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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY 0603-2024

Replacing YY 0603-2015

Cardiopulmonary bypass systems - Hard-shell cardiotomy/venous reservoirs (with or without filter) and soft venous reservoir bags

心肺转流系统 心脏手术硬壳贮血器、静脉贮血器系统（带或不带过滤器）和静脉贮血软袋

Issued on: July 8, 2024 **Implemented on: July 20, 2027**

Issued by: National Medical Products Administration

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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 0603-2015 "Cardiovascular Implants and Artificial Organs Heart Surgery Hard Shell Blood Reservoir/Venous Blood Reservoir System Compared with YY 0603-2015, in addition to structural adjustments and editorial revisions, the main technical The changes are as follows:

--- Deleted the static pre-charge of.2015 version 3.8;

--- Changed the term and definition "dynamic pre-charge" (see 3.11);

--- Added terms and definitions "thrombocytopenia", "free hemoglobin level in plasma", "leukopenia", "control blood reservoir", "filter (Removal rate) (see 3.12~3.16);

--- Added bacterial endotoxins and corresponding test methods (see 4.1.2, 5.2.2);

--- Deleted Note 2 in

4.2.3 of the.2015 edition;

--- Added requirements for dynamic pre-charge volume, minimum and maximum capacity and corresponding test methods (see 4.3.9, 4.3.10, 5.4.9, 5.4.10);

--- Modified the test methods for gas handling capacity, defoaming characteristics, filtration rate, and ethylene oxide residual (see 5.4.2, 5.4.4, 5.4.6, 5.6);

--- Deleted Chapter 6 and Chapter 7 of the.2015 edition. This document is modified to adopt ISO 15674.2016 Cardiovascular implants and artificial organs - Hard shell blood reservoirs/venous blood reservoirs for cardiac surgery Systems (with or without filters) and venous blood storage bags" and Amendment No. 1 of 2020.This document is consistent with ISO 15674.2016 and 2020 The main technical differences and reasons of the amendment No. 1 of.2017 are as follows:

--- The normative reference documents adopt the Chinese standards, and delete the ISO 80369-7.2016 cited in the 2020 amendment No. 1 to suit In our national conditions;

3.8 Static precharge. This term and definition are not referenced in the text;

--- Move all the contents of

1 Scope

YY 0603 is the mandatory standard for the reservoirs in a cardiopulmonary bypass circuit: the hard-shell cardiotomy and venous reservoir, with or without an integral filter, and the soft venous reservoir bag. The reservoir is the buffer that lets a perfusionist manage volume during open heart surgery, and it is also where blood suctioned from the surgical field is returned, filtered and defoamed before going back to the patient, which makes air handling its defining safety function: air that leaves the reservoir reaches the arterial line. The YY prefix without /T makes compliance compulsory in China. For a manufacturer or an importer of bypass circuit components, this is the governing standard.

This document specifies sterile, single-use, extracorporeal circulation cardiac surgery hard-shell blood reservoirs and hard-shell venous blood reservoir systems (with or without The requirements for filters) and venous blood storage bags (referred to as blood reservoirs) describe the corresponding test methods. Blood reservoirs are intended for cardiopulmonary bypass surgery. Used for blood storage during CPB. This document applies only to blood reservoirs in multifunctional systems which may have integrated components such as blood gas exchangers (oxygenators), blood Filters, defoamers, blood pumps, etc.

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 14233.1-2022 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 16886.11-2021, ISO 10993-11.2017, IDT)

GB/T 16886.12 Biological evaluation of medical devices Part

12.Sample preparation and reference materials (GB/T 16886.12- 2017, ISO 10993-12.2012,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 Characteristics of sterilization factors for medical health products and general requirements for the setting and confirmation of sterilization processes for medical devices Requirements (GB/T.19974-2018, ISO 14937.2009, IDT)

YY 0580-2024 Cardiovascular implants and artificial organs Cardiopulmonary bypass system arterial line blood filter

YY/T 0681.1-2018 Test methods for sterile medical device packaging Part

1.Guide to accelerated aging tests Pharmacopoeia of the People's Republic of China 2020 Edition Volume 4