

# Medical Protective Mask

## 1 Product model / specification and its division description

### 1.1 Model specification

Model: folding type (sterile type), folding type (non-sterile type) specification: L : 16cm x10cm, M : 16cm x9cm S: 4cm x9cm

Model: arch type (sterile type), arch type (non-sterile type) Specification: L: 14cm x11cm, M: 13cm x13cm, S: 13cm x12cm

### 1.2 Product size

Table 1: Specifications and Dimensions

Model specification	Size cm			
	Size	L	W	Deviation
Folding type	L	16	10	Not to be less than 90% of the indicated dimensions
	M	16	9	
	S	14	9	
Arch type	L	14	11	
	M	13	13	
	S	13	12	

## 2 Performance index

### 2.1 Basic Requirements

The mask should be able to cover the wearer's mouth and nose, and should have good facial tightness. The appearance of the mask should be clean and intact in shape, and the surface should not be damaged, stained or without air breathing valve.

### 2.2 Nose clip

The mask is equipped with a nose clip, which is adjustable.

### 2.3 Mask belt

2.3.1 The mask belt is easy to adjust

2.3.2 The fracture strength at the connection between the mask belt and the mask body should not be less than 10N

### 2.4 Particle filtration efficiency

At the gas flow rate of 85 L/min, the particle filtration efficiency should be 95%

### 2.5 Gas-flow resistance

With a gas flow rate of 85 L/min, the inspiratory resistance of the mask should not be greater than 343.2Pa (35mm H<sub>2</sub>O).

### 2.6 Synthetic blood penetration

2ml of synthetic blood is sprayed to the outside of the mask sample at 10.7kPa (80mmHg) pressure, and there should be no infiltration on the inner side of the mouth volume.

### 2.7 Surface humidity resistance

The water dip level of the outer surface of the mask should not be lower than the 2.8 microbial index specified in Grade 3 of GB / T 4745-2012 The non-sterile mouth with general grade shall meet the requirements of Table 2

Species of microorganisms	Standard requirements
Total number of fungal colonies (CFU/g)	≤100
Total number of bacterial colonies (CFU/g)	≤200
Standard requirements for coliform, Pseudomonas aeruginosa, Staphylococcus aureus, Streptococcus	Do not check out

### 2.9 Adaptation

The total fitness factor of masks should not be less than 100.

### 2.10 Sterile

Sterile mask marked with sterilization grade shall be sterile

### 2.11 Acetane epoxy residue

If ethylene oxide sterilization is used, the ethylene oxide residue is not greater than 10 ug / g

## 3 Inspection method

### 3.1 Basic requirements and dimensions

Conduct the test according to the method of 5.1 in GB19083-2010. The visual inspection shall comply with the requirements of 2.1 For general or special measuring tool, it shall comply with the requirements of 2.1

### 3.2 Nose clip

Conduct the daily inspection according to the method of 5.2 in GB19083-2010, and actually wear it, which shall comply with the requirements of 2.2

### 3.3 Mask belt inspection

Tensile according to the speed of 5.3 in GB 19083-2010, and the fracture force shall meet the requirements of 2.3 and 3.4 filtration efficiency

Conduct the test according to the method of 5.4 in GB 19083-2010, and it shall meet the requirements of 3.5 gas resistance of 2.4

Conduct the test according to the method of 5.4 in GB19083-2010 and it shall comply with the requirements of 3.6 of 2.5

Conduct the test according to the method of 5.5 in GB19083-2010; it shall comply with the requirements of 2.6

### 3.7 Surface humidity resistance

Conduct the test according to the specified method of GB / T4745-2012, and it shall comply with the requirements of 2.7

### 3.8 Microbial indicators

Conduct the test according to the method specified in Annex B of GB15979-2002, and it shall comply with the requirements of 2.8.

### 3.9 Adaptation

Conduct the test according to the method of 511 in GB19083-2010. It shall meet the requirements of 2.9 3.10 sterile

The sterile test according to the method specified in Chapter 2 of GB/T14233.2-2005 shall comply with the requirements of 2.10

3.11 Acetane epoxy residue

Conduct the test according to the method of 5.8 in GB19083-2010, and it shall comply with the requirements of 2.11