

Medical Device Product Technical Requirements No: : XTFDA 20200036

Medical Isolation Eye Shield

1. Product model / specification and its division description

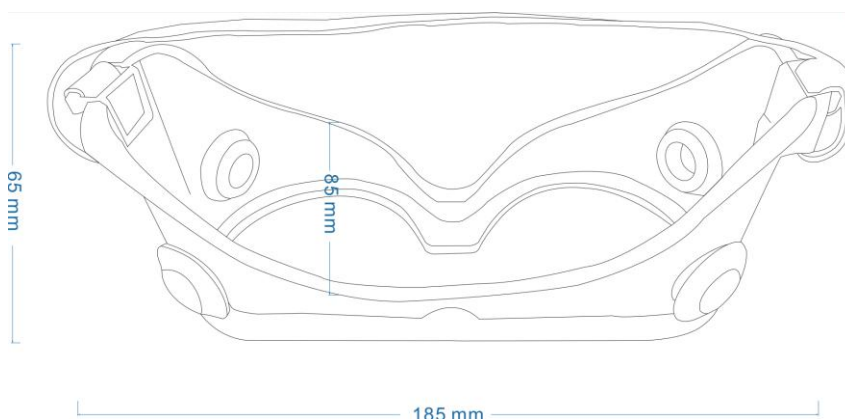
1.1 Description of the product model division

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

According to the medical device management classification, it belongs to class I 14-14-06 Medical personnel protective equipment-isolation cover, and the product structure is composed of lenses, frames and fixing devices of polymer materials. Non-sterile provided, single use.

1.2 The product specifications are divided into three models, 160x55x130mm、150x45x130mm、185x65x85mm。

185x85x65mm The schematic diagram is as follows:



2. Performance indicators

2.1 Appearance and structure

- a) The surface of the shield should be smooth, burr free, sharp Angle free, colorless and transparent, and should not cause discomfort to the eyes and face when wearing;
- b) The surface of the lens should be flat, smooth and free of scratches, ripples, bubbles, impurities or other obvious defects that may impair vision;
- c) Adjustable parts or structural components should be easy to adjust or replace, and the headband should have good elasticity.

2.2 Specifications

- a) The size of the eye mask shall meet the requirements of Article 1.2, and the error shall not be greater than $\pm 10\%$;
- b) The width of the headband should be greater than 10mm, the length should be adjustable, and the adjustment range should meet the requirements of the manufacturer;
- c) The design should be ergonomic and have a good fit with the face.

2.3 Materials

- a) The part in contact with the user should not use materials that can cause skin irritation;
- b) The lens material should use anti-fogging material or add anti-fogging coating.

2.4 Visible light transmittance of lens

2.4.1 Visual clarity: the visual value of the naked eye should not decrease by more than one line compared with the visual value of the eye mask.

2.4.2 Visible light transmittance: The material used in the field of view (lens area) should have a good visible light transmittance, and the visible light transmittance should not be less than 90%.

2.5 Fall resistance

The eye mask falls freely on the hard surface from a height of 1m with three different starting positions, the structural parts should not fall off, the appearance of the eye mask should not be damaged, and the lens should not have cracks.

2.6 Impact resistance

The lens and shield should be able to withstand the impact of a steel ball with a diameter of 22mm and weighing about 45g falling freely from a height of 1.3m.

2.7 Heat resistance

The eye mask should not be deformed after being kept in $67^{\circ}\text{C}\pm 2^{\circ}\text{C}$ water for 3min.

3. Test method

3.1 Appearance and structure test

Check with eye, hand and operation, and the result shall meet the requirements of 2.1.

3.2 Dimensional test

The measurement shall be carried out with a general measuring tool, and the result shall meet the requirements of 2.2.

3.3 Materials

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

3.4 Optical performance test

3.4.1 Visual clarity test

Post an international visual acuity chart in a suitable place in the room, select 5 subjects, test and record their binocular visual acuity values first; Then wear the eye mask according to the instructions, and record the subjects' binocular vision under the same conditions; The visual acuity values of the five subjects with naked eyes should not decrease by more than one line compared with the visual acuity values after wearing the blindfold.

3.4.2 Visible light transmittance test

According to GB/T 2410-2008 test, the results shall meet the requirements of 2.4.2. Or provide the relevant inspection report of the lens material.

3.5 Fall resistance test

The blindfold is freely dropped from a height of 1m to a 50mm thick hardboard placed flat on a hard foundation in three different starting positions once each, and the result should meet the requirements of 2.5.

3.6 Impact resistance test

The ball impact test shall be carried out according to 6.2.1.1, 6.2.1.2, 6.2.2.1 and 6.2.2.2 of GB 14866-2006, and the following defects shall not occur after the test:

- a) Lens breakage: If the lens breaks into two or more pieces, or a fragment greater than 5mg is shed from another surface impacted by the steel ball, or the steel ball penetrates the lens, the lens can be considered broken;
- b) Lens deformation: After the steel ball impact, there are spots on the white paper on the back of the lens, it can be considered deformed;
- c) Protection cover damage: after the impact of the steel ball, it is separated into several parts, or it no longer has the ability to clamp the lens, it can be considered damaged.

3.7 Heat Resistance

The eye mask should be immersed in water with a temperature of $67^{\circ}\text{C} \pm 2^{\circ}\text{C}$ for 3min and then taken out, and then cooled in water below 4°C for 1min. After taking out, the eye mask should not be deformed.