



TEST REPORT

Client Name: Hunan Zhenheyikang Medical Instrument Co.,Ltd

Name of product: Medical Isolation Face Shield

Manufacturer: Hunan Zhenheyikang Medical Instrument Co.,Ltd

Model: 290 × 240mm

Test sort: Commission Test

Shenzhen Boyuan Testing Technology CO.,LTD



Applicant: Hunan Zhenheyikang Medical Instrument Co.,Ltd

Address of Applicant: No.6 Building Jingxiang Energy, No.55 Xianguang east road, Gaoxin district, Xiangtan,Hunan

Manufacturer: Hunan Zhenheyikang Medical Instrument Co.,Ltd

Address of Manufacturer: No.6 Building Jingxiang Energy, No.55 Xianguang east road, Gaoxin district, Xiangtan,Hunan

Samples Receiving Date: December 30, 2020

Testing Period: From December 30, 2020 to January 06, 2021

Tested Standard: EN 166:2001 & EN 167:2001& EN 168:2001

The submitted sample and sample information was/were submitted and identified by/on behalf of client;

Sample Name: Medical Isolation Face Shield

Model No.: 290×240mm

Material: /

Trade Mark: /

Production batch: 20201218

Quantity: 18 Paris

Material: Plastic Metal Combined

Types of eye-protectors: Spectacles without lateral protection
 Goggles
 Face-shields

Filter Type: Uniform lenses Gradient lenses Polarizing Lenses

Tests Conducted: As requested by the applicant, refer to attached page(s) for details.

Fenghuiming

Approved by

2021-01-06

Date

wang chao

Checked by

2021-01-06

Date

LiuLin

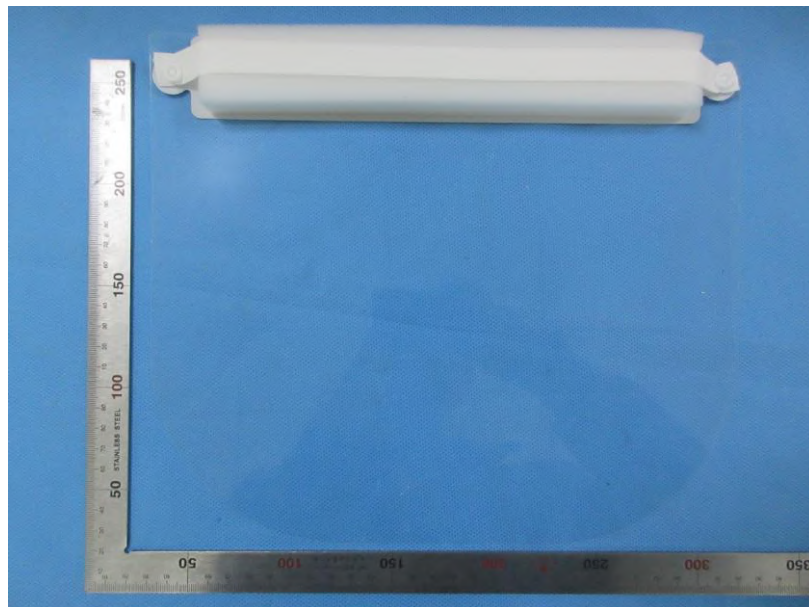
Edited by

2021-01-06

Date



1. Sample photo:



2.Conclusion:

Tested Samples

Medical Isolation Face Shield

Standard

EN 166:2001 & EN 167:2001& EN 168:2001

Result

Pass



3.Tests Conducted Summary

3.1 Requirements for Personal eye-protection

Test standard:

- EN 166:2001 Personal eye-protection - Specifications
- EN 167:2001 Personal eye-protection - Optical test methods
- EN 168:2001 Personal eye-protection - Non-optical test methods

3.2 Requirements for Personal eye-protection

Requirement	EN	Clause	Clause testing		Result
			EN	Clause	
Marking	166	9.1/9.2/9.4	Visual inspection		P
Information	166	10	Visual inspection		P
Construction and materials	166	6.1	Visual inspection		P
		6.2	Manufacturer's certificates		NR
Headbands	166	6.3	By measuring		P
Field of vision	166	7.1.1	168	18	P
Quality of material and surface	166	7.1.3	167	5	P
Refractive powers(Unmounted oculars covering one eye)	166	Spherical refractive powers	167	3.1	Optical Class 1
		Astigmatic refractive powers			
		Prismatic refractive powers			
Refractive powers(Mounted oculars and covering both eyes)	166	Spherical refractive powers	167	3.2	NA
		Astigmatic refractive powers			
		Prismatic refractive powers			
Transmittance	166	Oculars without filtering action	167	6	P
		Oculars with filtering action	167	6	NA
Diffusion of light	166	7.1.2.3	167	4	P
Minimum robustness	166	7.1.4.1	168	4	P
Increased robustness	166	Unmounted oculars	168	3.1	NA
		Complete eye-protectors and frames	168	3.2	NA
Thermal stability	166	7.1.5.1	168	5	P
UV stability	166	7.1.5.2	168	6	P
Corrosion	166	7.1.6	168	8	NA
Ignition	166	7.1.7	168	7	P
Protection against high-speed particles	166	7.2.2	168	9	NA
Protection against droplets and splashes of liquids	166	7.2.4	168	12	P
Lateral protection	166	7.2.8	168	19	NA

Remarks :P=Pass; F=Fail; NA=Not Applicable; NR=Not require; X=Checked



4. Test Results for Personal eye-protection

Marking- Clause9.1/9.2/9.4

Sample No.	Observed	Absent	Comment	Result
N1~N18		X	---	P

Requirements:

1. All markings shall be clear and permanent. The marking shall be fully visible when the complete eye-protector is assembled and shall not encroach into the minimum field of vision defined in 7.1.1. Outside of this area the marking shall not impede vision when worn.
2. The marking of oculars shall contain the relevant technical information.
3. The marking shall comprise the full ocular marking, a hyphen, the number of this standard and then any appropriate symbols for field of use and level of impact.

Information- Clause10

Sample No.	Observed	Absent	Comment	Result
N1~N18		X	---	P

Requirements:

The manufacturer provide with each eye-protector, replacement ocular and replacement frame information.

☆ **General Construction — Clause6.1**

Quality of material and surface — Clause 7.1.3

Sample No.	Defects				Comment	Result
	General Construction		Quality of material and surface			
	Observed	Absent	Observed	Absent		
N1~N3		X		X	---	P

Requirements:

1. Eye-protectors shall be free from projections, sharp edges or other defects which are likely to cause discomfort or injury during use.
2. Except for a marginal area 5 mm wide, oculars shall be free from any significant defects likely to impair vision in use, such as bubbles, scratches, inclusions, dull spots, pitting, mould marks, scouring, grains, pocking, scaling and undulation.

Headbands—6.3

Sample No.	Observed	Absent	Comment	Result
N1~N18		X	---	P

Requirements:

Headbands, when used as the principal means of retention, shall be at least 10 mm wide over any portion which may come into contact with the wearer's head. Headbands shall be adjustable or self-adjusting.

☆ **Field of vision — Clause 7.1.1**

Sample No.	Head-form		Exhibit minimum field of vision defined in the standard		Comment	Result
	Medium	Small	Yes	No		
N1~N3	X		X		---	P

Requirements:

Eye-Protectors shall be exhibit field of vision an area of not less than 22 mm in the horizontal length and 20mm in the vertical width in front of each eye.



Refractive powers — Clause 7.1.2.1.1

Sample No.	Refractive powers				Difference in prismatic refractive powers(cm/m)			Result
	Spherical(m ⁻¹)		Astigmatic(m ⁻¹)		Horizontal		Vertical	
	Left	Right	Left	Right	Base out	Base in		
N1	0.00	0.00	0.00	0.00	0.00	---	0.00	Optical Class1
N2	0.00	0.00	0.00	0.00	0.00	---	0.00	
N3	0.00	0.00	0.00	0.00	0.00	---	0.00	
Requirement: Permissible tolerances for refractive powers:								
Optical class1	±0.06		0.06		0.75	0.25	0.25	
Optical class2	±0.12		0.12		1.00	0.25	0.25	
Optical class3	+0.12~-0.25		0.25		1.00	0.25	0.25	

Transmittance of oculars— Clause 7.1.2.2.1

Sample No.	Requirements	Luminous Transmittance, τ _v (%)		Result
		Left	Right	
N1	τ _v >74.4%	90.2	90.2	P
N2		90.1	90.0	P
N3		90.0	90.2	P

Diffusion of light— Clause 7.1.2.3

Sample No.	Requirements	Diffusion of light (cd/m ²) /lx		Result
		Left	Right	
N1	III	0.32	0.33	P
N2		0.28	0.29	P
N3		0.30	0.31	P
Requirements: The maximum value of the reduced luminance factor shall be: III 0.50 (cd/m ²) /lx for all other oculars. II 0.75 (cd/m ²) /lx for oculars used in eye-protectors against high speed particles I 1.00 (cd/m ²) /lx for welding filters				

Minimum robustness — Clause 7.1.4.1

Sample No.	Observed	Absent	Comment	Result
N7~N14		X	---	P
Requirements: a) ocular fracture : an ocular shall be considered to have fractured if it cracks through its entire thickness into two or more pieces, or if more than 5 mg of the ocular material becomes detached from the surface away from the one in contact with the ball, or if the ball passes through the ocular; b) ocular deformation : an ocular shall be considered to have been deformed if a mark appears on the white paper on the opposite side to the one on which the force is applied.				



Thermal stability — Clause 7.1.5.1

Sample No.	Observed	Absent	Comment	Result
N4~N6		X	---	P

Requirements:
Assembled eye-protectors shall show no apparent deformation

UV stability — Clause 7.1.5.2

Samples		Sample No.					
		N1		N2		N3	
Test items		Left	Right	Left	Right	Left	Right
The relative change of luminous transmittance (%)	Before Expose	90.2	90.2	90.1	90.0	90.0	90.2
	After Expose	90.0	90.1	89.8	90.0	90.1	90.3
	Difference	-0.2	-0.1	-0.3	0.0	0.1	0.1
Reduced scattered light coefficient (cd/m ²) /lx	Before Expose	0.32	0.33	0.28	0.29	0.30	0.31
	After Expose	0.31	0.35	0.30	0.31	0.32	0.32
Result (s)		P		P		P	

1 The relative change of luminous transmittance			2 Reduced scattered light coefficient The maximum value of the reduced luminance factor shall be: - 0.50 (cd/m ²) /lx for all other oculars. - 0.75 (cd/m ²) /lx for oculars used in eye-protectors against high speed particles - 1.00 (cd/m ²) /lx for welding filters				
Luminous transmittance		Permissible relative Change (%)					
Less than (%)	Up to (%)						
100	17.8	±5					
17.8	0.44	±10					

Ignition — Clause 7.1.7

Sample No.	Not ignite or continue to glow	Requirements	Result
N4~N6	X	Not ignite or continue to glow after withdrawal of the test rod.	P

Protection against droplets and splashes of liquids — Clause 7.2.4

Sample No.	Observed	Absent	Comment	Result
N16~N18		X	---	P

On so testing the following defects shall not occur:
a) no pink or crimson colouration appears in the ocular regions defined by the two circles when assessing goggles for protection against droplets. No account shall be taken of any such colouration up to a distance of 6 mm inside the edges of the eye-protector;
b) face-shields cover the eye-region rectangle of the appropriate head-form as described in 10.2.2.2 of EN 168:2001 as assessed in accordance with 10.2 of EN 168:2001.

STATEMENT: STATEMENT: “☆” item to be outside the scope of authorized by CNAS.

*****End of report*****