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

YY/T 1982-2025

**Implants for surgery - Test method for morphological
characteristics of porous structures**

外科植入物 多孔结构形貌特征试验方法

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Foreword

This document conforms to GB/T 1.1-2020 "Standardization Work Guidelines Part

1. Structure and Drafting Rules of Standardization Documents". Drafting is scheduled. 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 National Technical Committee on Standardization of Surgical Implants and Orthopedic Devices (SAC/TC 110). This document was drafted by: Tianjin Medical Device Quality Supervision and Inspection Center, Xi'an Jiaotong University, and the National Medical Products Administration. Medical Device Technical Review and Inspection Center (Greater Bay Area Branch), Sichuan University, Beijing Institute for Medical Device Testing (Beijing Institute of Medical Biological Protective Equipment Testing) Research Center), Ninth People's Hospital Affiliated to Shanghai Jiao Tong University School of Medicine, Shanghai Jiao Tong University, Shanghai Jiao Tong University Analytical and Testing Center, Tongguang (Kunshan) Biotechnology Co., Ltd., Suzhou Ding'an Technology Co., Ltd., and Changzhou Jishuo Medical Device Co., Ltd. The main drafters of this document are. Zhang Chen, Ma Hui, Zhang Haocheng, Wang Ling, Dong Enchun, Liu Jiayin, Liu Bin, Ding Jinju, Zhu Xiangdong, and Li Xiangfeng. Xiao Yumei, Chen Yanmei, Wang Jianjun, Wang Jinwu, Tao Hairong, Xu Yuanjing, Zhang Changru, Zhu Yanhua, Zheng Wei, Chen Feihao, Li Yadong, Li Yajun Jiang Xiaofeng and Sun Qian.

This document aims to develop a comprehensive and scientific experimental method for evaluating the structural morphology characteristics of porous components in surgical implants. Establish standardized and unified test content and procedures to ensure that the test process is based on evidence, the results are accurately evaluated, and the same test can be performed in different enterprises. A comparative analysis of the morphological characteristics of porous structures manufactured by the process. Morphological characteristics of porous structures in surgical implants Test methods

1 Scope

YY/T 1982 is the measurement standard for the porous surfaces that additive manufacturing has made routine in orthopaedic implants. It specifies the test methods for the morphological characteristics of porous structures in surgical implants, and it names the parameters those methods produce: porosity, pore diameter, strut or wire diameter, internal connectivity, pore gradient and the thickness of the porous structure. Those numbers are how a bone-ingrowth claim is substantiated, and until they are measured the same way from one submission to the next they cannot be compared. It sits with YY/T 2008 on the PEEK powder used in powder bed fusion, from the other end of the same manufacturing chain. For a manufacturer of trabecular or lattice-structured implants seeking Chinese registration, this is the method behind the porosity data.

YY/T 0988.14 Surgical implant coatings - Part

2 Normative references

The contents of the following documents, through normative references within the text, constitute essential provisions of this document. Dated citations are listed below. 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/T 21650.1 Determination of pore size distribution and porosity of stationary materials by mercury porosimetry and gas adsorption methods - Part

GB/T 36984-2018 X-ray CT inspection method for porous metallic materials used in surgical implants

GB/T 41672-2022 Surgical Implants - Bone-Inducing Calcium Phosphate Bioceramics

3 Terms and Definitions

The following terms and definitions apply to this document.

14 Stereometric evaluation method for porous coatings ISO 13383-

1 Fine ceramics (advanced ceramics, advanced process ceramics) Microstructural characteristics - Part

1. Grain size and particle size Determination of distribution [Fine ceramics (advanced ceramics, advanced technical ceramics)-Microstructural characterization-Part