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

YY/T 1906-2023

Sterile ligation clips for single use

一次性使用无菌闭合夹

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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. Release of this document The Agency assumes no responsibility for identifying patents. This document is proposed by the National Medical Products Administration. This document is under the jurisdiction of the National Surgical Instruments Standardization Technical Committee (SAC/TC94). This document was drafted by: Hangzhou Kangji Medical Devices Co., Ltd., Shanghai Medical Device Inspection Institute, Beijing Medical Device Inspection Research Institute (Beijing Medical Biological Protective Equipment Inspection and Research Center), Shandong Weirui Surgical Medical Products Co., Ltd., Jiangsu Provincial Drug Supervision and Administration Administration Review Center, Anhui Institute of Food and Drug Inspection, Hangzhou Guangdian Medical Devices Co., Ltd., Jiangsu Sanlian Xinghai Medical Devices Co., Ltd. Company, Changzhou Kandi Medical Stapler Co., Ltd. The main drafters of this document. Tang Wenpeng, Qi Xia, Hu Guangyong, Wang Zewei, Yu Qi, Ding Fang, Xu Juan, Zhang Daojun, Xie Tanyi, Ma Xiaojian, Geng Xin, Tang Wen, Wei Sheng, Cheng Da, Huang Baohua, Yue Jiqiang, Zhao Ning, Ma Gang, Xue Yu, Yang Huibing. Disposable sterile closure clips

1 Scope

YY/T 1906 covers single-use sterile ligation clips, the metal or polymer clips applied to close a vessel or duct in open and laparoscopic surgery. It sets the requirements such clips have to meet and the test methods that verify them, covering the closure force and security of the clip on a vessel, its resistance to slipping off, the material, the fit with the applier and the sterility and packaging of the product. A clip that migrates after the abdomen is closed causes bleeding or a bile leak that will not be discovered until the patient deteriorates, which is why security under pressure is the central test rather than a nominal dimension. Clips are used in enormous volume in Chinese laparoscopic surgery. For a manufacturer,

this is the document a Chinese registration is assessed against.

This document specifies the structure and materials, requirements, labels, and instructions for single-use sterile closure clips (hereinafter referred to as closure clips), and describes Corresponding test methods. This document is suitable for clamping blood vessels or closing tubular tissues (including small and medium-sized arteries and veins, bile ducts, etc.) during surgical operations. It is not suitable for large arteries and large veins. This document does not apply to metal clips, absorbable closure clips, consecutive closure clips, and closures that temporarily clip tissue or blood vessels during surgery or remove them after surgery. Close folder.

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 6682 Specifications and test methods for water used in analytical laboratories

GB/T 14233.1-2022 Test methods for medical infusion, blood transfusion and injection equipment Part

3 Terms and definitions

There are no terms or definitions to be defined in this document.

4 Structure and materials

4.1 Structure The closing clamp consists of a lock buckle and a clamp arm. It is usually installed in the base and fixed with a pressure plate (see Figure 1).