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Technical Requirements for Single-Use Protective Clothing for Medical Use

医用一次性防护服技术要求

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Technical Requirements for Single-Use Protective Clothing for Medical Use

1 Scope

This Standard specifies the requirements, test methods, marking, instructions for use, packaging and storage of single-use protective clothing for medical use.

This Standard is applicable to single-use protective clothing for medical use (hereinafter referred to as protective clothing) that provides barrier and protection for medical personnel in contact with potentially infectious patients' blood, body fluids, secretions, particulate matter in the air, etc.

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 191 Packaging – Pictorial Marking for Handling of Goods (GB/T 191-2008, ISO 780:1997, MOD)

GB/T 3923.1-1997 Textiles - Tensile Properties of Fabrics - Part 1: Determination of Breaking Force and Elongation at Breaking Force - Strip Method

GB/T 4744-1997 Textile Fabrics - Determination of Resistance to Water Penetration -Hydrostatic Pressure Test (eqv ISO 811:1981)

GB/T 4745-1997 Textile Fabrics - Determination of Resistance to Surface Wetting -Spray Test (eqv ISO 4920:1981)

GB/T 5455-1997 Textiles - Burning Behavior - Vertical Method

GB/T 5549-1990 Surface Active Agents Determination of Surface Tension by Drawing up Liquid Films

GB/T 12703-1991 Electrostatic Test Methods for Textile

GB/T 12704-1991 Fabrics – Determination of Water Vapor Transmission Rate - Dish Method

GB/T 14233.1-2008 Test Methods for Infusion Transfusion Injection Equipment for Medical Use - Part 1: Chemical Analysis Methods

GB/T 14233.2-2005 Test Methods for Infusion Transfusion Injection Equipment for Medical Use – Part 2: Biological Test Methods

GB 15979-2002 Hygienic Standard for Disposable Sanitary Products

GB/T 16886.10-2005 Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Delayed - Type Hypersensitivity (ISO 10993-10:2002, IDT)

IST 40.2(01) Standard Test Method Electrostatic Decay Nonwoven Fabrics

3 Terms and Definitions

For the purpose of this Standard, the following terms and definitions apply.

3.1 Particle

Solid, liquid, or solid and liquid mixed particles suspended in air, such as microorganisms, dust, smoke and fog, etc.

3.2 Filtering efficiency

Percentage of airborne particles filtered out by protective clothing under specified conditions.

3.3 Synthetic blood

A synthetic liquid equivalent to blood surface tension and viscosity for testing.

3.4 Protective clothing's critical area

The front lapel, left- and right-arms, and back position of the protective clothing.

3.5 Electrostatic decay

The ability of a material to remove the charge induced to the surface of the material when grounded.

3.6 Decay time

The time required for the induced charge to decay to 10% of the initial level, in seconds.

The fracture strength of the protective clothing's critical area shall be no less than 45N.

4.6 Elongation at break

The elongation at break of the protective clothing's critical area shall be no less than 15%.

4.7 Filtering efficiency

The filtering efficiency of non-oily particles at the material and joints of the protective clothing's critical area shall be no less than 70%.

4.8 Flame retardant properties

Protective clothing with flame retardant properties shall meet the following requirements:

a) The damage length is no more than 200mm;

b) The after-flame time does not exceed 15s;

c) The after-glow time does not exceed 10s.

4.9 Antistatic

The charge of protective clothing shall be no greater than 0.6μC/piece.

4.10 Electrostatic decay performance

The electrostatic decay time of the protective clothing material shall not exceed 0.5s.

4.11 Skin irritation

The primary irritation score shall not exceed 1.

4.12 Microbial indicators

4.12.1 Protective clothing shall meet the requirements of microbial indicators in GB 15979-2002, see Table 4.

4.12.2 The protective clothing marked "sterilized" or "sterile" on the packaging or with such pictorial markings shall be sterile.

requirements of 4.4.2.

5.4.3 Anti-penetration of synthetic blood

The protective clothing materials shall be tested in accordance with Appendix A, and the results shall meet the requirements of 4.4.3.

5.4.4 Surface moisture resistance

The outer surface of the protective clothing material shall be carried out spray test in accordance with the provisions of GB/T 4745-1997, and the results shall meet the requirements of 4.4.4.

5.5 Fracture strength

The material of the protective clothing's critical area shall be tested in accordance with the strip method stipulated in GB/T 3923.1-1997, and the results shall meet the requirements of 4.5.

5.6 Elongation at break

The material of the protective clothing's critical area shall be tested in accordance with the strip method stipulated in GB/T 3923.1-1997, and the results shall meet the requirements of 4.6.

5.7 Filtering efficiency

Test at least three protective clothing samples, the results shall meet the requirements of 4.7.

Sodium chloride aerosol or similar solid aerosol [count median diameter (CMD)[1)]: 0.075μm±0.020μm; geometric standard deviation of particle distribution: ≤1.86; concentration: ≤200 mg/m^3]] shall be used for testing in an environment with a relative humidity of 30%±10% and a temperature of 25°C±5°C. The air flow rate is set to 15L/min±2L/min; and the cross-sectional area through which the airflow passes is 100cm^2.

5.8 Flame retardant properties

The protective clothing materials shall be carried out combustion performance test in accordance with the vertical method specified in GB/T 5455-1997, and the results shall meet the requirements of 4.8.

5.9 Antistatic

[1)] corresponds to the mass median aerodynamic diameter (MMAD) of 0.24μm ± 0.06μm.

6 Marking, and Instructions for Use

6.1 Marking

6.1.1 The minimum packaging of protective clothing shall have the following clearly identifiable markings. If the packaging is transparent, the following markings shall also be seen through the packaging:

a) The name of the product;

b) The name and address of the manufacturer or supplier;

c) Product size specifications;

d) The implementation standard number;

e) Product registration number;

f) If it is a sterilized product, indicate the sterilization method;

g) "Single-use" or equivalent words;

h) The date of production;

i) The storage conditions and the period of validity;

j) "Read the instructions before use" or equivalent words.

6.1.2 The packaging of protective clothing shall have at least the following markings:

a) The name of the product;

b) The name and address of the manufacturer or supplier;

c) Product size specifications;

d) The implementation standard number;

e) Product registration number;

f) The number of packages;

g) "Single-use" or equivalent words;

h) If it is a sterilized product, indicate the sterilization method;

i) The date of production;

Appendix A

(Normative)

Test Method for Anti-Penetration of Synthetic Blood

A.1 Range

This test uses synthetic blood to determine the resistance of protective clothing to penetration of synthetic blood under different test pressures.

A.2 Method

The protective clothing material was tested with synthetic blood under continuously applied pressure. Visually examine whether the synthetic blood penetrates the material.

A.3 Instrument

The equipment required for the test is as follows:

a) Penetration test slot in Figure A.1, and the test instrument shown in Figure A.2; they should be made of stainless-steel;

b) The square metal blocking screen shall meet the following requirements:

- Opening rate> 50%;
- Bend under 14kPa ≤5mm;

c) A gas source that can provide the air pressure of 14kPa±1kPa;

d) Stopwatch with an accuracy of ±1s;

e) Analytical balance with an accuracy of ±0.01g;

f) A clamp capable of generating a torque of 13.5 N·m;

g) Surface tension meter.

A.4 Synthetic blood

A.4.1 Constituents

Prepare 1L of synthetic blood[1)] according to the formula in Appendix A of YY/T 0700-2008:

[1)] The synthetic blood may be added the 2-methyl-4-isothiazolin-3-one hydrochloride (MIT) (0.5g/L) to extend the shelf life of the solution.

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