

# Medical Device Product Technical Requirements No: :

## Disposable Sterile Medical Rubber Examination Gloves

### 1.Product model / specification and its division description

1.1 Model: powder / hemp flour, powder / smooth, no powder / smooth, no powder / smooth.

1.2 Specifications: below 6 and 6 (special small), 6.5 (small), 7 and 7.5 (medium), 8 and 8.5 (large) And above 9 (overlarge number).

Model types are divided according to product surface form: specifications are divided according to product size code.

### 2 Performance index

#### 2.1 Dimensional requirement

2.1.1 The width, length and single layer thickness of gloves shall comply with the provisions in Table 1.

Table 1: Unit: mm

SPEC (Size)	Nominal specification (nominal size)	Width	minimum length	minimum thickness	maximum thickness
6 and 6 below	Special trumpet (XS)	$\leq 80$	220	For all sizes: Mill finish: 0.08 Pitting surface: 0.11	For all sizes: Mill finish: 2.00 Pitting surface: 2.03
6.5	Small size (S)	$80 \pm 5$	220		
7	Medium (M)	$85 \pm 5$	230		
7.5	Medium (M)	$95 \pm 5$	230		
8	Large size (L)	$100 \pm 5$	230		
8.5	Large size (L)	$110 \pm 5$	230		
9 and 9 above	Outsize (XL)	$\geq 110$	230		

Note: Cucuff ends can be cut or rolled

2.1.2 The thickness of the glove cuff edge shall not exceed 2.50mm.

#### 2.2 Water impermeability

The loves should be free from any obvious leakage

#### 2.3 Tensile property

The pulling force and elongation of gloves before and after aging shall comply with the provisions in Table 2 below

Performance	Requirement
Minimum / N of breaking force before aging	7

Minimum /% of breaking elongation before aging	650
Minimum / N of the breaking force after aging	6
Pull the minimum /% of elongation after aging	500

#### 2.4 Sterile

The gloves shall be sterile after the confirmed sterilization process.

#### 2.5 Ethylene oxide residue amount

The gloves shall be sterilized by ethylene oxide, and the ethylene oxide residue shall be less than 10 ug / g before delivery.

### 3. Inspection method

#### 3.1 Dimension requirement

Test method: Measure according to GB10213-2006, and gloves shall meet the requirements in Table 1

#### 3.2 Water impermeability

Test method: Make the test according to the method specified in Annex A of GB10213-2006, and the result shall meet the provisions of Article 2.2.

#### 3.3 Tensile property

Test method: determine the method specified in GB10213-2006, and the result shall comply with the provisions of Article 2.3

#### 3.4 Sterile

Test method: Product type test shall be conducted according to the method specified in GB / T 14233.2-2005 《Test Method for Medical Infusion, Blood Transfusion and Injection-Part 2: Biological Test Method》, and the glove sterilization process shall be routinely controlled according to GB18279-2000 《Confirmation and Routine Control of Ethylene Oxide for Medical Devices》, and the result shall comply with the provisions of Article 2.4.

#### 3.5 Ethylene oxide residue amount

Test method: Conduct the test according to the method specified in Chapter 9 of GB / T 14233.1-2008 Test Methods for Medical Infusion, Transfusion, Ininge, Part 1: Chemical Analysis Method, and the result shall comply with the provisions of Article 2.5.