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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

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YY/T 0698.5-2023

Packaging materials for terminally sterilized medical devices - Part 5: Sealable pouches and reels of porous materials and plastic film construction - Requirements and test methods

最终灭菌医疗器械包装材料 第5部分：透气材料与塑料膜组成的可密封组合袋和卷材 要求和试验方法

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1 Scope

YY/T 0698.5 covers the sterilization pouch, the paper-and-film bag that lets steam or ethylene oxide in during sterilization and keeps microorganisms out afterwards. It sets the requirements such pouches and reels have to meet and the test methods that verify them, covering the strength and integrity of the seal, the porosity and microbial barrier of the material, the resistance to handling and ageing, and the indicators printed on it. The pouch is what makes a sterilized device sterile at the point of use rather than at the moment it left the steriliser, and a seal that opens in transit invalidates everything upstream of it. These are used by the million in Chinese hospitals and device plants. This is the document a supplier certifies against.

This document specifies requirements and test methods for sealable pouches and reels of porous materials compliant with YY/T 0698.2, 0698.3, 0698.6, 0698.7, 0698.9, or 0698.10, and plastic film construction with Clause 4 of this document. These sealable pouches and reels are intended to be used as sterile barrier systems and/or packaging systems to maintain the sterility of finally sterilized medical devices until the point of use. In addition to the general requirements specified in GB/T 19633.1 and GB/T 19633.2, this document specifies the specific requirements and test methods for the materials covered by this Part. This document applies solely to packaging materials for single-use, terminally sterilized medical devices.

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2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

GB/T 7408, Data elements and interchange formats -- Information interchange -- Representation of dates and times

GB 18282.1, Sterilization of health care products -- Chemical indicators -- Part 1. General requirements

GB/T 19633.1, Packaging for terminally sterilized medical devices -- Part 1. Requirements for materials, sterile barrier systems and packaging systems

YY/T 0681.2, Test methods for sterile medical device package -- Part

3 Terms and definitions

For the purposes of this document, the terms and definitions defined in GB/T 19633.1 apply.

4 Requirements

4.1 General For any material, pre-formed sterile barrier system, or sterile barrier system, the requirements of GB/T 19633.1 must be met. This document specifies only the performance requirements and test methods for the materials covered herein. It does not add to or alter the general requirements stipulated in GB/T 19633.1. Therefore, the specific requirements in

4.5 may be used to verify one or more requirements of GB/T 19633.1, but not all requirements. NOTE

1.Compliance with the requirements of this document does not imply compliance with GB/T 19633.1.A declaration of compliance with the requirements of this document shall state whether it complies with GB/T 19633.1. NOTE

2.When additional materials are used within a sterile barrier system to facilitate organization, drying, or aseptic presentation (such as inner packaging, indicators, packing lists, mats, instrument sets, tray liners, or additional envelopes surrounding medical devices), other requirements including the confirmation of the acceptability of such materials may apply.

4.2 Materials

4.2.1 Porous materials Porous materials shall comply with the requirements of YY/T 0698.2,

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0698.3, 0698.6, 0698.7, 0698.9, or 0698.10. If the intended sterilization method is solely irradiation sterilization, the requirements for wet-state strength characteristics and air permeability of the porous material do not apply.

4.2.2 Plastic film

4.2.2.1 The plastic film shall be composed of two or more laminated layers. When tested after sterilization in accordance with Annex A, the interplybond shall not exhibit separation or whitening.

4.2.2.2 When tested in accordance with Annex B, the plastic film shall be free of pinholes.

4.2.2.3 When inspected under transmitted light (daylight or adequate artificial lighting) using normal or corrected vision, the plastic film shall be free from foreign matter and/or defects that would affect compliance with the requirements of 4.5. NOTE. Slight, continuous surface irregularities resulting from film extrusion shall not be considered defects.

4.2.2.4 The plastic film shall be capable of being heat-sealed to the porous material under the conditions specified by the manufacturer.

4.2.2.5 The breaking factor of the plastic film shall be no less than 20 N/15 mm. NOTE. The test method is specified in GB/T 1040.3.ASTM D882 may also be referenced for testing the tensile properties of plastic films.

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4.3 Structure and design

4.3.1 The roll structure shall consist of a layer of porous material and a layer of plastic composite film, sealed together in parallel along their two edges. The structure of the combination pouch shall consist of a layer of porous material and a layer of plastic laminate film heat-sealed together along three of their edges. It may include an area for closing the combination pouch.

4.3.2 The total width of the seal shall be no less than 6 mm. For ribbed seals, the sum of the widths of the individual ribs shall be no less than 6 mm.

4.3.3 The distance from one end of the combination pouch to the nearest edge of the transverse seal line shall be sufficient to allow the two sides to be separated and peeled apart. NOTE. The side seal line may extend beyond the transverse seal line to the edge of the pouch. This does not affect its peelability.

4.3.4 One side of a combination bag shall be one of the following.

a) A thumb notch, not exceeding 12 mm in depth, shall be provided at the top, bottom, or both ends of the combination pouch. The base of the thumb notch shall be positioned at least 1 mm away from the seal line.

b) There is an offset edge; one face is at least

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1.0 mm longer than the other. NOTE. The requirements of

4.3.4 do not apply to rolled materials sealed on three sides.

4.3.5 Pouches and/or reels shall be capable of being closed in accordance with the manufacturer's instructions. NOTE

1.The requirements for the validation of forming, sealing, and assembly processes are specified in GB/T 19633.2. NOTE

2.Closure and/or sealing systems can provide an indication of whether the seal has been opened.

4.4 Process indicators If a paper bag or tubular bag bears one or more Class 1 indicators, the performance of the indicators shall comply with the requirements of GB 18282.1.The area of each indicator shall be no less than 100 mm^2. The indicators shall not be affected by the sealing process.

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4.5 Performance requirements and test methods

4.5.1 When tested in accordance with the methods specified in Annex C, the strength of the sealed joints, both before and after the sterilization process, shall meet or exceed the requirements necessary for the intended application. NOTE

1.The technical requirements for seal strength before and after sterilization may differ. not exceed 155 mm. For other information mentioned in

4.6.1.1

a) and c), the repeat print interval shall not exceed 310 mm.

4.6.1.3 The labeling of pre-formed sterile barrier systems intended for sale to healthcare facilities shall not be confused with the labeling of the final product, such as the term "sterile".

4.6.2 Transport and/or storage packaging Each unit of transport and/or storage packaging shall be clearly and durably marked with the following information.

a) Product name or code;

c) Manufacturer's name and address;

d) Date of manufacture, in accordance with GB/T 7408;

e) Batch number 2;

f) Recommended storage conditions;

g) Compatible sterilization method(s).

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