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PHARMACEUTICAL INDUSTRY STANDARD

OF THE PEOPLE'S REPUBLIC OF CHINA

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YY/T 0698.2-2009

Packaging materials for terminal sterilized medical devices - Part 2: Sterilization wrap – Requirements and test methods

最终灭菌医疗器械包装材料

第 2 部分：灭菌包裹材料要求和试验方法

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Issued by: China Food and Drug Administration

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Foreword

YY/T 0698 *Packaging materials for terminal sterilized medical devices* consists of the following parts:

- Part 2: *Sterilization wrap - Requirements and test methods*
- Part 3: *Paper for use in the manufacture of paper bags (specified in YY/T 0698.4) and in the manufacture of pouches and reels (specified in YY/T 0698.5) - Requirements and test methods*
- Part 4: *Paper bags - Requirements and test methods*
- Part 5: *Heat and self-sealable pouches and reels of paper and plastic film construction - Requirements and test methods*
- Part 6: *Paper for manufacture of sterile ba*rrier systems intended for sterilization by low temperature sterilization pro
- Part 7: *Adhesive coated paper for the manufacture of sealable packs for medical use for sterilization by ethylene oxide*
- Part 8: *Re-usable sterilization containers for steam sterilizers - Requirements and test methods*
- Part 9: *Uncoated nonwoven materials of polyolefines for use in the manufacture of sealable pouches, reels and lids* - R
- Part 10: *Adhesive coated nonwoven materials of polyolefines for use in the manufacture of sealable pouches, reels and lids - Requirements and test methods*

This Part is the second part of YY/T 0698.

Other requirements and test methods for other packaging materials for terminal sterilized medical devices shall be stipulated in other parts.

This Part of YY/T 0698 refers to and adopts prEN 868-2:2007 *Packaging materials for terminal sterilized medical devices - Part 2: Sterilization wrap - Requirements and test methods*.

Annex A, Annex B, Annex C and Annex D of this Part are normative.

This Part was proposed by National Technical Committee on Infusion Equipment for Medical of Standardization Administration of China.

This Part shall be under the jurisdiction of China Food and Drug Administration Jinan Medical Device Quality Supervision and Inspection Center.

Packaging materials for terminal sterilized medical devices - Part 2: Sterilization wrap – Requirements and test methods

1 Scope

This Part of YY/T 0698 provides test methods and values for materials for preformed sterile barrier systems and packaging systems that are intended to maintain sterility of terminally sterilized medical devices to the point of use.

This Part introduces no additional requirements to the general requirements specified in ISO 11607-1. As such, the particular requirements in 4.2 can be used to demonstrate compliance with one or more but not all of the requirements of ISO 11607-1.

NOTE 1: If the intended use as specified by the manufacturer includes the possibility of the material being used as a sterile field or a surgical drape the YY/T 0506 series applies.

NOTE 2: If the intended use as specified by the manufacturer includes the possibility of the material being used as container filter or as an inner wrap for containers then additional and/or other requirements can apply, see e. g. YY/T 0698.8.

2 Normative references

The following standards contain the provisions which, through reference in this Part of YY/T 0698, constitute the provisions of this Part. For dated references, subsequent amendments (excluding corrections) or revisions do not apply to this Part. However, the parties who enter into agreement based on this Part are encouraged to investigate whether the latest versions of these documents are applicable. For undated reference documents, the latest versions apply to this Part.

GB/T 451.2 *Paper and board - Determination of grammage* (GB/T 451.2-2002, eqv ISO 536:1995)

GB/T 454 *Paper - Determination of bursting strength* (GB/T 454-2002, idt ISO 2758:2001)

GB/T 455 *Paper and board determination of tearing resistance* (GB/T 455-2002, eqv ISO 1974:1990)

GB/T 458 *Paper and board determination of air permeance* (GB/T 458-2008, ISO 5636-2:1984, ISO 5636-3:1992, ISO 5636-5:2003, MOD)

GB/T 465.1 *Paper and board - Determination of bursting strength after immersion in water* (GB/T 465.1-2008, ISO 3689:1983, IDT)

GB/T 465.2 *Paper and board - Determination of tensile strength after immersion in water* (GB/T 465.2-2008, ISO 3689:1983, IDT)

GB/T 1540 *Paper and board - Determination of water absorption - Cobb method* (GB/T 1540-2002, neq ISO 535:1991)

GB/T 1545.2 *Paper, board and pulp-Determination of pH of aqueous extracts* (GB/T 1545.2-2003, mod ISO 6588:1981)

GB/T 2678.6 *Paper， board and pulp-Determination of water soluble sulphates (Conductimetric titration method)* (GB/T 2678.6-1996, eqv ISO 9198:1989)

GB/T 3917.1-1997 *Textiles - Tear properties of fabrics - Part 1: Determination of tear force - Ballistic pendulum method (Elmendorf)* (GB/T 3917.1-1997, neq ISO/DIS 13937-1:1995)

GB/T 4744 *Textiles - Testing and evaluation for water resistance - Hydrostatic pressure method* (GB/T 4744-1997, eqv ISO 811:1981)

GB/T 4745-1997 *Textile fabrics - Determination of resistance to surface wetting - Spray test* (GB/T 4745-1997, eqv ISO 4920:1981)

GB/T 5453-1997 *Textiles - Determination of the permeability of fabrics to air*

GB/T 7408 *Data elements and interchange formats - Information interchange - Representation of dates and times* (GB/T 7408-2005, ISO 8601:2000, IDT)

GB/T 7742.1 *Textiles - Bursting properties of fabrics - Part 1: Hydraulic method for determination of bursting strength and bursting distension* (GB/T 7742.1-2005, ISO 13938-1:1999, MOD)

GB/T 7974-2002 *Paper, board and pulp - Measurement of brightness - Diff/Geometry* (neq ISO 2470:1999)

GB/T 12914 *Paper and board - Determination of tensile properties* (GB/T 12914-2008, ISO 1924-2:1994, MOD)

ISO 6588-2:2005 *Paper, board and pulps - Determination of pH of aqueous extracts - Part 2: Hot extraction*

ISO 9073-3 *Textiles - Test methods for nonwovens - Part 3: Determination of*

Bibliography

GB/T 10739 Paper, board and pulps standard atmosphere for conditioning and testing

GB/T 19633 Packaging for terminally sterilized medical devices

YY/T 0506.1 Surgical drapes gowns and clean air suits for patients clinical staff and equipment - Part 1: General requirements for manufacturers processors and products

EN 13795-3[6] Surgical Drapes, Gowns And Clean Air Suits, Used As Medical Devices For Patients, Clinical Staff And Equipment - Part 3: Performance Requirements and Performance Levels

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[6] YY/T 0506-2, the industrial standard corresponding to EN 13795-3 is under stipulation.

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