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

YY 0852-2023

Replacing YY 0852-2011

Sterile surgical films for single use

一次性使用无菌手术膜

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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. This document replaces YY 0852-2011 "Disposable Sterile Surgical Membranes". Compared with YY 0852-2011, except for structural adjustment and compilation In addition to editorial changes, the main technical changes are as follows:

- a) Changed the requirements for "marking" (see 4.2, 3.2 of the.2011 version);
- b) Changed the requirements for "size" (see 6.1, 5.1 of the.2011 edition);
- c) Changed "cleanliness" to "appearance" and changed the corresponding technical content (see 6.2, 5.2 of the.2011 version);
- d) Changed the requirements for "protective layer" (see 6.5, 5.5 of the.2011 version);
- e) The requirements and test methods for "glue coating weight" are deleted (see 5.7 and Appendix C of the.2011 edition);
- f) Changed the requirements for "stretchability" (see 6.8, 5.9 of the.2011 version);

1 Scope

YY 0852 is the mandatory Chinese standard for single-use sterile surgical incise films, the adhesive plastic membranes applied to prepared skin so that the incision is made through

the film and the wound edges stay isolated from skin flora. It sets the requirements such films have to meet and the test methods that verify them, covering the adhesion to skin and its persistence under moisture, the conformability of the film, the barrier it provides, the biocompatibility of the adhesive and the sterility and packaging of the product. A film that lifts at the wound edge during a long operation defeats its own purpose. Being a YY standard without the /T suffix, compliance is compulsory in China. The 2023 edition replaces YY 0852-2011 and takes effect in September 2026.

This document specifies the performance of polyurethane surgical membranes and polyethylene surgical membranes that are adhered to surgical sites to provide sterile protection for surgical incisions. requirements, the corresponding test methods are described. This document applies to polyurethane surgical membranes and polyethylene surgical membranes.

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 14233.1 Test methods for medical infusion, blood transfusion and injection equipment Part

3 Water barrier properties

YY/T 0471.4-2004 Test methods for contact wound dressings Part

4 Types and markings

4.1 Type The surgical membrane base material 1) is evenly coated with a synthetic adhesive material to form the adhesive surface of the surgical membrane. The pasting surface is covered with a protective layer. Remove the protective layer. The adhesive material will not be removed after the protective layer is applied. The two sides of the surgical membrane can be free of adhesive material or attached with suitable material (such as paper) for hand-holding operate.

4.2 Marking The surgical membrane is marked with the product material code and the width x length of the adhesive surface. Example 1.A surgical membrane with a base material of polyurethane (PU), an adhesive surface width of 30cm, and a length of 50cm is marked as. PU30x

50 Example 2.A surgical membrane with a base material of polyethylene (PE), an adhesive

surface width of 30cm, and a length of 50cm is marked as. PE30x50 1) The base materials applicable to this document are polyurethane (PU) film and polyethylene (PE) film. The production cost of polyethylene film is low, but its material has low water vapor permeability and It is not as stretchable as polyurethane materials and is generally not accepted by developed countries.

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