

# Disposable Medical Protective Coverall

## 1 Product model / specification and its division description

1.1 Medical disposable protective clothing is made of breathable membrane non-woven fabric material. According to its shape can be divided into: connected (sterile), connected (non-sterile), split (sterile), split (non-sterile), connected with foot (sterile), connected with foot (non-sterile), split with foot (sterile), split with foot (non-sterile);

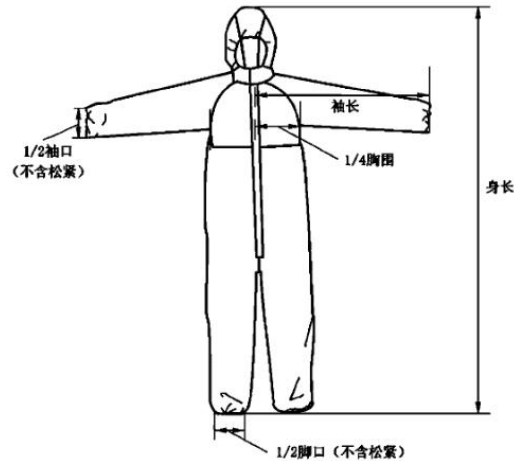


Figure 1 Drawing of the connected structure protective coverall

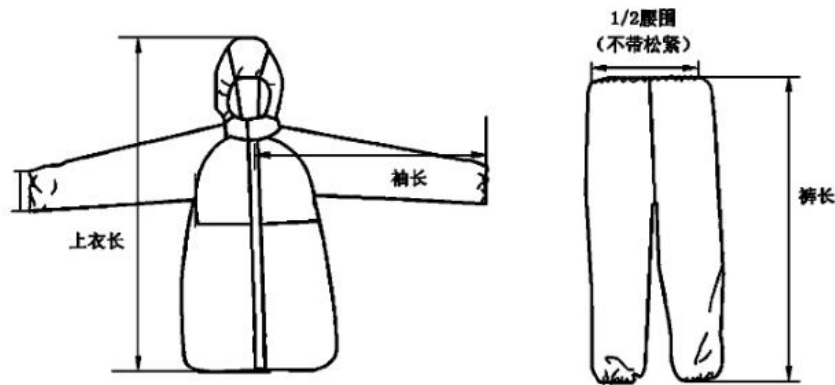


Figure 2 Split structure protective coverall

1.2 The types of protective clothing are divided into S / 160, M / 165, L / 170, XL / 175, XXL / 180, XXXL / 185, XXXXL / 190. The specifications are shown in Table 1 and Table 2.

## 2 Requirement

### 2.1 Appearance

2.1.1 Protective clothing should be dry, clean and free of mildew, with

no adhesion, cracks, holes and other defects.

2.1.2 The connecting parts of protective clothing can be processed by sewing, bonding or heating. The eye of the needle seam should be sealed, and the distance should be 8 ~14 needles per 3cm. The trace should be uniform and straight without jumping needle. The bonded or hot processing parts should be flat and sealed without bubbles.

## 2.2 Structure

2.2.1 The structure of protective clothing should be reasonable, convenient to wear and take off, and strict binding parts.

2.2.2 Cuff and ankle mouth use elastic closing, hat face closing and waist use elastic closing, pull rope closing or buckle.

## 2.3 Type specification

The types of protective clothing are 160, 165, 170, 175, 180, 185 and 190. See shown in Table 1 and Table 2.

**Table 1 Connecting body type specification**

**Unit is cm**

Mark	Size	Height	Chest	Outside sleeve	Cuff	Foot mouth	Foot length
S	160	165	120	84	18	24	36
M	165	169	125	86	18	24	36
L	170	173	130	90	18	24	36
XL	175	178	135	93	18	24	38
XXL	180	181	140	96	18	24	39
XXXL	185	188	145	99	18	24	39
XXXXL	190	192	150	101	18	24	40
	<b>Deviation</b>	±13	±7	±9	±5	±5	±3

**Table 2 Split body type specification**

Unit is cm

Mark	Size	Top length	Chest	outside length	Waistline	Foot length
S	160	76	120	105	100~105	36
M	165	78	125	108		36
L	170	80	130	111		36
XL	175	82	135	114	115~120	38
XXL	180	84	140	117	120~125	39
XXXL	185	86	145	120	125~130	39
XXXXL	190	88	150	123	130~135	40
	<b>Deviation</b>	±5	±5	±5	±5	

## 2.4 Liquid barrier function

### 2.4.1 Impermeability resistance

The hydrostatic pressure of the key parts of the protective clothing shall not be less than 1.67 kPa (17cmH<sub>2</sub>O).

### 2.4.2 The moisture

The moisture permeability of the protective clothing material shall not be less than 2500g / (m<sup>2</sup> d).

### 2.4.3 Resistance to synthetic blood penetration

The penetration of protective clothing against synthetic blood should not be lower than the requirements of Grade 2 in Table 3.

**Table 3 Penetrating grade of antisynthetic blood**

Class	Pressure strength value/kPa
6	20
5	14
4	7

3	3.5
2	1.75
1	0 <sup>a</sup>
It means that the pressure on the material is only the pressure generated by the synthetic blood in the test tank.	

#### 2.4.4 Surface humidity resistance

The water dip level of the outer side of the protective clothing should not be lower than the requirement of level 3.

#### 2.5 Breaking strength

The fracture strength of materials in key parts of protective clothing shall not be less than 45N.

#### 2.6 Filter efficiency

The filtration efficiency of non-oil particles at the key material and joints of protective clothing shall not be less than 70%.

#### 2.7 Anti-static property

The charge quantity of the protective clothing shall not be greater than 0.6  $\mu$  C / piece.

#### 2.8 Microbial indicators

2.8.1 The protective clothing marked as "sterilized" or "sterile" or shown on the package shall be sterile.

2.8.2 The protective clothing marked for non-sterile supply on the package shall meet the requirements of the below table, as shown in Table 4.

**Table 4 Microbial index of protective clothing**

Total number of bacterial colonies CFU/g	Coli group	Pseudomonas aeruginosa	auratus staphylococcus	haemolytic us streptococcus	Total number of fungal colonies CFU/g
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$\leq 200$	Do not check out	Do not check out	Do not check out	Do not check out	$\leq 100$
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## 2.9 Ethylene oxide residue amount

The ethylene oxide residue of the ethylene oxide shall not exceed 10  $\mu\text{g} / \text{g}$ .

## 3 Method of calibration

### 3.1 Extrinsic feature

3.1.1 Visual inspection, the result shall comply with the requirements of 2.1.1.

3.1.2 Visual inspection, the needle distance is measured using a general measuring tool, and the result shall comply with the requirements of 2.1.2.

### 3.2 Structure

Visual inspection shall comply with the requirements of 2.2.

### 3.3 Type specification

Measure 3 samples of protective clothing with general measuring gauge, and their specifications shall meet the requirements of 2.3.

### 3.4 Liquid barrier function

#### 3.4.1 Impermeability resistance

Sample from key parts of protective clothing and conduct hydrostatic test according to GB / T 4744-2013; the result shall comply with the requirements of 2.4.1.

#### 3.4.2 The moisture

The protective clothing material shall be tested in accordance with the method A specified in GB / T 12704.1-2009, and the result shall comply with the requirements of 2.4.2.

#### 3.4.3 Resistance to synthetic blood penetration

The protective clothing materials shall be tested in accordance with Annex A of

GB 19082-2009, and the result shall comply with the requirements of 2.4.3.

#### **3.4.4 Surface humidity resistance**

The outer side of the protective clothing materials shall be conducted according to the water dip test specified in GB / T 4745-2013, and the result shall comply with the requirements of 2.4.4.

#### **3.5 Breaking strength**

The materials of key parts of protective clothing shall be tested according to the sample method specified in GB / T 3923.1-2013, and the result shall comply with the requirements of 2.5.

#### **3.6 filter efficiency**

Take 3 samples and test according to the method specified in 5.7 of GB 19802-2009. The result shall comply with the requirements of 2.6.

#### **3.7 Anti-static property**

Conduct the test according to the method specified in 7.2 of GB / T 12703.3-2009, and the result shall comply with the requirements of 2.7.

#### **3.8 Microbial indicators**

3.8.1 Conduct the sterile test according to the method specified in Chapter 3 of GB / T 14233.2-2005, and the result shall comply with the requirements of 2.8.1.

3.8.2 Conduct the test according to the method specified in Annex B of GB 15979-2002, and the result shall comply with the requirements of 2.8.2.

#### **3.9 Ethylene oxide residue amount**

Conduct the test according to the gas chromatography method specified in GB / T 14233.1-2008. The gas phase spectrum of the limit extraction specified in Chapter 9 shall be sent as the arbitration method, and the result shall comply with the requirements of 2.12.

