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
≤200	≤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.