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)	≤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±5	220		
7	Medium（M）	85±5	230		
7.5	Medium（M）	95±5	230		
8	Large size（L）	100±5	230		
8.5	Large size（L）	110±5	230		
9 and 9 above	Outsize（XL）	≥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 Dimention 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.