

**Medical Device Product Technical Requirements No: :****Medical examination gloves****1. Product model/specification and division description**

1.1 Model: powder / smooth, 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), above 9 and 9 (large).

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

**1. 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

Specifications (size code)	Nominal specification (nominal size)	Width	Minimum length	Minimum thickness	Maximum thickness
6 and 6 below	(XS)	≤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	(S)	80±5	220		
7	(M)	85±5	230		
7.5	(M)	95±5	230		
8	(L)	100±5	230		
8.5	(L)	110±5	230		
More than 9 and 9	(XL)	≥110	230		

NOTE: Cuff ends may be sheared or rolled.

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

**2.2 Impermeability**

Gloves should be free of any visible leakage.

**2.3 Tensile properties**

The tearing force and elongation at break of gloves before and after aging shall meet the requirements in Table 2 below.

Table 2

Performance	requirement
Minimum value of breaking force before aging/N	7.0
Minimum elongation at break before aging/%	650
Minimum value of breaking force after aging/N	6.0
Minimum elongation at break after aging/%	500

2.4 Microbiological indicators to meet the requirements of Table 3 below

Table 3

Total number of bacterial colonies CFU/g	total fungal colonies CFU/g
$\leq 200$	$\leq 100$

### 3. Inspection method

#### 3.1 Size requirements

Test method: Test according to the method of GB10213-2006, and the gloves should meet the requirements in Table 1.

#### 3.2 Impermeability

Test method: Measure according to the method in Appendix A of GB10213-2006, and the result should meet the requirements of Article 2.2.

#### 3.3 Tensile properties

Test method: measure according to the method specified in GB10213-2006, and the result should meet the requirements of Article 2.3.

#### 3.4 Microbial indicators

Test method: Carry out the test according to the method specified in Appendix B of GB 15979-2002, and the result should meet the requirements of 2.4.

