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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1940-2024

Medical nickel titanium powders for additive manufacturing

用于增材制造的医用镍钛合金粉末

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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 under the jurisdiction of the technical standardization authority for medical additive manufacturing technology and medical devices. This document was drafted by: Xi'an Ouzhong Materials Technology Co., Ltd., China Food and Drug Inspection Institute, Beijing Keyi Bangen Medical Devices Technology Co., Ltd., Xi'an University of Technology, Northwestern Polytechnical University, Xi'an Juneng Medical Technology Co., Ltd., Northwest Institute of Nonferrous Metals, Shaanxi Provincial Medical Device Quality Inspection Institute, The Ninth People's Hospital Affiliated to Shanghai Jiao Tong University School of Medicine. The main drafters of this document are. Wang Qingxiang, Guo Qian, Hao Yongqiang, Han Qianqian, Mao Xin, Jia Qinggong, Jiao Hua, Yang Haiou, Yu Sen, Xue Sa, Liu Like, Li Lijuan and Deng Liang. Medical Nitinol Powders for Additive Manufacturing

1 Scope

YY/T 1940 is the raw material standard for medical nickel-titanium powder used in additive manufacturing. It specifies the performance requirements for the powder together with the labelling, packaging, transport and storage, and describes the corresponding test methods. Nitinol is valued in implants for superelasticity and shape memory, and both depend on composition and phase transformation behaviour that are set by the powder chemistry and then modified by the print, so the incoming material has to be controlled tightly for the finished part to behave predictably. Nickel content adds a biological dimension that other printing alloys do not carry. It is the nitinol counterpart of YY/T 2008 for PEEK powder. For

an implant manufacturer or a powder supplier serving the Chinese market, this is the incoming material specification.

This document specifies the performance requirements, labeling, packaging, transportation and storage of medical nickel-titanium alloy powders used in additive manufacturing, and describes the corresponding test method. This document applies to medical nickel-titanium alloy powders manufactured by powder bed fusion additive manufacturing process using laser or electron beam as energy source.

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 1479.1 Determination of bulk density of metal powders Part

3 Terms and definitions

The terms and definitions defined in GB/T 35351 apply to this document.

4 Performance requirements

4.1 Chemical composition The chemical composition of medical nickel-titanium alloy powder used for additive manufacturing should comply with the requirements of Table 1. The Ti content is determined by the difference method, Ti remainder = 100% - Ni content - impurity content. When the purchaser has special requirements, they shall be determined through negotiation between the supply and demand parties.