Disposable Surgical Mask

1：Product model/specification and division description

According to the shape of the product, wearing mode and whether sterilization or not, models are: flat and ear hanging type(sterile), flat and branding type (sterile), flat and ear hanging type(non-sterile), flat and branding type(non-sterile)

Specification and size: 175mm 95mm, tolerance ± 5%

2 Performance requirement

2.1 Extrinsic feature

The appearance of the mask should be clean and intact in shape, and there should be no damage or stains on the surface.2.2 Structure and dimensions

When the mask is worn, it should cover the wearer's nose and mouth to the chin. It shall comply with the design size and tolerance of the mark

2.3 Nose clip

2.3.1 The mask should be equipped with a nose clip, made of polypropylene material.

2.3.2 The length of nose clip shall not be no less than 8.0cm.

2.4 Mask belt

2.4.1 The mouth belt should be easily conveniently

2.4.2 The fracture strength at the connection between the mask belt and the mask body should not be less than 10N.2.5 Synthetic blood penetration After 2ml of synthetic blood is sprayed on the outer side of the mask sample at 16.0kPa (120mmHg) pressure, no penetration into the inner side of the mask.

2.5 Synthetic blood penetration

After 2ml of synthetic blood is sprayed on the outer side with 16.0kPa (120mmHg) pressure of the mask sample, there should be no infiltration of the inner side of the mask.

2.6 Bacterial filtration efficiency

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

2.7 Particle filtration efficiency

The filtration efficiency of masks for non-oily particles should not be less than 30%

2.8 Pressure difference (Δp)

The pressure difference (Δ p) for gas exchange on the two sides of the mouth shall not be greater than 49Pa

2.9 Flame resistance

Mask materials should be non-flammable materials. The combustion should not be greater than 5s after the mask is removed from the flame.

2.10 Ethylene oxide residue amount

The ethylene oxide residue should not exceed 10 ug / g

2.11 Microbial indicators

2.11.1 Non-sterile masks should meet the requirements of Table 1

2.11.2 Masks marked with the words "sterilized" or "sterile" or shown on the package shall be sterile

Table 1：Microbial indicators

Total number of bacterial colonies CFU/g	Coli group	Pseudomonas aeruginosa	Auratus staphylococcus	Haemolyticus streptococcus	Fungus
≤100	Do not check out	Do not check out	Do not check out	Do not check out	Do not check out

3 Method of calibration

3.1 Extrinsic feature

The visual inspection shall comply with the provisions of Article 2.1

3.2 Dimension

Measure by general or special measuring tools, where the number of layers shall be cut open with scissors, and the visual inspection shall comply with the provisions of article 2.2

3.3 Nose clip

3.3.1 Three samples were taken for testing, visually inspected and actually worn. Should comply with the provisions of Article 2.3.1.

3.3.2 Three samples were taken for testing. For measurement with general or special measuring tool, it shall comply with the provisions of Article 2.3.2 3.4 Mask belt.

3.4.1 Take 3 samples for test, and check the adjustment condition through wearing, which shall comply with the provisions of Article 2.4.1

3.4.2 Take 3 samples for test and measure with the static tension of 10N for 5s. The result shall comply with the provisions of Article 2.4.2

3.5 Synthetic blood penetration examination

Conduct the test according to the method of 5.5 in YY0469-2011, which shall comply with the provisions of Article 2.5

3.6 Examination of the bacterial filtration efficiency

Conduct the test according to the method of 5.6.1 in YY0469-2011, and it shall comply with the provisions of Article 2.6.1

3.7 Check for the particle filtration efficiency

Conduct the test according to the method of 5.6.2 in YY0469-2011, and it shall comply with the provisions of Article 2.6.2

3.8 Pressure difference

Conduct the test according to the method of 5.7 in YY0469-2011, which shall comply with the provisions of Article 2.8

3.9 Flame resistance

Conduct the test according to the method of 5.8 in YY0469-2011, which shall comply with the provisions of Article 2.9

3.10 Ethylene oxide residue amount

Conduct the test according to the gas chromatography method specified in GB / T 14233.1-2008, and it shall comply with the provisions of Article 2.10

3.11 Microbial indicators

According to the status of the sample:

3.11.1 Conduct the test according to the method specified in Annex B of GB15979-2002, and it shall comply with the provisions of 2.11.1.

3.11.2 The sterile test in accordance with the method specified in Chapter 2 of GB/T14233.2-2005 shall comply with the provisions of 2.11.2

4. Onomastion

None