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

YY/T 1866-2023

**Sterile hemorrhoidal ligator for single use - Rubber band or
elastic thread type**

一次性使用无菌肛肠套扎器 胶圈或弹力线式

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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 contents of this document may refer to patents: The issuing agency of this document assumes no responsibility for identifying patents: This document is proposed by the State Drug Administration: This document is under the jurisdiction of the National Surgical Instruments Standardization Technical Committee (SAC/TC94): This document was drafted by: Changzhou Vick Medical Devices Co., Ltd., Shanghai Medical Device Inspection Institute, Jiangsu Medical Device Inspection Institute, Evaluation Center of Jiangsu Provincial Drug Administration, Anhui Food and Drug Inspection Institute, Changzhou Ankang Medical Devices Co., Ltd., Beijing Medical Device Technology Evaluation Center: The main drafters of this document: Wang Wei, Hua Songhe, Shi Zhigang, Yu Qi, Huang Baohua, Li Gao, Wang Chen, Wang Hailong, Zhang Lihua, Xu Xiaohu, Tang Wen, Gu Kejia, Liu Liang, Geng Yuanyuan, Zhang Daojun, Ji Rong, Hu Yuwen: Disposable sterile anorectal ligation device Rubber ring or elastic thread type

1 Scope

YY/T 1866 covers the single-use hemorrhoidal ligator, the instrument that places a rubber band or elastic thread around the base of a haemorrhoid so that it necroses and separates. It sets the requirements such a device has to meet and the test methods that verify them, covering the strength and elasticity of the band or thread, the deployment mechanism, the dimensions, the biocompatibility of the materials and the sterility and packaging of the product. Band ligation is the most common office treatment for internal haemorrhoids, done without anaesthesia, and a band that slips or breaks turns a five-minute procedure into a bleeding complication. This is the document a Chinese registration is assessed against and the specification a hospital purchaser refers to.

This document specifies the structure, materials, requirements requirements, test methods, labels, instructions and packaging: This document is applicable to the ligation device for ligation treatment of various internal hemorrhoids and mixed hemorrhoids or rectal benign

polyps:

2 Normative references

The contents of the following documents constitute the essential provisions of this document through normative references in the text: Among them, dated references For documents, only the version corresponding to the date is applicable to this document; for undated reference documents, the latest version (including all amendments) is applicable to this document:

GB/T 6682 Analytical laboratory water specifications and test methods

GB/T 14233:1-2022 Test methods for medical infusion, blood transfusion and injection equipment Part 1: Chemical analysis methods Pharmacopoeia of the People's Republic of China Volume Four

3 Terms and Definitions

The following terms and definitions apply to this document: 3:

1 The change rate of elastic recovery due to the action of tensile force:

4 Structure and materials

1 Composition The ligation device is mainly composed of a body and a ligation device: The body of the ligation device can have its own negative pressure or an external negative pressure: Generally, it consists of a suction pipe, a firing device Set and the corresponding negative pressure device and so on: The ligation device is generally composed of rubber rings and/or elastic threads: 4:

2 Structure The names of the body components of the ligation device and the components of the ligation device are shown in Figure 1, Figure 2 and Figure 3: These illustrations show the structure of the ligation device, Other configurations can also be used as long as the same effect can be achieved: