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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1909-2023

Additive manufacturing for medical applications - Requirements for control and validation of the metal powder bed electron beam melting process

医用增材制造 金属粉末床电子束熔融工艺控制和确认要求

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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 be subject to patents. The publisher of this document assumes no responsibility for identifying patents. This document is proposed by the National Medical Products Administration. This document is under the jurisdiction of the China Institute for Food and Drug Control. This document was drafted by: Tianjin Qingyan Zhisu Technology Co., Ltd., Xi'an Sailong Additive Technology Co., Ltd., Shanghai Medical Devices Cosmetics Review and Verification Center, China Institute of Food and Drug Control, Ninth People's Hospital Affiliated to Shanghai Jiao Tong University School of Medicine. The main drafters of this document. Zhu Jilei, Zhao Dechen, Fan Zhijin, Wang Jinwu, Liu Xin, Xie Neng, He Ting, Jiang Xin, Han Qianqian, Mao Xin, Hao Yongqiang, Kan Wenbin, Jin Yuanyuan, Zhao Pei, Deng Liang.

Metal powder bed electron beam melting technology has the advantages of high energy utilization, pure materials, small stress deformation, and high forming efficiency. It is an ideal choice for metal Important methods for additive manufacturing of medical devices. Additive manufacturing medical devices ensure product quality through process control, which requires effective process validation and must meet the requirements of relevant regulations. beg. This document aims at the risk points of each link of "man-machine-material-method-environment" in the metal powder bed electron beam melting process, and provides guidance on personnel, equipment, Clear requirements have been put forward in terms of environment, raw materials, process, especially installation qualification, operation qualification and performance qualification. This document is based on the current development status of this technology. Enterprises can modify this document

based on the actual conditions of specific processes and products. Applicable provisions shall apply. Medical Additive Manufacturing Metal Powder Bed Electron Beam Melting process control and validation requirements

1 Scope

YY/T 1909 sets the requirements for controlling and validating electron beam melting of metal powder beds in medical additive manufacturing. Electron beam melting is how porous titanium orthopaedic implants are made: acetabular cups, spinal cages and patient-specific reconstructions whose lattice structure encourages bone ingrowth and cannot be machined. Because the part is created and the material properties are set in the same operation, the process is the product, and a drift in beam parameters or powder condition changes the mechanical behaviour of an implant that will carry load for decades. This document specifies what has to be controlled, recorded and revalidated. For a Chinese manufacturer of printed implants, this is the text an auditor and a registration reviewer apply to the process file.

This document specifies a standard for routine control and process validation of powder bed fusion additive manufacturing processes for metal materials using electron beams as energy sources. General requirements. This document applies to the processing of medical devices manufactured using powder bed electron beam melting technology for metallic materials.

2 Normative reference documents

The contents of the following documents constitute essential provisions of this document through normative references in the text. Among them, the dated quotations For undated referenced documents, only the version corresponding to that date applies to this document; for undated referenced documents, the latest version (including all amendments) applies to this document.

GB/T 3836.1 Explosive atmosphere Part

3 Terms and definitions

The terms and definitions defined in GB/T 35351, GB/T 42061 and the following apply to this document.

3.1 Confirmation A documented procedure for obtaining, recording, and interpreting the results required to determine that a process will continue to produce product that meets predetermined specifications. [Source: GB/T.19971-2015,2.55]

3.2 The process of obtaining and forming documented evidence to prove that equipment has been provided and installed according to specification requirements. [Source:

GB/T.19971-2015,2.22]

3.3 The process of obtaining and forming documented evidence to prove that installed equipment can operate within predetermined limits when used according to operating procedures. [Source: GB/T.19971-2015,2.27]

9 Equipment protected by casting type "m"

GB/T 3836.31 Explosive atmospheres Part

31.Equipment protected by dust ignition resistant enclosure "t"

GB/T 13277.1-2008 Compressed air Part