ICS 11.030.30
CCS C30

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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1950-2024

Tissue engineering medical device - Silk fibroin

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Issued on: September 29, 2024 **Implemented on: October 15, 2025**

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 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: Zhejiang University, China Food and Drug Administration, Fudan University, Zhejiang Xingyue Biotechnology Co., Ltd. Co., Ltd., Fuxiang Sitai Medical Technology (Suzhou) Co., Ltd., and Jiangxi Sike Biotechnology Co., Ltd. The main drafters of this document are. Ouyang Hongwei, Xu Liming, Shao Zhengzhong, Zhao Hongshi, Liu Yezhuo, Liu Keyin, Liu Zhenqi, Wang Yanyan, Chen Xin, Yang Wenhua, Yang Tao, and Liu Li.

The issuing authority of this document draws attention to the fact that claims of compliance with this document may involve the determination of molecular weight by rheological method in Appendix B. The use of patents related to methods and data fitting calculations. The issuing organization of this document takes no position on the authenticity, validity and scope of this patent. The patent holder has promised to the issuing agency of this document that Appendix B has publicly provided the method operation instructions. The patent holder is willing to The patent holder intends to share the application of this method with any user of the standard under reasonable and non-discriminatory terms and conditions. The issuing agency of this document is on record. Relevant information can be obtained through the following contact information. Patent holder name. Fudan University

Address. No. 220 Handan Road, Shanghai Please note that in addition to the above patents, some of the contents of this document may still involve patents. The issuing agency of this document does not assume the responsibility for identifying patents responsibility. Tissue Engineering Medical Devices Silk Fibroin

1 Scope

YY/T 1950 is the material standard for silk fibroin used in tissue engineered medical devices. It specifies the performance requirements for the material together with the labelling, packaging, transport and storage, and the corresponding test methods. Silk fibroin has moved from suture thread to a platform biomaterial for scaffolds, films and hydrogels, and its behaviour depends on how the sericin was removed and how the protein was processed rather than on the silk it came from, which is why a raw material standard is needed before any device standard can mean anything. It sits with YY/T 1985 on collagen and YY/T 1940 on nickel-titanium powder in the group of Chinese standards that specify tissue engineering input materials. For a supplier or a device manufacturer working with silk fibroin, this is the incoming specification.

This document specifies the performance requirements of silk fibroin used in tissue engineering medical device products, as well as the labeling, packaging, transportation and storage. requirements and describes the corresponding test methods. This document applies to silk fibroin for the preparation of tissue engineering medical device products. Note

1.The silk fibroin referred to in this document is the product obtained by removing the sericin from the cocoon layer or raw silk of natural silkworms (i.e. natural silk fibroin fiber). Products obtained by processes such as degumming, dissolution and regeneration (i.e. regenerated silk fibroin). It does not include silk fibroin obtained by genetic engineering or genetic modification. protein. Note

2.For silk fibroin used in other surgical implants or dressing products, refer to this document.

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 16886 (all parts) Biological evaluation of medical devices

GB/T 32016 Determination of amino acids in silk FZ/T 40006 Test method for oil content of silk SN/T 2843 Determination of rubber content in raw silk

YY/T 0771.1 Medical devices of animal origin Part

3 Terms and definitions

The following terms and definitions apply to this document.

3.1 Silk fibroin Fibrous silk protein synthesized and secreted by the posterior silk gland of the silkworm.

Note. The core protein in mulberry silk fiber consists of a heavy chain (H chain protein) with a theoretical molecular mass of about 391 kDa, a light chain (L chain protein) of 25 kDa and a kDa or 27kDa P25 (also called fiber hexamer), the amount ratio of H chain protein, L chain protein and P25 protein is 6.6.1. The heavy chain and light chain are connected by a single disulfide bond. P25 is a glycoprotein containing asparagine (ASN) oligosaccharide chains. P25 is connected to the heavy chain and light chain by a disulfide bond. They are bound by non-covalent bonds such as hydrophobic bonds.

3.2 Regenerated Silk Protein Silk core fiber (fibroin fiber) dissolves the protein mixture after desalting.