

ICS 11.040.30  
CCS C31

**YY**

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

**YY/T 1980-2025**

---

**Sterile wound protector for single use**

一次性使用无菌切口保护套

**Issued on: June 18, 2025**

**Implemented on: July 1, 2026**

---

**Issued by: National Medical Products Administration**

# Table of Contents

- 1 Scope
- 2 Normative references
- 3 Terms and Definitions
- 4 Classification and Labeling

## 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 involve patents, and the issuing organization of this document assumes no responsibility for identifying patents. This document was proposed by the National Medical Products Administration. This document is under the jurisdiction of the National Technical Committee on Standardization of Surgical Instruments (SAC/TC94). This document was drafted by: Anhui Aofu Medical Equipment Technology Co., Ltd., Shanghai Institute for Medical Device Testing and Inspection, and Anhui Provincial Food Safety Bureau. Drug Inspection and Testing Institute, Shandong Weirui Surgical Medical Products Co., Ltd., Changzhou Ankang Medical Device Co., Ltd., Changzhou Weike Medical Device Co., Ltd. Limited Liability Company, Hangzhou Kangji Medical Devices Co., Ltd., and Hangzhou Mindray Medical Technology Co., Ltd. The main drafters of this document are: Miao Changsheng, Yang Zhiyuan, Tang Wenpeng, Xie Tanyi, Zhao Jianyin, Yang Sen, Wang Wei, Wei Sheng, Zhang Lihua, and Wang Chunhua. Huang Baohua, Ma Xiaojian, Leng He'en, Guo Hongbo, Guo Yanli, Lu Wen, Wang Hailong. Disposable sterile incision protector

## 1 Scope

YY/T 1980 is the product standard for the single-use sterile incision protector, the retractor sleeve that lines a surgical wound to hold it open and shield its edges. It specifies the classification and marking, the materials, the requirements, the labelling and instructions, the packaging, transport and storage, and describes the corresponding test methods. The device does two jobs at once, mechanical retraction and a barrier against contamination of the wound edge, and the standard has to cover both. For a manufacturer or an importer of wound protectors and retractor systems selling into China, this is the standard the registration test report follows, including the labelling and instructions for use, which for a sterile single-use device are part of the regulated product rather than an accessory to it.

1.Evaluation and testing in the risk management process Pharmacopoeia of the People's Republic of China (2020 Edition, Part IV)

## 2 Normative references

The contents of the following documents, through normative references within the text, constitute essential provisions of this document. Dated citations are not included. For references to documents, only the version corresponding to that date applies to this document; for undated references, the latest version (including all amendments) applies. This document.

GB/T 6682-2008 Specifications and test methods for water used in analytical laboratories

GB/T 14233.1-2022 Medical infusion, transfusion and injection equipment test methods - Part

GB/T 16886.1 Biological evaluation of medical devices - Part

## 3 Terms and Definitions

The following terms and definitions apply to this document.

3.1 A cut-out protective sleeve with a relatively stable channel height and no adjustable channel height.

3.2 The height of the incision is adjusted according to the needs of the surgery. The outer retaining ring is rolled up from the outside to the inside and adjusted to the required height of the incision protective sleeve.

## 4 Classification and Labeling

4.1 Classification Cut-out protective sleeves are divided into two main categories. fixed-height and variable-height, and consist of an outer retaining ring, an inner retaining ring, and a channel. The design is based on the outer diameter of the outer retaining ring and the inner retaining ring... The outer diameter and channel height can be divided into different specifications.

4.2 Marking The markings on the cut-off protective sleeve should include at least the following elements.