

Medical Device Product Technical Requirements No.:

Medical Isolation Face Shield

1. Product model / specification and its division description

1.1 Description of the product model division

Medical isolation mask (hereinafter referred to as: products), used in medical institutions for examination and treatment, to block body fluids, blood splashing or splashing.

According to the management classification of the medical device, it belongs to Class I 14-14-06 Medical personnel protective equipment-isolation cover, and the product structure is composed of protective cover, foam strip and fixing device made of polymer material. Non-sterile provided, single use.

1.2 Product specifications and models: The types of products and components are divided into three models: large, medium and small size, which shall comply with the provisions of Table 1.

2. Performance index

2.1 Dimension

Model mark	Diameter (mm)	Length (mm)	Allowance
L	330mm	220mm	±5%
M	320mm	220mm	
S	290mm	240mm	

2.3 Materials

2.3.1 The part in contact with the user should not use materials that will cause skin irritation;

2.3.2 The lens material should use anti-fogging material or add anti-fogging coating.

2.4 Structure

After the medical isolation mask is worn well, it should be able to completely cover the protective part, and the longitudinal side should be kept upright, not sagging, and there is no crease when bending horizontally.

2.5 Rubber band elongation (applicable to rubber band fixation)

The rubber band should be relaxed, and the elongation of the rubber band should be less than 50%

2.6 Connection fastness

2.6.1 The breaking strength of the connection between the fixing device and the mask shall not be less than 10N.

2.6.2 The joint of the medical barrier mask should be firm. The horizontal plane is subjected to 10N gravity pull, the vertical direction is subjected to 7N gravity pull, lasting 30 seconds, and should not fall off.

3. Test method

3.1 Appearance

Visual inspection shall comply with the requirements of 2.1.

3.2 Dimensions

General or special measuring tools shall comply with the requirements of 2.2.

3.3 Materials

Check the relevant qualification report of the materials used in the mask and the processing process certification materials.

3.4 Structure

Actual wear, visual observation, the results should meet the requirements of 2.4.

3.5 Rubber band elongation (applicable to rubber band fixation)

Take out the rubber band, make it restore the natural straight line shape, measure its length with a steel ruler with a division of 1mm, and then measure its stretching to 1.5 times the length of the original length, the rubber band should not break, the result should meet the requirements of 2.5.

3.6 Connection Fastness

3.6.1 Stretch the fixed belt with 10N static tension for 5s, check the breaking strength at the connection point between the fixed belt and the isolation mask, and the result shall meet the requirements of 2.6.1.

3.6.2 Use 10N force to pull the upper and lower ends of the mask horizontally and 7N force to pull the joint of the separate parts of the mask vertically for 30s, and the results should meet the requirements of 2.6.2.