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**PHARMACEUTICAL INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

YY/T 1951-2024

**Tissue engineering medical device products - Generic
requirements for bio-derived peripheral nerve repair implants**

组织工程医疗器械产品 生物源性周围神经修复植入物通用要求

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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. 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 organized by the National Technical Committee for Standardization of Surgical Implants and Orthopedic Devices, Technical Committee for Engineering Medical Device Products (SAC/TC110/SC3) is responsible for this matter. This document was drafted by: China Food and Drug Administration, Nantong University, the First Affiliated Hospital of Sun Yat-sen University, Nankai University, People's Liberation Army General Hospital, Sichuan University, Tianjin Medical Device Quality Supervision and Inspection Center, Jiangsu Yitong Biotechnology Co., Ltd., Guangzhou Zhongda Medical Devices Co., Ltd., Beijing Huifukang Medical Technology Co., Ltd., Shandong Junxiu Biotechnology Co., Ltd., Tianxinfu (Beijing) Medical Medical Equipment Co., Ltd. The main drafters of this document are. Shao Anliang, Xu Liming, Yang Yumin, Zhu Qingtang, Zhu Meifeng, Peng Jiang, Ao Qiang, Li Libin, Zhang Tian, Yang Yuexiong, Cheng Huijing, Gao Xiuwei, Li Xiaojing, Zhao Danmei, Li Chongchong, Zhao Yahong, Zheng Canbin, Dong Xianhao, Wang Yu, Cheng Junqiu, Li Jia, Zhao Minjian, Zhang Yang, Wang Chao, Ren Xiaomin, and Zhang Wei. Biogenicity of Tissue Engineering Medical Devices General requirements for peripheral nerve repair implants

1 Scope

YY/T 1951 is the general requirements standard for the bio-derived peripheral nerve repair implant, the decellularised nerve graft or conduit used to bridge a gap in a damaged nerve. It specifies the general requirements for performance indicators, packaging, labelling, storage and transport of biogenic peripheral nerve implants, and the corresponding test methods. A device made from processed tissue has to satisfy two families of requirement at once: the residual biological burden left by the source material and the mechanical and structural properties that let a regenerating axon cross it. It cites an unusually long list of normative references, reflecting how much of the biological evaluation is inherited from the GB/T 16886 series. For a manufacturer of nerve grafts or conduits seeking Chinese registration, this is the governing product standard.

This document specifies the performance indicators, packaging labels, storage, transportation, etc. of bioderived peripheral nerve implants used for peripheral nerve repair. General requirements and corresponding test methods are described. This document applies to bioderived peripheral nerve repair implants. This document does not apply to peripheral nerve implants of non-biological origin.

Note. Peripheral nerve repair implants mainly include: peripheral nerve implants used to repair peripheral nerve defects of varying degrees; Provide a nerve growth microenvironment for the spontaneous repair of damaged or ruptured peripheral nerves, and guide the selective growth (chemotaxis-induced) of nerve fibers Nerve sleeve; peripheral nerve implant used to prevent local adhesion of peripheral nerve injury or prevent neuroma formation.

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 191 Pictorial markings for packaging, storage and transportation

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

3 Tests for genotoxicity, carcinogenicity and reproductive toxicity

GB/T 16886.5 Biological evaluation of medical devices Part

5 In vitro cytotoxicity test

GB/T 16886.6 Biological evaluation of medical devices Part

6 Local reaction test after implantation

GB/T 16886.7 Biological evaluation of medical devices Part

7 Ethylene oxide sterilization residues

GB/T 16886.10 Biological evaluation of medical devices Part

10 Irritation and skin sensitization tests

GB/T 16886.12 Biological evaluation of medical devices Part

12 Sample preparation and reference materials

GB/T 16886.20 Biological evaluation of medical devices Part

20 Principles and methods of immunotoxicology testing of medical devices

GB/T 36988 Guidelines for the operation of human tissues for tissue engineering SN/T 2843 Determination of rubber content in raw silk

YY 0167 Non-absorbable surgical suture

YY/T 0313 Requirements for packaging of medical polymer products and information

provided by manufacturers

YY/T 0513.1 Allogeneic repair materials Part

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