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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY 0580-2024

Replacing YY 0580-2011

Cardiovascular implants and artificial organs - Cardiopulmonary bypass systems - Arterial line blood filters

心血管植入物及人工器官 心肺转流系统 动脉管路血液过滤器

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Foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for standardization work Part

1.Structure and drafting rules for standardization documents" Drafting. This document replaces YY 0580-2011 "Cardiovascular Implants and Artificial Organs Cardiopulmonary Bypass System Arterial Line Blood Filters" and Compared with YY 0580-2011, in addition to structural adjustments and editorial modifications, the main technical changes are as follows:

--- Deleted some terms (see 3.4, 3.5, 3.6,

3.9 of the.2011 edition);

--- Changed the definitions of some terms (see 3.5);

--- Changed the requirements for joints (see 4.2.3,

4.2.3 of the.2011 edition);

--- Added particle indicators (see 4.2.4, 5.3.4);

--- The test methods for sterility, pyrogen-free and connectors have been changed (see 5.2.1, 5.3.3, 5.2.1,

5.3.5 of the.2011 edition);

--- Changed the preparation requirements of the test solution for bubble removal capability (see 5.4.5.1,

5.4.4.1 of the.2011 edition);

--- Deleted the information and packaging provided by the manufacturer (see Chapter 6 and Chapter 7 of the.2011 edition). This document is modified to adopt ISO 15675.2016 "Cardiovascular implants and artificial organs - Arterial blood filtration in cardiopulmonary

bypass systems" ISO 15675.2016/AMD1.2020 "Connectors", the clauses that have changed with ISO 15675.2016/AMD1.2020 have been approved. The pages are indicated by double vertical lines () in the blank space outside the page number. This document has technical differences compared to ISO 15675.2016 and ISO 15675.2016/AMD1.2020. The provisions involved in the.2016 differences are marked with a vertical line (|) in the blank space outside the page number. The corresponding technical A summary of technical differences and their causes. Please note that some of the contents of this document may involve patents. The issuing organization of this document does not assume the responsibility for identifying patents. This document is proposed by the State Food and Drug Administration. This document is under the jurisdiction of the National Technical Committee for Standardization of Medical Extracorporeal Circulation Equipment (SAC/TC158). The previous versions of this document and the documents it replaces are as follows:

---First issued in.2005 as YY 0580-2005, first revised in.2011;

1 Scope

YY 0580 is the mandatory standard for the arterial line filter in a cardiopulmonary bypass circuit, the last barrier between the machine and the patient's arterial circulation. Its job is to trap gaseous microemboli and particulate debris before they reach the brain, which is why it is fitted at all: the neurological outcome of open heart surgery is measurably affected by embolic load. The requirements therefore centre on filtration efficiency at the relevant particle and bubble sizes, pressure drop across the filter at full flow, and the blood-contact behaviour of the materials. The YY prefix without /T makes compliance compulsory in China. For a manufacturer or an importer of bypass circuit filters, this is the governing standard.

This document specifies the requirements for single-use sterile arterial line blood filters (hereinafter referred to as filters) and describes the corresponding tests method. This document applies to filters used in cardiopulmonary bypass surgery and does not apply to blood circuits in cardiopulmonary bypass systems.

Note. The filter is used to filter out various particles in human blood during cardiopulmonary bypass surgery, such as blood clots, debris, air embolism and other potentially dangerous of substance.

2 Normative references

The contents of the following documents constitute essential clauses of this document through normative references in this document. For referenced documents without a date, only the version corresponding to that date applies to this document; for referenced documents without a date, the latest version (including all amendments) applies to This document.

GB/T 14233.1 Inspection methods for medical infusion, blood transfusion and injection equipment Part

3 Terms and definitions

The following terms and definitions apply to this document.

11 Systemic toxicity tests (GB/T 16886.11-2011, ISO 10993-11.2006, IDT)

GB 18278.1 Sterilization of health care products by moist heat Part

1.Development, validation and routine control of sterilization processes for medical devices Request (GB 18278.1-2015, ISO 17665-1.2006, IDT)

GB 18279.1 Sterilization of healthcare products with ethylene oxide Part

1.Development, validation and routine control of sterilization processes for medical devices System requirements (GB 18279.1-2015, ISO 11135-1.2007, IDT)

GB 18280.1 Radiation sterilization of health care products Part

1.Development, validation and routine control of sterilization processes for medical devices Request (GB 18280.1-2015,

ISO 11137-1.2006, IDT) GB/T.19974 Sterilization of health care products - Characteristics of sterilization factors and development, validation and routine control of sterilization processes for medical devices General requirements (GB/T.19974-2018, ISO 14937.2009, IDT)

YY/T 0916.7 Small-bore connectors for medical liquids and gases Part

7.Connectors for intravascular or subcutaneous applications (YY/T 0916.7-2024, ISO 80369-7.2021,IDT)

YY/T 1556-2017 Test method for particulate contamination of medical infusion, blood transfusion and injection equipment Pharmacopoeia of the People's Republic of China