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

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Implants for sports medicine - Suture buttons

运动医学植入器械 带袢固定板

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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: Tianjin Medical Device Quality Supervision and Inspection Center, National Medical Products Administration Medical Device Technical Review Center Center, National Medical Products Administration Medical Device Technical Review and Inspection Greater Bay Area Center, Yunyi (Beijing) Medical Device Co., Ltd., Beijing De Yidamei Medical Technology Co., Ltd., Beijing Tianxing Bomaidi Medical Equipment Co., Ltd., Beijing Medical Equipment Inspection Institute (Beijing Medical Equipment Inspection Institute Biological Protection Equipment Inspection and Research Center), Dabao Medical Technology Co., Ltd., Beijing Fule Technology Development Co., Ltd., Beijing Natong Technology Group Co., Ltd., Shanghai Ligetai Biotechnology Co., Ltd., Johnson & Johnson (Shanghai) Medical Devices Co., Ltd., Smith & Nephew Medical Products Pin International Trading (Shanghai) Co., Ltd. and Beijing Aikang Yicheng Medical Equipment Co., Ltd. The main drafters of this document are. Li Wenjiao, Jing Ming, Wang Ying, Guo Xiaolei, Zhai Bao, Zhang Yidan, Peng Pu, Liu Jimei, Zhao Xuedong, Kong Qingjun, Wei Ning, Hou Suhua, Dong Wenxing, Han Qizhi, Wang Lixia, Zeng Da, Ye Yanjie, Bai Yanli, Zhao Wenwen, Chen Dandan, Chen Ruikai, He

Xueqin, Wang Caimei. Sports Medicine Implants with Loop Fixation Plates

1 Scope

YY/T 1927 is the product standard for the suture button, the small plate with a suture loop used to fix a graft against cortical bone, most familiar as the cortical suspension device used in cruciate ligament reconstruction and in syndesmosis repair. It specifies the performance requirements for these loop fixation plates and describes the test methods. The device is asked to hold a graft under load with a construct made of a plate, a loop and the bone it sits on, so the properties that decide the outcome are loop strength, elongation under cyclic load, and the plate's behaviour where it bears on cortex. It belongs to the Chinese sports medicine implant series with YY/T 1922 and YY/T 1988. For a manufacturer seeking Chinese registration, this is the governing product standard.

This document specifies the performance requirements for sports medicine implants with loop fixation plates (hereinafter referred to as "loop fixation plates") and describes the corresponding The standard specifies test methods, manufacturing, sterilization, biological safety evaluation, packaging and information provided by the manufacturer. This document applies to the testing and evaluation of fixation plates with loops for fixation of soft tissue to bone or bone to bone.

2 Normative references

The contents of the following documents constitute the 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 4340.1 Vickers hardness test for metallic materials Part

3 Terms and definitions

The following terms and definitions apply to this document.

3.1 Suturebutton with loop fixing plate Medical devices used to connect and fix ligaments or tendons to bones, or bones to bones in orthopedic reconstruction surgery. See Figure 1 for a schematic diagram.