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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

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Human factors design requirements and evaluation methods of orthopedic implants and surgical instruments

骨科植入物及手术器械的人因设计要求与测评方法

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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 National Technical Committee for Standardization of Surgical Implants and Orthopedic Devices (SAC/TC110). This document was drafted by: Peking Union Medical College Hospital, Chinese Academy of Medical Sciences, Tianjin Medical Device Quality Supervision and Inspection Center, Beijing Fule Technology Development Co., Ltd., National Medical Products Administration Medical Device Technology Review Center, National Medical Products Administration Medical Device Technology Review Center The Greater Bay Area Center, Peking University Shougang Hospital, Peking University First Hospital, Tongji Hospital Affiliated to Huazhong University of Science and Technology, Yunnan Province First Hospital People's Hospital, Tianjin Hospital, the Fourth Medical Center of the General Hospital of the Chinese People's Liberation Army, Shanghai Changzheng Hospital, Affiliated Hospital of Zhejiang University School of Medicine Run Run Shaw Hospital, Qilu Hospital of Shandong University, First Affiliated Hospital of Xinjiang Medical University, Shengjing Hospital of China Medical University, Inner Mongolia Medical University The Second Affiliated Hospital of Beijing University, Beijing Jishuitan Hospital, and Beijing Lidakang Technology Co., Ltd. The main drafters of this document are. Zhao Yu, Wang Li, Jing Ming, Hu Huanyu, Zhang Jiazhen, Shen Hainan, Guan Zhenpeng, Cao Yongping, Xiao Jun, Lu Sheng, Yang Qiang, Zhang Lihai, Chen Huajiang, Xiangfangqian, Liu Xinyu, Sheng Weibin, Li Lei, Zhao Yan, Sun Zhijian, Li Wenjing, Zhai Jiliang, Qi Jianli, Ma Shuqin, Li Xiaoyun, Zhang Yidan and Zhao Binghui. Human factors design requirements and Evaluation Method

1 Scope

YY/T 1934 applies human factors engineering to orthopaedic hardware. It sets the terms and definitions, the human factors design requirements and the evaluation methods for orthopaedic implants and orthopaedic surgical instruments. Usability standards are usually written for devices with screens, but an orthopaedic system is used under time pressure with gloved hands in a sterile field, where instrument handling, tray organisation, implant sizing and the sequence a system imposes on the surgeon decide whether the right component ends up in the right place. Making that assessable rather than anecdotal is what the standard is for. It is one of the few documents anywhere to address human factors in orthopaedics specifically. For a manufacturer of implant systems and their instrument sets for China, this is the reference for the usability file.

This document specifies the human factors design and evaluation of orthopedic implants and orthopedic surgical instruments (hereinafter referred to as "orthopedic implants and surgical instruments"). Terms and definitions, human factors design requirements, human factors assessment methods, etc. This document applies to orthopedic implants and surgical instruments.

Note. For the human factors design requirements for orthopedic implant boxes/surgical instrument boxes, see Appendix A.

2 Normative references

This document has no normative references.

3 Terms and definitions

The following terms and definitions apply to this document.

3.1 Orthopedic implants Implanted in whole or in part by surgery (permanent or temporary) to assist in the repair of bones/related tissues, temporarily Or a medical device that permanently replaces the function of bone/related tissue.

3.2 Orthopedic surgical instrumentssurgicalinstruments Medical devices that participate in and assist the process of orthopedic implants being placed into the human body during surgery.

3.3 Human factors design Through the study of human behavior needs, functional needs, and operational capabilities, we can rationally design orthopedic implants and surgical instruments. Design, so as to achieve the purpose of functional recovery, safety, comfort and efficiency.

3.4 Perform validation testing of human factors design for orthopedic implants and surgical instruments.

4 General requirements for human factors design

4.1 General requirements for human factors design of orthopedic implants The general requirements for human factors design of orthopedic implants are as follows:

a) Osteosynthesis implants should be compatible with the patient's bone tissue structure;

b) Spinal implants should be compatible with the patient's spinal tissue structure;