

Medical Device Product Technical Requirements No:

Disposable Isolation Gown

1. Product model / specification and its division description

1.1 Product name: disposable isolation gown

1.2 Product models are divided into: Sewing type conjoined、 Sewing split type、 Sewing reverse wear type、 Thermal conjoined type、 Thermal split type、 Thermal reverse wear type.

1.3 Product specifications are divided into: S (small), M (medium), L (large), XL (plus), XXL (plus), XXXL (three plus).

1.4 According to the medical device management classification, it belongs to Class I 14-14-03, non-sterile, single use.

1.5 Basic structure of disposable medical isolation gown: It is made of nonwoven cloth material, the cuff is elastic, the back is fully opened by tight cloth belt, and the cloth belt is heated or sewn with non-woven cloth. Split type for the jacket with pants, the jacket can be long sleeve closed or short sleeve mouth structure. The conjoined type is zipper structure for the upper body.

1.6 Product classification

The non-woven fabric for medical disposable isolation gown is classified as grade I, gradeII, grade III and gradeIV according to its internal quality requirements, and its protective performance is improved step by step.

Note: Grade I-generally used for visitation, cleaning, etc.

Grade II—Generally used for routine care and examination.

Grade III—Generally people wear in a certain amount of bleeding, fluid secretions occasions

Grade IV—Generally people wear when clean medical waste or face large amounts of patients' blood and body fluid for a long time.

2、 Performance index

2.1 Dimensional requirement

It shall meet the requirements of Table 1.

Table 1

Unit : cm

Model Size		Sewing reverse wear type, Thermal reverse wear type					
		S (small)	M (medium)	L (large)	XL (large plus)	XXL(large 2 plus)	XXXL(large 3 plus)
length×width		110 ~ 119×110 ~120	120 ~ 130×120 ~ 130	120 ~ 130×131 ~ 144	120 ~ 130×145 ~ 149	120 ~ 130×150 ~ 159	120~ 140×160~170
shoulder breadth		55	55	56	56	57	58
outside sleeve		54	56	56	58	58	60
deviation		±3cm	±3cm	±3cm	±3cm	±3cm	±3cm
Model Size		Sewing split type, Thermal split type					
		S (small)	M (medium)	L (large)	XL (large plus)	XXL(large 2 plus)	XXXL(large 3 plus)
j	length×width	70~79×11	80~89×120 ~	85~95×120~	90~100×120	95~105×12	105~110×120
	h	0~119	129	130	~130	0~130	~140
a	shoulder breadth	55	55	56	56	57	58
	outside sleeve	50	50	55	55	60	60
t	length×width	±3cm	±3cm	±3cm	±3cm	±3cm	±3cm
	h	±3cm	±3cm	±3cm	±3cm	±3cm	±3cm
p	length×width	110×15	115×150	120×150	120×155	125×155	125×160
	h	0					
a	deviation	±3cm	±3cm	±3cm	±3cm	±3cm	±3cm

n							
ts							
Model	Sewing type conjoined、Thermal type conjoined						
Size	S (small)	M (medium)	L (large)	XL (large plus)	XXL(large 2 plus)	XXXL(large 3 plus)	
length×width	165×120	169×125	173×130	178×135	181×140	187× 145	
shoulder breadth	58	60	62	64	66	68	
outside sleeve	84	86	90	93	96	99	
deviation	±5cm	±5cm	±5cm	±5cm	±5cm	±5cm	±5cm

2.2 Appearance Requirements

2.2.1 The cloth surface of the isolation clothing is uniform and smooth, without micro-holes and crystal points, no obvious creases, broken edges, holes, oil stains, and neatly packed.

2.2.2 The hot closing or sewing mouth is uniform and straight, and the sewing shall not be less than 2 stitches per centimeter.

2.2.3 No raw edges, leaky seams, cracking and other phenomena are allowed in the hot closing or sewing place.

2.3 Structural Requirements

2.3.1 The structure of the isolation clothing should be reasonable, easy to put on and take off, and the structure of the binding part should be consistent.

2.3.2 Cuff adopts elastic closing and tight combination.

2.4 Material characterization requirements

The requirements for physical properties of non-woven materials are shown in Table 2

Table 2

Product classification	Grade I	Grade II	Grade III	Grade IV
Square meter mass deviation rate (%)	±6			
Breaking strength(N)	≥20	≥20	≥30	≥45

Spray impact water seepage (g)	≤4.5	≤1.0	≤1.0	Not require
Hydrostatic pressure (kPa)	Not require	≥1.8 (18cmH ₂ O)	≥4.4 (45cmH ₂ O)	≥9.8 (100cmH ₂ O)
Microbial penetration resistance	Not require	Not require	Not require	Pass ^a
Resistance to synthetic blood penetration grade	Not require	Not require	Not require	≥4
Bursting strength (kPa)	≥40			
Moisture permeability g/(m ² · 24h)	≥3600			
Antistatic property (surface resistivity) Ω	Not require	≤1X10 ¹²		
Whether the results of microbial penetration resistance are qualified shall be judged according to YY/T 0689-2008.。				

2.5 Microorganisms

The microbiological indicators of the product shall comply with the provisions of Table 3

Table 3

Project	requirement
Total number of bacterial colonies CFU/g	≤150
Total number of fungal colonies CFU/g	≤80
Coliform bacteria	non-detectable
Bacillus pseudomonas aeruginosa	non-detectable
Staphylococcus aureus	non-detectable
Streptococcus hemolyticus	non-detectable

3. Test method

3.1 Size Requirements

Test method: Use a general measuring tool or a special measuring tool to measure, the results should meet the requirements of 2.1.

3.2 Appearance Requirements

Test method: visual, hand feel, the results should meet the requirements of Article 2.2.

3.3 Structural Requirements

Test method: visual, hand feel, the results should meet the requirements of Article 2.3.

3.4 Material characterization requirements

Test method:

3.4.1 The measurement of mass per unit area shall be carried out in accordance with GB/T24218.1. The mass deviation rate per unit area is calculated according to formula (1), and the calculation result is reserved for one decimal place.

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

Formula:

G - mass deviation rate per unit area;

m₁ - Measured value of mass per unit area in grams per square meter (g/m²)

m₀ - nominal mass value per unit area, in grams per square meter (g/m²)

3.4.2 The determination of breaking strength shall comply with the requirements of Table 2 in accordance with the test specified in GB/T 24218.3.

3.4.3 The measurement of spray impact water seepage shall be conducted in accordance with the test stipulated in GB/T 24218.17, and the minimum value as the test result shall meet the requirements of Table 2.

3.4.4 Determination of hydrostatic pressure According to GB/T 24218.16, the water pressure rise rate is (1±0.05) kPa [(10±0.5) cmH₂O/min], and the minimum value is taken as the test result. The requirements in Table 2 shall be met.

Note: When more than two drops of water appear in one position during the test, but it does not affect the judgment of water droplets in other parts, the pressure can continue until the end of the test.

3.4.5 The determination of microbial penetration resistance shall be carried out according to YY/T 0689-2008 program A or Program B, and the minimum value shall be taken as the test result. The requirements in Table 2 shall be met.

3.4.6 The anti-synthetic blood penetration level shall be determined in accordance with Appendix A of GB 19082-2009, with the minimum value as the test result. The requirements in Table 2 shall be met.

3.4.7 The bursting strength shall be measured according to GB/T 7742.1, the experimental area shall be 7.3cm², and the experimental results shall comply with the requirements of Table 2.

3.4.8 The measurement of moisture permeability shall be carried out in accordance with conditions a) in GB/T 12704.1-2009, and the experimental results shall meet the requirements of Table 2.

3.4.9 The measurement of antistatic property (surface resistivity) shall be carried out in accordance with GB/T 12703.4, and the experimental results shall meet the requirements of Table 2.

3.5 Microorganisms

Test method: The determination of microorganisms shall be tested in accordance with the provisions of Appendix B of GB 15979-2002 and shall comply with the provisions of Table 3.