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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB 19082-2023

Replacing GB 19082-2009

Disposable protective clothing for medical use

医用一次性防护服

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1 Scope

China's mandatory standard for single-use medical protective clothing - the full-body coverall worn by healthcare workers where there is a risk of contact with blood, body fluids or infectious aerosols, and the garment that in 2020 became the most produced medical device in the world. It specifies the requirements, the marking, the instructions for use, and the packaging, transport and storage of disposable medical protective clothing, and describes the corresponding test methods. The requirements are shaped by a single conflict that cannot be designed away: the garment has to stop liquid and microorganisms getting in, and the same properties that achieve that also stop heat and moisture getting out, so the wearer overheats. Everything in the standard is a position taken on that trade-off. On the barrier side: the liquid barrier performance, with the resistance to hydrostatic pressure and to penetration by synthetic blood, the resistance to penetration by blood-borne pathogens, the filtration efficiency of the material, and the integrity of the seams, which are the weakest part of any protective garment and where failures actually occur. On the wearer side: the moisture vapour transmission rate, which is what decides how long the garment can be worn, together with the tensile and tear strength, the flame retardance, the antistatic properties and the skin irritation and biological requirements. To those are added the sterility requirements where the garment is supplied sterile, and the marking and instructions, which have to tell the user the level of protection, the correct donning and, most important, the correct doffing - because a contaminated garment removed carelessly infects the person who wore it safely for a whole shift. Issued on 27 November 2023 and in force since 1 December 2025, it replaces GB 19082-2009.

This document specifies the requirements, markings, instructions for use, packaging, transportation and storage, etc. of disposable protective clothing for medical use, and describes the corresponding test methods. This document is applicable to disposable protective clothing for medical use (hereinafter referred to as the "protective clothing") worn by personnel in medical institutions when performing medical treatment, disease prevention and control, etc. in potential risk-exposure scenarios, such as. possible contact with infectious blood, body fluids, secretion and airborne particles, etc.

2 Normative References

The contents of the following documents constitute indispensable clauses of this document through the normative references in the text. In terms of references with a specified date, only versions with a specified date are applicable to this document. In terms of references without a specified date, the latest version (including all the modifications) is applicable to this document.

GB/T 3917.3 Textiles - Tear Properties of Fabrics - Part

3 Terms and Definitions

The following terms and definitions are applicable to this document.

3.1 particle filtration efficiency Under specified testing conditions, the percentage of airborne particles being filtered out by protective clothing materials.

3.2 synthetic blood A mixture of red dye, surfactant, thickener and distilled water.

3.3 water-vapor transmission rate Under the condition that both sides of the specimen maintain the specified temperature and humidity, the mass of water vapor vertically passing through the unit area of the specimen within the specified time.

4 Requirements

4.1 Basic Requirements The material and structural design of the protective clothing shall comply with the following requirements.

4.2 Dimensions The body length, sleeve length, chest circumference, cuffs and ankle cuffs of the protective clothing shall comply with the dimensions and tolerance requirements specified by the manufacturer.

4.1 a) and

4.1 b). At different positions of the zipper of each protective clothing, pull the zipper on and off to check whether it complies with the requirements of

4.1 c). Conduct appearance inspection, and if necessary, actually wear it to check whether it complies with the requirements of

5.3 Dimensions Select at least 3 PCS of the protective clothing. In accordance with the method specified by the manufacturer, measure the dimensions of each part. If they comply with the requirements of 4.2, the protective clothing shall be determined as qualified.

4.4 Material Liquid Barrier Function

4.4.1 Impermeability to water The hydrostatic pressure resistance level of the protective

clothing material and the seam shall not be lower than the requirements of Level 1 in Table 2.

4.4.2 Surface moisture resistance The spray rating on the outer side of the protective clothing material shall not be lower than the requirements of Level 3 in Table 3.

4.5 Material Resistance to Penetration by Infectious Agents

4.5.1 Resistance to penetration by phage The resistance to penetration by phage shall not be lower than the requirements of Level 1 in Table 4.

4.5.2 Particle filtration efficiency The filtration efficiency of the protective clothing material and the seam for non-oily particles shall not be less than 70%.

4.7 Flammability (if applicable) If the manufacturer expressly states that the protective clothing is not flammable, the material of the protective clothing shall not melt or drip, and the burning time after leaving the flame shall not exceed 5 s.

4.8 Antistatic Property The electric charge of the protective clothing shall not be greater than 0.6 C/PCS.

4.9 Biocompatibility It shall be free of biocompatibility hazards.

4.10 Microbiological Indicators

4.10.1 Sterile protective clothing shall be aseptic.

5.1 Test Conditions

5.2 Basic Requirements Select at least 3 PCS of the protective clothing and visually check whether they comply with the requirements of

5.4 Material Physical Properties

5.4.3 Resistance to puncture Select at least 2 PCS of the protective clothing and cut samples from non-seam parts. Cut 2 specimens from each PCS of the protective clothing and conduct the test in accordance with the method specified in GB/T 20655.Respectively take the arithmetic mean of the test results of the specimens on each PCS of the protective clothing. When all the means comply with the requirements of 4.3.3, the protective clothing shall be determined as qualified.

5.4.6 Flexural damage resistance Select at least 2 PCS of the protective clothing and cut samples from non-seam parts. For each PCS of the protective clothing, respectively cut 2 specimens in the longitudinal direction and transverse direction, and each specimen shall contain all layers. In accordance with the method in Appendix K of GB 24539-2021, carry out the test, and select the specified hydrostatic pressure method to determine the end point. Respectively take the arithmetic mean of the hydrostatic pressure values of the