Medical Device Product Technical Requirements No：

Rubber Surgical Gloves

1.Product model / specification and its division description

1.1Model: hemp surface, smooth surface; powder / surface, no powder / surface; sterilized and not sterilized.

1.2 Specification: 5、5.5、6、6.5、7、7.5、8、8.5、9、9.5。

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

1.3 Design

There are two types of design: straight gloves, gloves with fingers bent to the palm

The glove fits the physiological structure, where the thumb is located in front of the surface of the hand where the index finger is located rather than in the same plane. The thumb and other fingers can be straight or curved to the palm.

1.4 Surface type: the surface type of gloves is divided according to the finish of the used surface of gloves and whether there is powder in the production and processing process. The surface type is divided into the following four types:

a)pitting surface

b)mill finish

c)powder surface

d)Powder-free surface

Note: Cucuff ends can be cut or rolled

2.Performance index

2.1Dimensional 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

Specification （Size）	Width	minimum length	minimum thickness
5	67±4	250	For all sizes： mill finish ： 0.10 pitting surface： 0.13
5.5	74±4	250	
6	77±4	260	
6.5	83±4	260	
7	89±4	270	
7.5	95±4	270	
8	102±4	270	
8.5	108±4	280	
9	114±4	280	
9.5	121±4	280	

2.2 Water impermeability
Gloves should be free of leakage
2.3 Tensile property
The pulling force, pulling elongation rate and 300% fixed extension load of gloves before and after aging shall comply with the provisions of Table 2 below.

Table 2

Performance	Requirement
Minimum / N of breaking force before aging	12.5
Minimum /% of breaking elongation before aging	700
300% maximum load maximum / N before aging	2
Minimum / N of the breaking force after aging	9.5
Pull the minimum /% of elongation after aging	550

2.4 Endotoxin content

It shall comply with the requirements of Article 4.3 in YY / T0616.1-2016

2.5 Sterile

The gloves shall be sterile after the confirmed sterilization process.

2.6 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 Dimensional requirement

Test method: Make the test according to GB7543-2006 Single Use Sterilone Rubber surgical gloves, and the gloves shall comply with the provisions of Table 1

3.2 Water impermeability

Test method: Make the method according to Annex A of GB7543-2006 Disposable Sterilized Rubber Surgical Gloves, and the result shall comply with the provisions of Article 2.2

3.3 Tensile property

Experimental method:

Pull force and pull elongation before aging: According to the test method specified in ISO37-2011, the determination of the results shall comply with the provisions of Table 2 of Article 2.3.

Pull force and breaking elongation after aging: According to the test method specified in ISO188-2011 Sulcanized Rubber or thermoplastic Rubber Hot air accelerated aging and Heat resistance test, the test piece cut from the gloves is aged at 70℃± 2℃ and 168h ± 2h on the tensile test machine. The pull force and breaking elongation of the gloves after aging shall comply with the provisions of Table 2 of Article 2.3.

300 Fixed extension load: according to the test method specified in IS 037-2011 《Determination of tensile stress and strain properties of vulcanized rubber or thermoplastic rubber》, the type 2 dumbbell test piece shall comply with the provisions of Table 2 of Article 2.3.

3.4 Endotoxin

Test method: Conduct the test according to Article 5.1 of YY / T0606-2016, and the endotoxin content shall meet the provisions of Article 2.4.

3.5 Sterile

Test method: The product type test shall be conducted according to the method specified in GB / T 14233.2-2005《Test Methods for Medical Infusion, Transfusion, and Injection, Part 2: Biological Test Method》,and《the glove sterilization process shall be routinely controlled》 according to GB18279-2000 Ethylene oxide of Medical Devices, and the result shall comply with Article 2.5

3.6Ethylene 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 and Ininge-Part 1: Chemical Analysis Method》, and the result shall comply with the provisions of Article 2.6