ICS 11.040.30
CCS C30

YY

PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 2008-2026

Medical additive manufacturing - Powders of polyether-ether-ketone for powder bed fusion

医用增材制造 粉末床熔融用聚醚醚酮粉末

Issued on: March 9, 2026 **Implemented on: March 1, 2027**

Issued by: National Medical Products Administration

Table of Contents

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 unit responsible for the standardization of medical additive manufacturing technology for medical devices. This document was drafted by: Xi'an Jiaotong University, the Greater Bay Area Branch Center of the Medical Device Technical Review and Inspection Center of the National Medical Products Administration, and China Food and Drug Administration. Drug Testing and Inspection Institute, Tianjin Medical Device Quality Supervision and Inspection Center, Xi'an Kangtuo Medical Technology Co., Ltd., Shenzhen University, Jilin Jilin Zhongyan Polymer Materials Co., Ltd., Zhejiang Zhongju Biotechnology Co., Ltd., and the Ninth People's Hospital Affiliated to Shanghai Jiao Tong University School of Medicine Institute, South China University of Technology Medical Device Research and Testing Center. The main drafters of this document are. Sun Changning, Li Dichun, Han Dan, Han Qianqian, Zhang Shu, Mao Xin, Ding Jinju, Shang Weiwei, Ni Zhuo, Tong Yanling, and Chen Kejin. Zhao Feng, Deng Liang, Wang Zhijie, and Li Bing. Medical Additive Manufacturing Polyetheretherketone powder for powder bed melting

1 Scope

YY/T 2008 governs the raw powder that goes into a medical 3D printer. It specifies the technical requirements for polyether-ether-ketone (PEEK) powder used in medical additive manufacturing by powder bed fusion, and for the properties of the specimens moulded from it, together with the marking, packaging, transport, storage and quality certification documents, and it describes the test methods. PEEK is the polymer of choice for printed

cranial, spinal and maxillofacial implants, and in powder bed fusion the powder is not merely a supply item: particle characteristics and reuse history determine what comes out of the machine. An informative annex covers monomer and solvent residues in the material. For an implant manufacturer or a powder supplier, this is the incoming material specification a Chinese reviewer expects to see cited.

This document specifies the technical requirements, labeling, and packaging for the properties of polyetheretherketone (PEEK) powder and molded specimens used in medical additive manufacturing. The packaging, transportation, storage, and quality certification documents describe the test methods. This document applies to PEEK powders produced using a powder bed melting process with laser as the energy source.

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. document.

GB/T 1033.1 Determination of density of non-foamed plastics - Part