ICS 11.040.40
CCS C45

YY

PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1925-2024

Cardiovascular implants and endovascular devices - Neurovascular thrombectomy stent retrievers

心血管植入器械 神经血管取栓支架

Issued on: February 7, 2024 **Implemented on: March 1, 2025**

Issued by: National Medical Products Administration

Table of Contents

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. 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 was prepared by the National Technical Committee for Standardization of Surgical Implants and Orthopedic Devices, Cardiovascular Implants Subcommittee (SAC/ TC110/SC2) is responsible for this. This document was drafted by: Tianjin Medical Device Quality Supervision and Inspection Center, National Medical Products Administration Medical Device Technical Review Center Center, National Medical Products Administration Medical Device Technical Review and Inspection Greater Bay Area Center, Aike Medical Devices (Beijing) Co., Ltd., Jiangsu Nuanyang Medical Equipment Co., Ltd. The main drafters of this document are. Zhang Zhenghui, Ma Jinzhu, Jiao Yongzhe, Qiao Jiaqi, Zhu Lili, Cheng Maobo, Mu Lanlan, Lian Xiaoqi, Chen Yibei, Lü Yiran, Gao Hongliang, and Sun Bing. Cardiovascular implantable device Neurovascular thrombectomy stent

1 Scope

YY/T 1925 is the product standard for the neurovascular stent retriever, the device that has

transformed the treatment of acute ischaemic stroke by pulling the clot out of a cerebral artery. It specifies the general requirements, the intended performance, the design attributes, the materials, the laboratory design evaluation, the post-market surveillance, the manufacture, the sterilisation and the packaging. That breadth is deliberate: a retriever is deployed into a clot, embedded in it and withdrawn through tortuous intracranial vessels, so clot integration, retrieval force, radiopacity and resistance to fracture matter together, and post-market data is treated as part of the evidence rather than an afterthought. For a manufacturer or an importer seeking Chinese registration, this is the governing standard.

This document specifies the general requirements, expected performance, design attributes, materials, laboratory Requirements for design evaluation, post-market surveillance, manufacturing, sterilization, and packaging. This document applies to thrombectomy procedures intended to remove thrombi from the nerve vessels of patients with ischemic stroke, thereby restoring vascular blood flow. Bracket. This document does not apply to other instruments and/or accessories that may be used in thrombectomy, such as balloon catheters, microguidewires, microcatheters, etc.

Note. YY/T 1747 specifies the general requirements for the performance of intracranial artery stents. If the manufacturer expects that the thrombectomy stent may be dislodged intracranially, it is recommended that the stent be left in place as an implant. In patients, refer to the relevant requirements for intracranial artery stents.

2 Normative references

The contents of the following documents constitute the 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 16886.1 Biological evaluation of medical devices Part

3 Terms and definitions

The following terms and definitions apply to this document.

3.1 determine A quantitative assessment or analysis.

3.2 evaluate Qualitative assessment or analysis.

7 Ethylene oxide sterilization residues

GB 18278.1 Sterilization of health care products by moist heat Part

1.Development, validation and routine control of sterilization processes for medical devices Require

GB 18279.1 Sterilization of healthcare products with ethylene oxide Part

1.Development, validation and routine control of sterilization processes for medical devices Requirements

GB 18280.1 Radiation sterilization of health care products Part

1.Development, validation and routine control of sterilization processes for medical devices Require

GB/T 19633.1 Terminally sterilized medical device packaging Part