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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 0730-2023

Cardiovascular implants and artificial organs - Requirements for single-use tubing packs used in cardiopulmonary bypass and extracorporeal membrane oxygenation (ECMO)

心血管外科植入物和人工器官 心肺旁路和体外膜肺氧合(ECMO)使用的一次性使用管道套包的要求

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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/T 0730-2009 "Cardiovascular Surgical Implants and Artificial Organs Cardiopulmonary Bypass and Extracorporeal Membrane Oxygenation (ECMO) Requirements for Single-Use Conduit Packages, compared with YY/T 0730-2009, except for structural adjustments and editorial changes In addition, the main technical changes are as follows:

--- Deleted some normative references (GB/T 19633 and ASTM standards in Chapter 2 of the.2009 edition);

--- Added some terms (see 3.9, 3.10, 3.11);

--- Added the requirement of validity period and test method (see 4.3.4, 5.4.4);

--- Added coating requirements and test methods (see 4.4, 5.5);

--- Deleted the information and packaging provided by the producer (see Chapters 6 and 7 of the.2009 edition). This document is modified to adopt ISO 15676.2016 "Cardiopulmonary

bypass and extracorporeal membrane oxygenation for implants and artificial organs in cardiovascular surgery Requirements for Single-Use Tubing Sets for Use by (ECMO)". A description of the technical differences between this document and ISO 15676.2016 and their reasons is given in Appendix A. The following editorial changes have been made to this document.

--- Chapter 1 adds a note to explain the terms "membrane oxygenation" and "membrane oxygenation".

---Chapter 2 cites Chinese standards that adopt international standards, not international standards;

--- Added Appendix B (informative) "Particle Shedding Reference Test Method". Please note that some contents of this document may refer to patents. The issuing agency of this document assumes no responsibility for identifying patents. This document is proposed by the State Drug Administration. This document is under the jurisdiction of the National Standardization Technical Committee of Medical Extracorporeal Circulation Equipment (SAC/TC158). This document was drafted by: Guangdong Medical Device Quality Supervision and Inspection Institute, Ningbo Filar Medical Supplies Co., Ltd., Tianjin Plastic Research Institute Research Institute Co., Ltd., Dongguan Kewei Medical Devices Co., Ltd. The main drafters of this document. Ke Jun, Yuan Qin, Xu Chaosheng, Hong Liangtong, Wu Bijun, Zhang Yun, Shen Lisi, Ye Qing, Hong Huangli, Wu Minyu, Hu Xianghua, Xie Yan, Wen Shaojun. The release status of previous versions of this document and the documents it replaces are as follows:

---First published as YY/T 0730-2009 in.2009;

--- This is the first revision.

The purpose of formulating this document is to ensure a standard for blood circulation during cardiopulmonary bypass (CPB) and extracorporeal membrane oxygenation (ECMO) procedures. The medical-grade tubing in the tubing kit is used for one-time use for adequate safety and functional testing. Users generally need to provide the details of the pipeline package. Detailed description. In addition, this document also includes guarantees to clarify the characteristics of the piping package in the accompanying documents and production information. It is specified in this document Tubing performance characteristics are provided as part of a disposable tubing kit. The recommended methods given in this document are intended to be used in procedures for evaluating the medical-grade pipeline of CPB therapy and ECMO. introduced for the The test method for the material properties of the body, the service life of the pipeline used in the rolling blood pump and the method of sanitation and cleaning, but there is no test method for these indicators Limits are explained. This document also includes minimum reporting requirements. Existing functional characterization methods can help users to choose the appropriate treatment for patients and related patients according to therapy. medical grade tubing for allergies. This

information can inform clinical quality control processes aimed at improving the safety of CPB and ECMO therapy. for help. This document refers to other standards as methods of testing common characteristics of medical devices. This document does not include animal and clinical studies, but the manufacturer's quality system includes these studies. This document only includes requirements corresponding to medical-grade tubing used in CPB and ECMO. For other requirements not specified, you can See some of the other standards listed in the references. Cardiovascular Surgical Implants and Artificial Organs Cardiopulmonary bypass and extracorporeal membrane oxygenation (ECMO) Requirements for single-use tubing kits

1 Scope

YY/T 0730 sets the requirements for the single-use tubing packs that carry a patient's blood outside the body during cardiopulmonary bypass and ECMO. These circuits run for hours in cardiac surgery and for days or weeks in ECMO, with the entire circulating volume passing through them, so the specification covers the things that decide whether that is survivable: the biocompatibility of the surfaces the blood touches, the mechanical strength and kink resistance of the tubing, the integrity of the connections, the sterility of the pack and the information supplied with it. ECMO capacity expanded sharply in China after the pandemic years, and with it the demand for circuits. For a manufacturer of bypass or ECMO disposables this is the text a Chinese registration is judged against.

This document specifies the requirements for single-use tubing sets (hereinafter referred to as sets) used in cardiopulmonary bypass and extracorporeal membrane oxygenation (ECMO). beg. This document applies to all medical tubing intended for cardiopulmonary bypass (CPB) and/or extracorporeal membrane oxygenation (ECMO), except that Tubing intended to be used with a blood pump during CPB surgery (short-term, i.e. less than 6h) or ECMO (long-term, i.e. more than 24h) has specific requirements. Sum test method. The provisions of this document regarding sterility and pyrogen-free apply to tubing sets marked "sterile". This document applies only to piping for multifunctional systems that can have complete components such as blood gas exchangers (oxygenators), storage blood vessels, blood microemboli filters, defoamers, blood pumps, etc.

Note. This document does not make a special distinction between the terms "membrane oxygenation" and "membrane oxygenation". Refer to "About Printing and Distributing the Diagnosis and Treatment Plan for Novel Coronavirus Pneumonia (Trial Eighth Edition) Revised Edition)" (National Health Office Medical Letter [2021] No. 191), "On Printing and Distributing Respiratory Support Therapy and Extracorporeal Membrane Lung for Severe Patients with Novel Coronavirus Pneumonia For the usage of terminology in the "Notice on Guidance Program for Clinical Application of Oxygenation (Trial)" (National Health Office Medical Letter [2020] No. 585), this document generally uses "membrane oxygenation".

2 Normative references

The contents of the following documents constitute the essential provisions of this document through normative references in the text. Among them, dated references For documents, only the version corresponding to the date is applicable to this document; for undated reference documents, the latest version (including all amendments) is applicable to this document.

GB/T 529 Determination of tear strength of vulcanized rubber or thermoplastic rubber (pants-shaped, right-angled and crescent-shaped specimens) (GB/T 529- 2008, ISO 34-1.2004, MOD)

GB/T 1040.1 Determination of tensile properties of plastics - Part

11 Systemic Toxicity Test (GB/T 16886.11-2021, ISO 10993-11.2017, IDT)

GB 18278.1 Sterilization of medical and healthcare products with moist heat - Part

1.Requirements for the development, validation and routine control of sterilization processes for medical devices Seek (GB 18278.1-2015, ISO 17665-1.2006, IDT)

GB 18279.1 Ethylene oxide for sterilization of healthcare products Part

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

GB 18280.1 Radiation for sterilization of healthcare products Part

1.Requirements for the development, validation and routine control of sterilization processes for medical devices Seek (GB 18280.1-2015, ISO 11137-1.2006, IDT)

GB 18280.2 Sterilizing radiation for healthcare products Part

2.Establishing sterilization dose (GB 18280.2-2015,

ISO 11137-2.2006, IDT) GB/T.19974 Sterilization characteristics of healthcare products and development, validation and routine control of sterilization process for medical devices