

**PHARMACEUTICAL INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

YY/T 0500-2021

**Cardiovascular implants and extracorporeal systems. vascular
prostheses. tubular vascular grafts and vascular patches**

心血管植入物 血管假体 管状血管移植物和血管补片

(English Translation)

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Table of Contents

Foreword
1 Scope
2 Normative references

Foreword

This standard was drafted in accordance with the rules given in GB/T 1.1-2009:

This standard replaces YY 0500-2004 "Cardiovascular Implant Artificial Vascular":
Compared with YY 0500-2004, except for editorial changes the main technical changes are as follows:

- Added technical requirements and test methods for vascular patches;
- Added the contents of "expected performance", "design properties" and "material" (see Chapter 5, Chapter 6, Chapter 7);
- Modify "Test Method" to "Appendix A Informative Appendix":

This standard uses the redrafted method to modify and adopts ISO 7198:2016 "Cardiovascular Implants and Vascular Prosthesis Tubes of Extracorporeal Circulation System" Vascular Grafts and Vascular Patches:" the technical differences between this standard and ISO 7198:2016 and their reasons are as follows:

--- Regarding normative reference documents, this standard has made adjustments with technical differences to adapt to the technical conditions of our country:

as follows:

- Replace ISO 10993 with GB/T 16886 which is equivalent to adopting international standards;
- Replace ISO 11135-1 with GB 18279.1 which is equivalent to adopting international standards;
- Replace ISO 11135-2 with GB/T 18279.2 which is equivalent to adopting international standards;
- Replace ISO 11137-1 with GB 18280.1 which is equivalent to adopting international standards;
- Replace ISO 11137-2 with GB 18280.2 which is equivalent to adopting international standards;

- Replace ISO 11137-3 with GB/T 18280.3 which is equivalent to adopting international standards;
 - Replace ISO 11607-1 with GB/T 19633.1 which is equivalent to adopting international standards;
 - Replace ISO 11607-2 with GB/T 19633.2 which is equivalent to adopting international standards;
 - Replace ISO 14937 with GB/T:19974 which is equivalent to adopting international standards;
 - Replacing ISO 14155 with YY/T 0297 which is equivalent to adopting international standards;
 - Replacing ISO 14971 with YY/T 0316 which is equivalent to adopting international standards;
 - Replacing ISO 14630:2012 with YY/T 0640-2016 which is equivalent to adopting international standards;
 - Replacing ISO 14160 with YY 0970 which is equivalent to adopting international standards:
- Revised Appendix A:5 and added the number "A:5:1 Overview" to meet the requirements of GB/T 1.1-2009;
- The numbers of appendix A:5:1~A:5:9 in ISO 7198:2016 are sequentially revised to A:5:2~A:5:10:

Certain content of this standard may involve patents, and the issuing body of this document does not undertake the responsibility to identify these patents:

This standard is proposed by the State Drug Administration:

This standard is approved by the National Technical Committee for Standardization of Surgical Implants and Orthopedic Devices Subcommittee on Cardiovascular Implants (SAC/TC110/SC2) focal point:

1 Scope

1.1

This standard specifies requirements for evaluating vascular prostheses and requirements related to terminology, design attributes and information provided by the manufacturer:

NOTE: Due to changes in implant design covered by this standard and in some cases novel implants (e.g. bioabsorbable vascular prostheses, cell-based it is difficult for this standard to provide all acceptable standardized in vitro test and clinical results: With more scientific and clinical the

acquisition of data requires appropriate revisions to this standard:

1.2

This standard applies to implantation by direct vision surgery (rather than radiography or other indirect imaging techniques, such as CT or MRI), Sterile tubular vascular grafts for intersegmental replacement of the vascular system, bypassing or shunt formation, and repair and reconstruction of the vascular system vascular patch:

1.3

This standard applies to vascular prostheses made of synthetic woven materials and synthetic non-woven materials:

1.4

This standard applies to vascular prostheses, including tissue-engineered vascular prostheses, made in whole or in part from inactive biologically derived materials, but this standard does not cover the procurement, acquisition, manufacture and all testing requirements of biologically derived materials:

1.5

This standard applies to composite, coated, composite and externally reinforced vascular prostheses:

1.6

This standard does not apply to endovascular prostheses that are delivered by catheter and implanted by indirect surgery: This standard covers graft materials appropriate for Information on test method development:

Note: YY/T 0663.1 specifies the requirements for endovascular prostheses:

1.7

This standard does not apply to valved conduits and valve parts composed of tubular vascular grafts and valves, which can be used for tubular vascular grafts:

The graft part is evaluated, but this standard does not describe the specific requirements and test methods for this type of device:

1.8

This standard does not apply to cardiac and pericardial patches, vascular stents, accessory devices (such as anastomotic devices, staplers, tunnelers and sutures) and gasket:

Note: YY/T 0663.2 specifies the requirements for vascular stents:

1.9

This standard does not apply to requirements related to cell seeding:

1.10

This standard does not cover the pharmacology of drug-eluting or drug-coated vascular prostheses:

NOTE: ISO 12417 specifies requirements for vascular device-drug combination products:

1.11

This standard does not cover degradation of absorbable vascular prostheses, tissue ingrowth and/or tissue replacement and other time-related aspects:

2 Normative references

The following documents are essential for the application of this document: For dated references, only the dated version applies to this article pieces: For undated references, the latest edition (including all amendments) applies to this document:

GB/T 16886 (all parts) Biological evaluation of medical devices [ISO 10993 (all parts)] GB 18279.1 Sterilization of Healthcare Products Ethylene Oxide Part 1: Development, Validation and Routine Control of Sterilization Processes for Medical Devices requirements (GB 18279.1-2015, ISO 11135-1:2007, IDT) GB/T 18279.2 Ethylene Oxide Sterilization for Healthcare Products Part 2: Application Guidelines for GB 18279.1 (GB/T 18279.2-2015, ISO 11135-2:2008, IDT) GB 18280.1 Sterilization Radiation for Healthcare Products Part 1: Requirements for Development, Validation and Routine Control of Sterilization Processes for Medical Devices Seek (GB 18280.1-2015, ISO 11137-1:2006, IDT)