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Medical Non-woven and Medical Composite Materials for Surgery and Medical Devices

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Contents

Foreword

- This document has been drafted in compliance with the provisions of GB/T 1.1-2020, 'Guidelines for Standardization Work – Part 1: Structure and Drafting Rules for standardization Documents.
- Certain aspects of this document may be subject to patents. The issuing organization does not assume any responsibility for identifying such patents.
- This document has been proposed by the China Association of Medical Devices.
- This document is under the authority of the Standardization Technical Committee of the Medical Device Packaging Subcommittee of the China Association of Medical Devices.
- This document was drafted by the following organizations: Jiangsu ProMed Medical Co.,Ltd., Renji Hospital Affiliated to Shanghai Jiaotong University, Beijing Tongren Hospital, CMU, Jiangsu Medplus Non-Woven Manufacturer Co., Ltd., Nanjing Gulou Hospital Group Suqian Hospital, SGS-CSTC Standards Technical Services Co., Ltd., MICRO-TECH, SIR RUN RUN HOSPITAL NANJING MEDICAL UNIVERSITY, Yadu Holdings Group Co., Ltd., Beijing Anzhen Hospital, Capital Medical University, Jiangsu Huawei Standard Certification Group Co., Ltd., SCMC, Jiangxi Medical Device Testing Center, Suqian Institute for Food and Drug Control, GRI Medical & Electronic Technology Co., Ltd., Foshan King Wonder Hi-tech Co., Ltd., Beijing University of Chemical Technology, Tongji Hospital of Tongji University, Disinfection Center of Guangdong Provincial People's Hospital, Peking University Shenzhen Hospital(PKUSZH), Union Hospital of Huazhong University of Science and Technology Shenzhen Hospital, Lianyungang Boulder Industrial Co., Ltd. , Haining Meidikang Nonwoven New Materials Co., Ltd., CHTC Jiahua Nonwoven Co., Ltd., Winner Medical Co., Ltd. , and Zhongshan Hospital, Fudan University.
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Medical non-woven and composite materials for surgical and instrument protection

1 Scope

- This document outlines the material classification, requirements, testing methods, packaging, labeling, as well as the storage and transportation of medical non-woven and composite materials used for surgical and instrument protection.
- This document applies to single-use medical non-woven materials and non-woven composite materials for surgical and instrument protection.

2 Normative Cited Documents

- The contents of the following documents, referenced normatively in this document, form an essential part of its provisions. For documents with a date of publication, only the version corresponding to that date is applicable to this document; for documents without a date, the latest version (including all amendments) applies to this document.

GB 19082-2023 Medical Disposable Protective Suit

GB/T 191 Packaging and Storage/Transportation Pictorial Markings

GB/T 250 Textiles Colorfastness Test Gray Scale for Evaluating Color Change

GB/T 3917.3 Textiles Tear Performance of Fabric

Part 3: Determination of Tear Strength of Trapezoidal Samples

GB/T 4666 Textiles Determination of Fabric Length and Width

GB/T 7742.1 Textiles Tear Performance of Fabric Part 1: Determination of

Burst Strength and Burst Elongation Hydraulic Method

GB/T 24218.1 Textiles Non-woven Fabric Testing Methods

Part 1: Determination of Mass per Unit Area

GB/T 24218.3 Textiles Non-woven Fabric Testing Methods

Part 3: Determination of Tensile Strength and Elongation at Break (Strip Method)

GB/T 24218.6 Textiles Non-woven Fabric Testing Methods

Part 6: Determination of Absorbency

GB/T 24218.10 Textiles Non-woven Fabric Testing Methods

Part 10: Testing of Dry Fibrillation

GB/T 24218.16 Textiles Non-woven Fabric Testing Methods

Part 16: Determination of Water Resistance (Hydrostatic Pressure Method)

GB/T 24218.17 Textiles Non-woven Fabric Testing Methods Part 17: Determination of Water Resistance (Spray Impact Method) YY/T 0506.1-2023 Medical Surgical Drapes, Surgical Gowns, and Cleanroom Garments - Part 1: General Requirements

YY/T 0689-2008 Test Method for the Penetration Resistance of Protective Suit Materials Against Bloodborne Pathogens in Blood and Bodily Fluid Protective Equipment - Phi-X174 Bacteriophage Test Method

YY/T 0700 Test Method for the Penetration Resistance of Protective Suit Materials Against Blood and Bodily Fluids in Blood and Bodily Fluid Protective Equipment - Synthetic Blood Test Method

YY/T 0855.1 Surgical Drapes and/or Patient Protection Covers - Laser Resistance Test Methods and Classification, Part 1: Primary Ignition and Penetration

3 Terms and Definitions

The following terms and definitions apply to this document.

3.1

Medical Non-woven Materials

Medical nonwoven materials are engineered fiber assemblies, primarily in planar form, that have achieved structural integrity at the designed level through physical and/or chemical methods, excluding woven, knitted, or paper-based materials.

Note: The materials involved include spunbond/meltblown/spunbond nonwoven materials, spunbond nonwoven materials, and films, but exclude nonwoven materials produced by hydroentangling, needle punching, and flash-spun processes.[Source: ISO 9092:2019, 3.3.1, with modifications.]

3.2

Medical Composite Materials

Medical nonwoven composite materials are permanently bonded through lamination of two or more layers of pre-formed materials, with at least one layer being medical nonwoven material. If necessary, additional media (such as adhesives) are used to secure the bonded composite materials.

Note: The materials involved include two-layer laminated composites, two-layer adhesive composites, multi-layer composites, etc. [Source: ISO 11224:2003, 4.5.2, with modifications.]

4 Material Classification

Medical non-woven and composite materials for surgical and instrument protection are classified into four levels: Level I, Level II, Level III, and Level IV, with performance increasing progressively from Level I to Level IV.

Table 1: Material Grades, Key Indicators, and Recommended Application Scope

Level	Key Indicators	Recommended Application Scope
Level I	Spray Impact Water Permeation≤4.5g	Materials suitable for basic care and standard isolation, applicable to surgical gowns, isolation gowns, instrument protection covers, isolation protective suits, and accessories for isolation protective suits.
Level II	Spray Impact Water Penetration Volume ≤1.0g Hydrostatic Pressure≥ 30cmH2O	Materials suitable for blood collection, suturing, intensive care units (ICU), or pathology laboratories, applicable to surgical gowns, isolation gowns, instrument protection covers, other gowns, isolation protective suits, surgical drapes, and surgical drape accessories.
Level III	Spray Impact Water Permeation Volume≤ 1.0g Hydrostatic Pressure ≥50cmH2O	Materials suitable for arterial blood collection, intravenous catheter insertion in emergency rooms, or for trauma cases, applicable to surgical gowns, isolation gowns, other protective garments, surgical drapes, and surgical drape accessories.

Level Ⅳ	Passes Bacteriophage Penetration Resistance, Synthetic Blood Penetration Resistance ⩾ Level 5	Materials suitable for use in long-duration, high-intensity fluid surgical procedures, when pathogen barrier or protection against suspected infectious diseases (non-airborne) is required, applicable to surgical gowns, isolation gowns, other protective garments, and protective garment accessories.

5 Requirements

5.1 Performance Indicators

Performance indicators shall comply with the provisions of Table 2.

Table 2 Performance Indicators

Testing Items	Unit	Testing Methods	Performance Indicators			
			Level I	Level II	Level III	Level IV
Unit Area Mass Deviation Rate	%	GB/T 24218.1	±6.0			
Spray Impact Water Penetration	g	GB/T 24218.17	≤4.5	≤1.0	≤1.0	—
Hydrostatic Pressure	cmH20	GB/T 24218.16	—	≥30	≥50	≥100
Bacteriophage Penetration Resistance	/	YY/T 0689-2008	—	—	≥1	≥5
Synthetic Blood Penetration Resistance	Grade	YY/T 0700	—	—	≥2	≥5
Tear Strength	N	GB/T 3917.3	≥10			
Tensile Strength	N	GB/T 24218.3	≥20	≥20	≥45	≥45
Burst Strength	kPa	GB/T 7742.1	≥50	≥50	≥50	≥50
Particulate Release	/	GB/T 24218.10	≤4.0			
Biological Load	CFU/dm^2	YY/T 0506.1-2023	≤200			
Laser Flame Retardancy	/	YY/T 0855.1	I3 P2	I2 P3	I1 P4	I1 P4
Liquid Absorption Capacity	%	GB/T 24218.6	-	100	200	300

Note 1: Laser flame retardancy can be adjusted based on the specific type of surgery for the material's laser flame retardancy classification level.
Note 2: Synthetic blood penetration resistance and bacteriophage penetration resistance levels are shown in Table 4 of GB 19082-2023.
Note 3: Liquid absorption capacity is suitable for hydrophilic materials.

5.2 Visual Quality

5.2.1 The surface of the material should be uniform and smooth, free from obvious creases, frayed edges, holes, oil stains, and blemishes, with the roll neatly packaged.

5.2.2 The width deviation shall comply with the provisions of Table 3.

Table 3 Width Deviation

Width/mm	Width Deviation/mm
＜500	±3
500～1000	-3 ～+4
＞1000	-3 ～+5

5.2.3 The material color difference and the color difference within the same batch shall not be lower than Grade 3.

6 Testing Methods

6.1 The unit area mass deviation rate shall be tested according to the method specified in GB/T 24218.1. The unit area mass deviation rate is calculated using formula (1), with the result rounded to one decimal place.

$$G = \frac{m_1 - m_0}{m_0} \times 100\% \quad \cdots\cdots (1)$$

In this formula:
G -Unit Area Mass Deviation Rate;
m_1-Measured Unit Area Mass,unit(g/m^2);
m^0-Nominal Unit Area Mass,unit(g/m2)

6.2 The spray impact water penetration amount shall be tested according to the method specified in GB/T 24218.17, with the average value taken as the test result.

6.3 Hydrostatic pressure shall be tested according to the method specified in GB/T 24218.16, with the water pressure rise rate set at（60±3）cmH2O/min.

6.4 Phage penetration resistance shall be tested according to the methods specified in Program C or Program D of YY/T 0689-2008.

6.5 The resistance to synthetic blood penetration shall be tested according to the method specified in YY/T 0700.

6.6 Tear strength shall be tested according to the method specified in GB/T 3917.3.

6.7 Breaking strength shall be tested according to the method specified in GB/T 24218.3.

6.8 Bursting strength shall be tested according to the method specified in GB/T 7742.1, with a test area of 10cm2.

6.9 Particle release shall be tested according to the method specified in GB/T 24218.10.

6.10 Biological load shall be tested according to the method specified in Appendix B of YY/T 0506.1-2023.

6.11 Laser flame retardancy shall be tested according to the method specified in YY/T 0855.1.

6.12 Liquid absorption shall be tested according to the method specified in GB/T 24218.6.

6.13 Visual inspection of appearance defects should be conducted on a horizontal inspection table, with the table surface illumination not less than 600 lx and the eye level approximately 60 cm from the table surface.

6.14 The width should be tested according to the method specified in GB/T 4666.

6.15 Color difference should be tested according to the method specified in GB/T 250.

7 Packaging, labeling, and storage

7.1 The product should be sealed in packaging using at least two layers of protective material.

7.2 A clear and easily recognizable label should be affixed to a prominent area of each individual packaging unit, containing the following information:

a) Name and address of the manufacturing company;

b) Name of the products;

c) Main product specifications (such as unit area weight, width, roll length/net weight, etc.);

d) Production date, production batch number;

e) Material grade.

7.3 The transportation and storage pictorial symbols should comply with the provisions of GB/T 191.

7.4 During transportation, product packaging should be protected from moisture, damage, contamination, and rain, and should not be exposed to direct sunlight for extended periods.

7.5 Product packaging should be stored in a dry, well-ventilated, and clean environment.

References

[1] ISO 9092：2019 Nonwovens -Vocabulary

[2] ISO 11810:2015 Lasers and laser-related equipment Test method and classification for thelaser resistance of surgical drapesand/or patient protective coversPrimary ignition, penetration, flamespread and secondary ignition

[3] ISO 11224：2003 Textiles-Web formation and bonding in nonwovens-Vocabulary

[4] ANSI/AAMI PB70:2022 Liquid barrier performanceand classification of protective apparel and drapesintended for use in healthcare facilities

[5] ASTM F1670/F1670M-24 Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Synthetic Blood

[6] ASTM F1671/F1671M-22 Standard Test Method for Resistance of Materials Used in Protective Clothing to Penetration by Blood-Borne Pathogens Using Phi-X174 Bacteriophage Penetration as a Test System

[7] ASTM F2407-20 Standard Specification for Surgical Gowns Intended for Use in Healthcare Facilities

[8] EN 13795-1:2019 Surgical clothing and drapes Requirements and test methods Part 1: Surgical drapes and gowns