Medical Device Product Technical Requirements No:

Disposable Medical Mask

1.Product model / specification and its division description

1.1Product model: tie type：100×180（Unit mm）、Ear hanging type：75×125、90×145、95×145、100×180（Unit mm）

1.2 Classification by medical device management: classification code is 14-13, and management category is category II

1.3 Classification by supply status: sterile supply, non-sterile supply.

1.4 According to its wear of the crowd and can be divided into: adult type and child type

2. Performance index

Dimensional requirement

It shall meet the requirements of Table 1.

Table 1 Unit ：mm

	Model / specification	L/W allowance±	Belt length	Pine tight belt length allowance±
Child Type	Ear hanging type 75×125	5	140	5
	Ear hanging type 90×145	5	145	5
	Ear hanging type 95×145	5	150	5
Adult type	Ear hanging type 100×180	5	900	5
	Ear hanging type 100×180	5	160	5

2.2 Appearance requirements

The appearance of the mask should be clean and intact in shape, and there should be no damage or stains on the surface.

2.3 Nose clip

2.3.1The mask must be equipped with a nose clip, which shall be made of flexible

plastic material. 2.3.2 shall not be no less than 8.0cm.

2.4 Mask belt

The breaking strength of each mask band between the connection point and the mask body is not less than 10N.

2.5 Bacterial filtration efficiency

The bacterial filtration efficiency of the mask should not be less than 95%

2.6 Air resistance

The ventilatory resistance for gas exchange on both sides of the mask should not be greater than 49Pa / C ㎡

2.7 Microbial indicators

2.7.1 The microbial indicators of non-sterile supplied masks shall conform to the requirements of table 2 below

Table 2 Microbial indicators

Species of microorganisms	Standard requirements
Total number of bacterial colonies (CFU / g)	S100
Escherichia coli, Pseudomonas aeruginosa, Staphylococcus aureus, Streptococcus hemoltica, fungus	Do not check out

2.7.2 The mask supplied aseptically shall undergo an effective sterilization process to ensure that the product is sterile.

2.8 Ethylene oxide residue amount

Ethylene oxide residue should not exceed 10 ug / g

3 Empirical method

3.1 Dimensional requirement

Experimental method: 3 products are randomly selected and measured with general measuring tools or special measuring tools, which shall comply with the provisions of Table 1

3.2 Appearance requirements Experimental method: randomly select 3 products, and the visual inspection should comply with the provisions of Article 2.2.

3.3 Nose clip

3.3.1 Experimental method: randomly select 3 products, visual inspection, and the actual wear should comply with article 2.3.1.

3.3.2 Experimental method: 3 products are randomly selected, and the general or special measuring tools shall comply with the provisions of Article 2.3.2.

3.4 Mask belt

Experimental method: randomly selected 3 products, measuring with 10N static tension or measuring with tension meter shall comply with article 2.4.

3.5 Bacterial filtration and filtration

Experimental method: 3 products are randomly selected, and the bacterial filtration efficiency test in YY 0469 should comply with Article 2.5.

3.6 Air resistance

Experimental method: 3 products are randomly selected, and the test according to the

method of Article 5.6 of YY / T 0969 shall comply with the provisions of Article 2.6.

3.7 Microbial indicators

3.7.1Empirical method :Conduct the test according to the method specified in Annex B of GB15979-2002 and shall comply with the provisions of 2.7.1.

3.7.2 Experimental method: The test according to the sterile test method specified in GB/T14233.2-2005 Chapter 3 shall comply with the provisions of Article 2.7.2

3.8 Ethylene oxide residue amount

Experimental method: the test according to the method specified in Part 1 of GB/T14233.1-2008 shall comply with Article 2.8.