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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1973-2025

Medical powered lower extremity exoskeleton robot

医用下肢外骨骼机器人

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Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part

1.Structure and Drafting Rules of Standardization Documents". Drafting. Please note that some content in this document may involve patents. The issuing organization of this document assumes no responsibility for identifying patents. This document was proposed by the National Medical Products Administration. This document is under the jurisdiction of the medical robot standardization technical management unit (SMD/T U005). This document was drafted by: China National Institutes for Food and Drug Control, Zhejiang Provincial Institute for Medical Device Testing, and Tianjin Municipal Medical Device Quality Supervision Bureau. Supervision and Inspection Center, Shanghai Institute for Medical Device Testing, Hangzhou Chengtian Technology Development Co., Ltd., Beijing Daai Robotics Technology Co., Ltd. Guangdong Jiahuamei Certification Co., Ltd., Shenyang Siasun Robot & Automation Co., Ltd., Shanghai Yangzhi Rehabilitation Hospital (Shanghai Sunshine Rehabilitation Center) (Rehabilitation Center), Hebei Provincial Institute for Drug and Medical Device Testing, Zhejiang University Ningbo "Five-in-One" Campus Education Development Center, Soochow University, Tianjin University. The main drafters of this document are. Zhang Chao, Meng Xiangfeng, Huang Dan, Yang Jiangang, Zhou Xue, Wang Tian, Shuai Mei, Ge Yanqing, Chen Yuxi, Qi Qi, and Wu Shaoshuai. Yang Wei, Zhang Ting, Liu Yuan, Hong Wei, and Li Hui.

Compared to GB/T 37704-2019, this document focuses more on the characteristics of powered exoskeleton robots as medical devices. Because the scope of application and technology in this field are still evolving, the technical features and test methods specified in this document can only be based on current practices. For products that have been defined and designed, new technologies and methods adopted after careful consideration of risks are not subject to the restrictions of this document. The contents of this document are intended as helpful guidance and reference only. Medical lower limb exoskeleton robot

1 Scope

YY/T 1973 is the product standard for the medical lower limb exoskeleton, the powered wearable robot used in gait rehabilitation and mobility support for patients with spinal cord injury or stroke. It specifies the requirements for medical lower limb exoskeleton robots and describes the corresponding test methods. An exoskeleton is unusual among devices in that it carries a person: the failure modes are mechanical, electrical and behavioural at once, and the standard has to reach all three. It is part of the recent build-out of Chinese standards for medical robotics, alongside the surgical robot documents YY/T 1992, YY/T 1993 and YY/T 1994. For a manufacturer or an importer of rehabilitation exoskeletons seeking Chinese registration, this is the standard the type test is run against.

This document specifies the requirements for medical lower limb exoskeleton robots (hereinafter referred to as "exoskeleton robots") and describes the corresponding test methods. This document applies to medical lower limb exoskeleton robots.

2 Normative references

The contents of the following documents, through normative references within the text, constitute essential provisions of this document. Dated citations are not included. For references to documents, only the version corresponding to that date applies to this document; for undated references, the latest version (including all amendments) applies. This document.

GB 9706.1 Medical electrical equipment - Part

3 Terms and Definitions

The terms and definitions defined in GB 9706.1, YY 9706.278, YY/T 1686, and GB/T 37704, as well as the following terms and definitions, apply to this document.

3.1 Powered by external force, it is placed on the outside of the patient's lower limb where motor function is impaired, providing support and assisting the patient in standing upright. A walking medical robot. Note

1.The affected areas include one or more sites such as the hip, knee, ankle, and foot on one or both sides. Note

2.Figures AA.16 and AA.18 in YY 9706.278-2023 are examples of medical lower limb exoskeleton robots. Note

3.According to their intended use, medical lower limb exoskeleton robots are classified into rehabilitation training, walking assistance, etc. Note

4.Medical lower limb exoskeleton robots generally include the exoskeleton robot body and accessories.

4.1 Operating Performance

4.1.1 Walking speed/cadence When using passive training mode, the exoskeleton robot's movement speed/step frequency should be adjustable. The adjustment range and tolerances should conform to the manufacturer's specifications.

4.1.2 Stride length When using passive training mode, the step length of the exoskeleton robot should be adjustable.