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Packaging materials for terminal sterilized medical devices – Part 5: Heat and self-sealable and reels of paper and plastic film construction – Requirements and test methods

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Foreword

YY/T 0698 *"Packaging materials for terminal sterilized medical devices"* composes of the following parts [Translator note: Part 1 is not existed]:

- 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: Sealable pouches and reels of porous materials and plastic film construction - Requirements and test methods;
- Part 6: Paper for the manufacture of sterile barrier systems intended for use for sterilization by ethylene oxide or irradiation - Requirements and test methods;
- Part 7: Adhesive coated paper for the manufacture of sealable sterile barrier systems for medical use for sterilization by ethylene oxide or irradiation - Requirements and test methods;
- Part 8: Re-usable sterilization containers for steam sterilizers - Requirements and test methods;
- Part 9: Uncoated nonwoven materials of polyolefins for use in the manufacture of sealable pouches, reels and lids - Requirements and test methods;
- Part 10: Adhesive coated nonwoven materials of polyolefins for use in the manufacture of sealable pouches, reels and lids - Requirements and test methods.

This Part is Part 5 of YY/T 0698.

Other requirements and test methods of packaging materials for terminal sterilized medical devices will be specified in other parts.

This Part of YY/T 0698 makes reference to prEN 868-5:2007 *"Packaging materials for terminal sterilized medical devices – Part 5: Heat and self-sealable pouches and reels of paper and plastic film construction – Requirements and test methods".*

Appendix A, appendix B and appendix C are normative.

This Part was proposed by the Standardization Technical Committee of National Medical Infusion Equipment.

This Part shall be under the jurisdiction of Jinan Quality Inspection and supervision Center For Medical Devices of China Food and Drug Administration.

Chief drafting organizations of this Part: Shandong Quality Inspection Center For Medical Devices, Shanghai Jianzhong Medical Packing Co., Ltd.

Participating drafting organizations of this Part: Shanghai Kindly Enterprise Development Group (KDL), Shandong SHINVA Medical Devices Co., Ltd.

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Packaging materials for terminal sterilized medical devices - Part 5: Heat and self-sealable and reels of paper and plastic film construction - Requirements and test methods

1 Scope

This Part of YY/T 0698 provides requirements and test methods for sealable pouches complying with the Part 3, Part 6, Part 7, Part 9 and Part 10 in YY/T 0698 and reels manufactured from porous materials specified in 4.2.2 of this Part.

This Part adds no additional requirements to the general requirements specified in ISO 11608-1. As such, the particular requirements in 4.2~4.5 can be used to verify compliance with one or more but not all of the requirements specified in ISO 11607-1.

Sealable pouches and reels specified in this Part apply to the packaging of medical devices which are to be terminally sterilized.

The use of sealable pouches and reels as preformed sterile barrier systems enables ease of presentation; most importantly, the users are able to see the contents of the pack before it is opened.

2 Normative references

The provisions in following documents become the provisions of this Standard through reference in this Standard. For dated references, the subsequent amendments (excluding corrigendum) or revisions do not apply to this Standard, however, parties who reach an agreement based on this Standard are encouraged to study if the latest versions of these documents are applicable. For undated references, the latest edition of the referenced document applies.

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

GB 18282.1 Sterilization of health care products - Chemical indications - Part 1: General requirements

YY/T 0698.3 Packing material for terminal sterilized medical devices - 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

YY/T 0698.6 Packing material for terminal sterilized medical devices - Part 6: Paper for manufacture of sterile barrier systems intended for sterilization by low temperature sterilization processes or irradiation - Requirements and test methods

YY/T 0698.7 Packing material for terminal sterilized medical devices - Part 7: Adhesive coated paper for the manufacturer of sealable packs for medical use for sterilization by ethylene oxide or irradiation - Requirements and test methods

YY/T 0698.9 Packing material for terminal sterilized medical devices - Part 9: Uncoated nonwoven material of polyolefines for use in the manufacture of sealable pouches, reels and lids - Requirements and test methods

YY/T 0698.10 Packing material for terminal sterilized medical devices - Part 10: Adhesive coated nonwoven materials of polyolefines for use in the manufacture of sealable pouches, reels and lids - Requirements and test methods

ISO 11607-1 Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems

ASTM D 822:1995 Test Methods for Tensile Properties of the Thin Plastic Sheeting

3 Terms and definitions

The following terms and definitions given in ISO 11607-1 apply to this Part in YY/T 0698.

3.1 Healthcare facility

Location where patients are medically treated and medical devices are terminally sterilized.

Such as: hospital, dentist office and practitioner.

4 Requirements

4.1 General

The requirements in ISO 11607-1 apply.

Note 1: the following particular requirements and test methods can be used to verify one or more but not

Bibliography

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

GB/T 19633 Packaging for terminally sterilized medical devices (GB/T 19633-2005, ISO 11607:2003, IDT)

YY 0331 Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and viscose gauze

YY 0503 Ethylene oxide sterilizer

YY 1007 Vertical mode steam sterilizers

ISO 11607-2 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes.

ISO 14937 Sterilization of health care products - General requirements for characterization of a sterilizing agent and the development, validation and control of a sterilization process for medical devices

EN 285 Sterilization - Steam sterilizers - Large sterilizers

EN1422 Sterilizers for medical purposes - Ethylene oxide sterilizers - requirements and test methods

EN 14180 Sterilizers for medical purposes - Low temperature steam and formaldehyde sterilizers - Requirements and testing

ASTM F 88-06 Standard test method for seal strength of flexible barrier materials

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