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Application Guide of Packaging Materials for Terminally Sterilized Medical Devices in Medical Institution

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Preface

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This document was proposed and administered by China Health Inspection Association.

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Application Guide of Packaging Materials for Terminally Sterilized Medical Devices in Medical Institution

China Health Inspection Association

1 Scope of Application

This document specifies the product categories, management requirements, test report requirements, label and marking requirements, warehousing and storage requirements, application and precautions for sterilization packaging materials used in medical institutions.

This document applies to sterilization packaging materials used in all types and levels of medical institutions.

2 Normative References

The following normative documents contain provisions, which, through reference in this text, constitute provisions of this document. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. For undated references, the latest edition of the normative document (including any amendments) referred to applies.

Biological evaluation of medical devices—Part 5: Tests for in vitro cytotoxicity (GB/T 16886.5)

Biological evaluation of medical devices—Part 10: Tests for skin sensitization (GB/T 16886.10)

Packaging for terminally sterilized medical devices—Part 1: Requirements for materials, sterile barrier systems and packaging systems (GB/T 19633.1)

Packaging for terminally sterilized medical devices—Part 2: Validation requirements for forming, sealing and assembly processes (GB/T 19633.2)

General requirement for label and instruction book of disinfection products (GB 38598)

Central sterile supply department (CSSD) —Part 1: Management standard (WS 310.1—2016)

Central sterile supply department (CSSD)—Part 2: Standard for operating procedure of cleaning, disinfection and sterilization (WS 310.2—2016)

Central sterile supply department (CSSD) —Part 3: Surveillance standard for cleaning, disinfection and sterilization (WS 310.3—2016)

Technical requirements for the hygiene and safety evaluation of disinfectant products (WS 628)

Test methods of disinfection products (WS/T 10009)

Test methods for sterile medical device package—Part 1: Test guide for accelerated aging (YY/T 0681.1)

Test methods for sterile medical device package—Part 4: Detecting seal leaks in porous packages by dye penetration (YY/T 0681.4)

Test methods for sterile medical device package—Part 10: Test for microbial barrier ranking of porous package material (YY/T 0681.10)

Test methods for sterile medical device package—Part 11: Determining integrity of seals for medical packaging by visual inspection (YY/T 0681.11)

Packaging materials for terminal sterilized medical devices—Part 2: Sterilization wrap—Requirements and test methods (YY/T 0698.2)

Packaging materials 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 0698.3)

Packaging materials for terminally sterilized medical devices—Part 8: Re-usable sterilization containers for steam sterilizers—Requirements and test methods (YY/T 0698.8)

Packaging materials for terminally sterilized medical devices—Part 9: Uncoated nonwoven materials of polyolefines for use in the manufacture of sealable pouches, reels and lids—Requirements and test methods (YY/T 0698.9)

3 Terms and Definitions

The terms and definitions defined as follows apply to this document.

3.1 Sterile barrier system, SBS

A minimum packaging that prevents microbial ingress and allows the sterile presentation of reusable medical devices, instruments and items at the point of use.

[Source: GB/T 19633.1—2024]

3.2 Preformed sterile barrier system

A sterile barrier system that has been partially assembled and is ready for final closure or sealing after loading of reusable medical devices, instruments and items. Examples include medical paper-plastic composite packaging materials, medical polyethylene (PE) composite packaging materials and medical rigid sterilization containers.

[Source: GB/T 19633.1—2024, modified]

3.3 Protective packaging

A protective material structure used to prevent damage to SBS and its contents from assembly until final use, such as plastic film, paper/plastic packaging bags/boxes and other outer packaging.

[Source: GB/T 19633.1—2024, modified]

4 Product Categories

The sterilization packaging materials used in medical institutions are categorized into medical textile packaging materials, medical nonwoven packaging materials, medical paper-plastic composite packaging materials, medical PE composite packaging materials, medical paper/paper bag packaging materials, medical crepe paper packaging materials, medical rigid sterilization containers, etc.

4.1 Medical textile packaging materials

Medical textile packaging materials are made of long-fibre polyester fibres and carbon fibre fabrics with antistatic properties, and are reusable for steam sterilization.

4.2 Medical nonwoven packaging materials

Medical nonwoven packaging materials are single-use packaging materials made of polypropylene materials compounded via spunbond, meltblown and other processes, and are commonly used for steam sterilization, ethylene oxide (ETO) sterilization and low-temperature steam and formaldehyde (LTSF) sterilization.

4.3 Medical paper-plastic composite packaging materials

Medical paper-plastic composite packaging materials are single-use preformed SBS composed of breathable materials such as medical paper and composite film, e.g., medical paper-plastic reels and medical paper-plastic pouches. They are commonly used for steam sterilization, ETO sterilization and LTSF sterilization.

4.4 Medical polyethylene composite packaging materials

Medical PE composite packaging materials are single-use preformed SBS composed of 100% high-density PE and composite film, e. g., medical PE composite sterilization reels and medical PE composite sterilization pouches. They are commonly used for low-temperature vaporized hydrogen peroxide (VH_2O_2, VHP) sterilization.

4.5 Medical paper bag packaging materials

Medical paper bag packaging materials are single-use preformed SBS made by bonding breathable materials such as medical paper. They are commonly used for steam sterilization.

4.6 Medical crepe paper packaging materials

Medical crepe paper packaging materials are single-use sterilization packaging materials made from medical paper that has been sensitized to improve its softness. They are commonly used for steam sterilization.

4.7 Medical rigid sterilization containers

Medical rigid sterilization containers are reusable rigid sterilization containers composed of a lid, body or base, instrument basket, handle, sterilization identification card slot, gasket and sterilizing agent penetration pathways (valves or filter components), and serve as SBS for sterilization, storage and transport of medical devices. They are commonly used for steam sterilization, ETO sterilization, VHP sterilization, LTSF sterilization, etc.

5 Management Requirements

5.1 Medical institutions shall establish a quality control system for terminally sterilized packaging materials and define the responsibilities of the

relevant departments.

5.2 Medical institutions shall establish a quality feedback mechanism. When product quality issues are identified, they shall be reported to the supplier and addressed in time.

5.3 Medical institutions shall select qualified sterilization packaging materials in accordance with the characteristics of reusable medical devices, instruments and items, the applicable sterilization methods, the management requirements of the standard WS 310.1, and this guide, and shall use them according to the manufacturer's instructions. When new sterilization packaging materials and new packaging methods are adopted, biological monitoring shall be conducted in accordance with the standard WS 310.3; they may be used only when complying with the monitoring criteria, and the packaging materials and packaging methods after sterilization shall meet packaging integrity and closure integrity.

5.4 Before purchasing sterilization packaging materials, medical institutions shall organize the healthcare-associated infection management department, the central sterile supply department and other relevant departments to carry out quality review and evaluation, and shall verify the relevant certification documents of the products:

5.4.1 Business license of the manufacturer and/or supplier (contract manufacturer).

5.4.2 Sales authorization letter from the manufacturer within the valid period; for imported packaging materials, the content of the authorization letter shall be consistent with the products sold.

5.4.3 Test report showing that the manufacturer's production workshop has a cleanliness level not lower than Class 100,000.

5.4.4 The manufacturer shall provide a list of laboratory equipment and supporting documents that meet the requirements for release inspection and batch testing.

5.4.5 Product performance test report.

5.4.6 Product label and instructions.

5.4.7 Sterilization packaging materials with external chemical indicators shall be provided with the hygiene and safety evaluation report of disinfection products and the filing certificate.

5.4.8 ISO 13485 or ISO 9001 quality management system certificate may be provided.

5.4.9 Clinical use report from medical institutions may be provided.

6 Test Report Requirements

6.1 Product performance test requirements

6.1.1 Product performance test reports shall be provided in accordance with the standards WS/T 10009 or YY/T 0681.

6.1.2 Product performance test reports shall bear CMA and/or CNAS markings.

6.1.3 When changes in sterilization packaging materials affect SBS, updated performance test reports shall be provided in accordance with the standard GB/T 19633.1.

6.1.4 Performance test reports shall be provided according to the product model/characteristics of the packaging materials (such as different basis weight materials, composite pouches, double-layer composite single-use packaging or other structural packaging types). For reusable medical textile packaging materials, the performance test reports shall be provided for the maximum allowable number of processing cycles in accordance with the instructions.

6.1.5 For the sterilization packaging materials used for the first time, the biological monitoring reports shall be provided in accordance with the standard WS 310.3.

6.2 Product performance test reports

6.2.1 Microbial barrier performance test report

Tests shall be conducted in accordance with the standards WS/T 10009 or YY/T 0681.10.

6.2.2 Product shelf-life and sterility shelf-life test report

Accelerated aging tests shall be conducted in accordance with the standards WS/T 10009 or YY/T 0681.1; real-time aging tests shall be used to determine of sterility shelf-life.

6.2.3 Biocompatibility and toxicological character-

istics test report

Tests for *in vitro* cytotoxicity, skin irritation and skin sensitization shall be conducted in accordance with the standards GB/T 16886.5 and GB/T 16886.10.

6.2.4 Physical and chemical characteristics test report

a) For medical textile packaging materials, test reports shall be provided for physical performance indicators including basis weight, drape, dry and wet breaking strength in warp and weft directions, dry and wet tear strength in warp and weft directions, dry and wet bursting strength, air permeability, water repellency, etc., in accordance with the standard YY/T 0698.2. Test reports for chemical performance indicators such as colour bleeding, basis weight, pH, sulfate content, chloride content, fluorescence brightness, number of fluorescent spots and drape coefficient shall also be provided.

b) For medical nonwoven packaging materials, test reports shall be provided for physical performance indicators such as internal tear resistance, bursting strength, wet bursting strength, elongation at break, tensile strength, wet tensile strength and water repellency, in accordance with the standard YY/T 0698.2. Test reports for chemical performance indicators such as colour bleeding, basis weight, pH, sulfate content, chloride content, fluorescence brightness, number of fluorescent spots and drape coefficient shall also be provided.

c) For medical paper-plastic composite packaging materials and medical PE composite packaging materials, test reports from raw material suppliers on the performance of raw materials shall be provided; for example, plastic film materials shall comply with the standard YY/T 0698.5, breathable materials such as medical paper shall comply with the standard YY/T 0698.3, and the nonwoven material used in medical PE composite packaging materials shall comply with the standard YY/T 0698.9.

d) For medical rigid sterilization containers, test reports shall be provided for indicators such as shape and dimensions, lid or lid locking device, handles, stacking capability, sterilizing agent entry and marking, in accordance with the standard YY/T 0698.8.

6.2.5 Conformity test report for preforming and sealing process

The preforming and sealability of medical paper-plastic composite packaging materials and medical PE composite packaging materials shall be validated in accordance with the standards GB/T 19633.2, YY/T 0681.11 or YY/T 0681.4.

6.2.6 Conformity test report for the intended sterilization process

For each sterilization method applicable to the sterilization packaging material, test reports for sterilizing agent penetration performance tested in accordance with the standard WS/T 10009 shall be provided separately.

6.2.7 Medical paper-plastic composite packaging materials and medical PE composite packaging materials with external chemical indicators

These materials shall comply with the management requirements for hygiene and safety evaluation of disinfection products, and shall be tested and evaluated according to the test items specified in Annex F of the standard WS 628 (Table 1).

6.2.8 For medical textile packaging materials and medical nonwoven packaging materials, the dry linting test reports shall be provided.

6.2.9 For medical paper-plastic composite packaging materials and medical PE composite packaging materials, the clean peel test reports shall be provided.

7 Label and Marking Requirements

7.1 Product instructions for use

7.1.1 The product instructions for use shall include at least: product name, model and specification; product standard(s) applied; product material and applicable sterilization method(s); service life; storage requirements and precautions for use; name, address and contact information of the manufacturer; if the manufacturing is contract manufactured, the name and production address of the contract manu-

Table 1 Test items for sterilization packaging materials with external chemical indicators

Test items	Material type	
	Permeable materials	Impermeable materials
Sterility shelf-life test	+	+
Basis weight determination	+	+
Determination of sterilizing agent penetration performance	+	+
Effect of sterilization on packaging marking[a]	+	+
Microbial barrier test for permeable materials	+	-
Permeability test for impermeable packaging materials	-	+
Determination of sterilizing agent residue[b]	±	±
Packaging material shelf-life test[c]	+	+

Note: + indicates mandatory item; - indicates not required; ± indicates optional item.

a) For packaging materials bearing multiple sterilization indicators, the determination of corresponding sterilizing agent penetration shall be carried out separately.

b) Physical sterilization methods do not require this test.

c) When stored up to the shelf life indicated in the label/instructions, perform sterility shelf-life validation test, determination of color change of packaging marking caused by the sterilizing agent, and microbial barrier test for permeable packaging materials.

facturer shall also be marked.

7.1.2 The instructions of medical paper-plastic composite packaging materials and medical PE composite packaging materials shall provide data on sealing conditions (e.g., ranges of sealing temperature, pressure and time) and the method of aseptic opening.

7.1.3 The instructions of medical rigid sterilization containers shall provide instructions for use, cleaning procedures, performance inspection methods, criteria for continued use, requirements for disassembly and assembly of accessories, service life of containers and gaskets, sterilization parameters, etc.

7.1.4 The instructions of medical textile packaging materials shall provide cleaning methods (including detergent type, cleaning and disinfection parameters, etc.) and methods for checking service performance.

7.2 Product packaging labels

7.2.1 The product packaging labels shall bear the product name, model, specification, quantity, date of manufacture and expiry date, or batch number and expiry date, scope of use, storage conditions, warnings, precautions, and the name, address and contact information of the manufacturer.

7.2.2 The labels shall indicate whether the product is for single use or for reuse.

7.2.3 The labels and markings of medical paper-plastic composite packaging materials and medical PE composite packaging materials with external chemical indicators shall comply with the standard GB 38598.

8 Warehousing and Storage Requirements

8.1 Incoming inspection requirements

8.1.1 Test reports for physical and chemical properties shall be related to the product batch.

8.1.2 A product delivery note and a product batch certificate of conformity shall be provided.

8.1.3 If the outer packaging is damaged, wet, or stained, it shall be rejected.

8.1.4 The information on the product packaging label and outer packaging, such as name, specification/model and batch number, shall be consistent with that on the batch test report.

8.1.5 The product shelf-life shall meet the usage requirements of the medical institution.

8.2 Storage requirements

8.2.1 The storage area shall be clean, dry and well-ventilated, and protected from direct sunlight. Indoor temperature and humidity should meet the storage requirements specified in the product instructions for the sterilization packaging ma-

terials.

8.2.2 The materials shall be stored in dedicated cabinets/shelves by category, with clear markings and intact packaging; shall be used within the validity period and follow the first-in-first-out principle.

8.2.3 Nonconforming materials shall bear warning markings and be stored separately from conforming products.

9 Application and Precautions

9.1 Single-use sterilization packaging materials

9.1.1 The materials shall be used within the validity period and shall not be reused.

9.1.2 The selection of sterilization packaging materials shall be compatible with the sterilization method (steam sterilization, VHP sterilization, ETO sterilization, LTSF sterilization), and the specification/model shall be appropriate for the weight and volume of the instruments. The selected materials and packaging method shall ensure the integrity of the sealed/closed packaging.

9.1.3 Before use, inspection shall be carried out under adequate lighting; there shall be no holes, cracks, tears, creases or other quality defects that could impair their performance.

9.1.4 For medical paper-plastic composite packaging materials and medical PE composite packaging materials with external chemical indicators, the printed chemical indicator marks shall be uniform, without migration or penetration, and the colour before and after sterilization shall be consistent with the product instructions.

9.1.5 The sealing parameter ranges of the medical sealing machine shall be set according to the product instructions for the sterilization packaging materials. For sterilization packaging materials that require manual sealing with adhesive (such as paper bags), the seal shall be continuous and cover the specified width.

9.1.6 Medical paper-plastic composite packaging materials should be used for instruments with small volume and light weight. Each packaging pouch shall have at least one chemical indicator colour block corresponding to the sterilization method; the external label shall be affixed to the plastic side of the pouch, and aseptic opening after sterilization shall be ensured; the sealing width shall be ⩾6 mm, and the instruments inside the packaging shall be ⩾2.5 cm from the seal from either side of the pouch.

9.1.7 If the colour change of the internal chemical indicator can be directly observed through the packaging material, an external chemical indicator is not required.

9.1.8 The external chemical indicator on sterilization packaging materials is a process indicator; its colour change to the acceptable end-point only indicates that sterilization processing has occurred, and shall not be used as the sole basis for determining sterilization qualification.

9.1.9 If double-layer packaging is required for medical paper-plastic composite packaging materials, the paper sides shall face each other and the plastic sides shall face each other; both the inner and outer layers shall be sealed; the outer layer shall be larger than the inner layer; the inner layer shall be flat without folds; and the internal chemical indicator shall be placed inside the inner packaging material.

9.1.10 During packaging, the sharp ends and irregular surfaces of instruments shall be protected to avoid piercing the packaging material.

9.1.11 The sealing and closure methods for sterilization packaging materials shall comply with the standard WS 310.2.

9.2 Reusable sterilization packaging materials

9.2.1 Medical textile packaging materials

9.2.1.1 Before first use and after each use, cleaning, disinfection and drying shall be carried out in accordance with the product instructions. Sealing tape shall be removed before cleaning to avoid adhesive residue.

9.2.1.2 The number of uses shall not exceed the maximum allowable number of processing cycles given in the product instructions; alterna-

tively, the end-of-use judgement shall be made in accordance with the product instructions.

9.2.1.3 Before each use, the textile packaging materials shall be visually inspected on an inspection table with a light source. The appearance shall be clean, dry, free from odour, foreign matter, damage, delamination from use, and the peripheral seams shall not be unravelled. They may be used only if they pass the inspection.

9.2.1.4 The closing method shall be appropriate for the medical textile packaging materials.

9.2.1.5 If a traceability label is provided, its integrity shall be verified.

9.2.1.6 Medical textile packaging materials shall be stocked according to usage, and the temperature and humidity of the storage environment shall meet the requirements of the product instructions.

9.2.2 Medical rigid sterilization containers

9.2.2.1 The use shall follow the manufacturer's product instructions.

9.2.2.2 Before first use, sterilization effectiveness tests shall be conducted in accordance with the product instructions and/or the standard WS 310, including physical monitoring, chemical monitoring and biological monitoring, and a wet pack inspection shall be performed.

9.2.2.3 After each use, cleaning, disinfection, inspection and maintenance shall be carried out in accordance with the standard WS 310.2.

9.2.2.4 The structural integrity of the medical rigid sterilization container shall be inspected, and its condition for continued use shall meet the product instructions.

9.2.2.5 The integrity of the "locking device" shall be checked, and it shall provide a clear indication when closure integrity is compromised.

9.2.2.6 The placement of reusable medical devices, instruments and items inside the medical rigid sterilization container shall not impede penetration of the sterilizing agent.

9.2.2.7 The use and replacement of medical rigid sterilization containers and their accessories shall comply with the product instructions.

9.2.2.8 Medical rigid sterilization containers shall be regularly maintained and serviced, and records shall be kept.