: Local Regulatory Guidance.

This Part is Part 1 of GB/T 39381.

This Part was drafted as per the rules specified in GB/T 1.1-2009.

This Part uses re-drafting method to modify and adopt ISO 12417-1:2015 Cardiovascular Implants and Extracorporeal Systems - Vascular Device-Drug Combination Products - Part 1: General Requirements.

Compared with ISO 12417-1:2015, the technical differences and causes of this Part are as follows:

--- For the normative references, this Part adjusts according to the technical

differences, so as to adapt to China's technical conditions. The adjustment is reflected in Clause 2 "Normative References", which are specially as follows:

? Use GB/T 16886.1 that equivalently adopts the international standard to replace ISO 10993-1;

? Use GB/T 16886.2 that equivalently adopts the international standard to replace ISO 10993-2;

? Use GB/T 16886.7 that equivalently adopts the international standard to replace ISO 10993-7;

? Use GB/T 19633.1 that equivalently adopts the international standard to replace ISO 11607-1;

? Use GB/T 19974 that equivalently adopts the international standard to replace ISO 14937;

? Use YY 0285.4 that equivalently adopts the international standard to replace ISO 10555-4;

? Use YY 0450.1 that equivalently adopts the international standard to replace ISO 11070;

? Use YY/T 0466.1 that equivalently adopts the international standard to replace ISO 15223-1;

? Use YY/T 0663.2 that equivalently adopts the international standard to replace ISO 25539-2.

--- Add the "solvent residue" to supplement the relevant requirements for the design attributes of the drug-containing part of the device-drug combination products (see 7.2.4.3.8 of this Edition).

--- Delete the "clinical evaluation" to avoid inconsistencies with Guidelines for Medical Devices Clinical Evaluation (see 7.3 of ISO12417-1:2015).

This Part made the following editorial modifications:

--- Modify the standard name;

--- Delete the Annex B of ISO 12417-1:2015.

Please note some contents of this document may involve the patents. The issuing agency of this document shall not assume the responsibility to identify these patents.

This Part was proposed by National Medical Products Administration.

This Part shall be under the jurisdiction of National Technical Committee for Standardization of Implants for Surgery and Orthopaedic Devices (SAC/TC 110).

Drafting organizations of this Part: Tianjin Medical Device Quality Supervision and Inspection Centre; Centre for Medical Device Evaluation, NMPA; Shanghai Microport Medical (Group) Co., Ltd.; Lepu Medical Technology (Beijing) Co., Ltd.; and Medtronic (Shanghai) Management Co., Ltd.

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Cardiovascular Implants - Vascular Device-Drug Combination Products - Part 1: General Requirements

1 Scope

This part of GB/T 39381 specifies the requirements for the intended performance, design attributes, materials, design evaluation, manufacturing, sterilization, packaging, and information provided by the manufacturer, etc. of the vascular device-drug combination products (VDDCPs).

NOTE 1: Due to variations in the design of combination products covered by this Part 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 development and clinical data accumulation, appropriate revision of this Part might be necessary.

Delivery systems or parts of the delivery system are included in the scope of this Part, if they comprise an integral component of the vascular device and if they are drug-covered (e.g.: drug-covered balloon catheters and drug-covered guidewires). This Part

is also applicable to the non-permanent implantable VDDCPs.

Devices whose PMOA is to provide a conduit for delivery of a drug, are excluded from the scope of this Part (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 central venous catheter).

Procedures and devices used prior to and following the introduction of the VDDCP (e.g.: balloon angioplasty devices) are excluded from the scope of this Part if they do not affect the drug-related aspects of the device.

This Part includes the requirements for the absorbable components (such as coating) related to the device drug in the VDDCPs.

NOTE 2: See also ISO/TS 17137.

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

This Part 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 essential to the application of this document. For the dated documents, only the versions with the dates indicated are applicable to this document; for the undated documents, only the latest version (including all the amendments) is applicable to this document.

GB/T 16886.1 Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process (GB/T 16886.1-2011, ISO 10993-1:2009, IDT)

GB/T 16886.2 Biological Evaluation of Medical Devices - Part 2: Animal Welfare Requirements (GB/T 16886.2-2011, ISO 10993-2:2006, IDT)

GB/T 16886.7 Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals (GB/T 16886.7-2015, ISO 10993-7:2008, IDT)

GB/T 19633.1 Packaging for Terminally Sterilized Medical Devices - Part 1: