SUNWAY

SUNWAY (SHENZHEN) PRODUCTS LIMITED

Disposable Medical Goggles

SW-0613

SUNWAY (SHENZHEN) PRODUCTS LIMITED

Summary

- **Product Brand:** Sunway Medical, Inc.
- **Product Description:** Fully Enclosed / Anti-fog, Protective Safety Goggle
- **Supplier Ref Number:** SW-0613
- **Product Country of Origin:** China
- **Product Name Submitted:** Protective Safety Goggle
- **Name of Reg. Authority:** UL / POSI / PEL / SGS
- **Product Standards:**
  - UL - E41613
  - POSI: ISO13485 : 2016 Cert
  - PEL - Report No. PL 2004867
  - SGS – No. GZHL2005014983CE
- **Product Mktg Lic Number:** 914403007992014 4/02/07
- **Product Shelf Life:** 2yr
- **Product Intended Use:** Fully Enclosed Eye Protection

Contents

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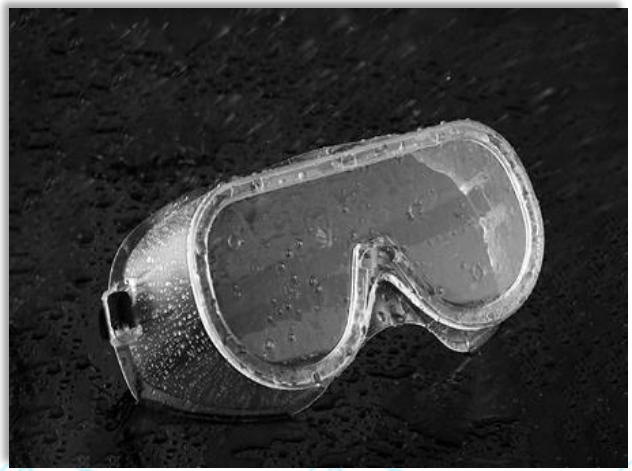
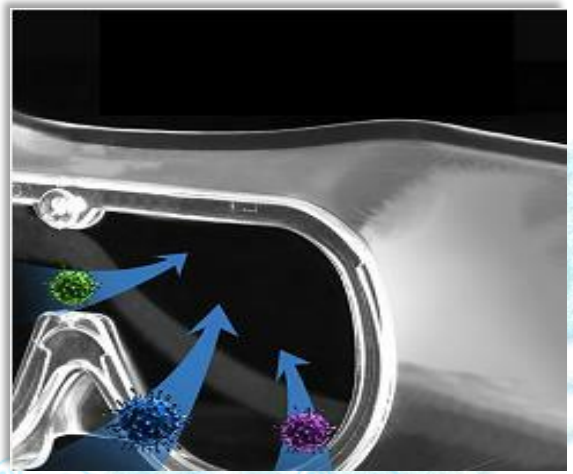
Photos of the Sample





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认证证书 ◆ CERTIFICATE ◆ 认证证书 ◆ CERTIFICATE ◆

POSI

CERTIFICATE

This is to certify that the Quality Management System of

SUNWAY (SHENZHEN) PRODUCTS LIMITED

Business license number: 91440300799201478B

Registered Address: 101, 201, East of 301, 401 &501, Building E, Junxuan Company, No.16 Yinkui Road, Kuixin Community, Kuichong Street, Dapeng New District, Shenzhen, Guangdong Province, China

Audit Address: 101, 201, East of 301,401 &501, Building E, Junxuan Company, No.16 Yinkui Road, Kuixin Community, Kuichong Street, Dapeng New District, Shenzhen, Guangdong Province, China

applicable to

Production and sales of disposable medical isolation clothing, medical isolation face shield, medical isolation eye mask, disposable medical coverall isolation clothing，medical isolation shoe cover(in the filing certificate)；Production and sales of daily protective face masks；Production and sales of disposable protective clothing(export only)

has been assessed and registered by POSI against the provisions of

ISO13485:2016

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by POSI.

Please consult the website: www.posicert.com

The certificate information is also available on the CNCA official website: http://cx.cnca.cn.

ANAB ACCREDITED ISO/IEC 17021-1 MANAGEMENT SYSTEMS CERTIFICATION BODY

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

General Manager

Certificate Registration No：381200045R0M

Initial issue date：2020.06.11 Issue date：2020.06.11 Valid until: 2023.06.10

Shanghai POSI Certification Co., Ltd.

Room 1002A, No.1500, Century Avenue, Pudong New Area, Shanghai ,China.Email:info@posicert.com

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SUNWAY (SHENZHEN) PRODUCTS LIMITED.
101, EAST OF 301, 401 &501, BUILDING E, JUNXUAN COMPANY, NO.16 YINKUI ROAD, KUIXIN COMMUNITY, KUICHONG STREET, DAPEND NEW DISTRICT, SHENZHEN, 518119, CHINA

Sample Description : DISPOSABLE MEDICAL GOGGLES
Style / Item No. : SW-0613

As above test item and its relevant information regarding to the submission are provided and confirmed by the applicant. SGS is not liable to either the test item or its relevant information, in terms of the accuracy, suitability, reliability or/and integrity accordingly.

****

Sample Receiving Date : May 08, 2020
Test Performing Date : May 08, 2020 to May 11, 2020
Test Performed : Selected test(s) as requested by applicant
Test Result(s) : For further details, please refer to the following page(s)

Signed for and on behalf of
SGS-CSTC Standards Technical Services Co., Ltd. Guangzhou Branch

Arthur Mak
Authorized Signatory

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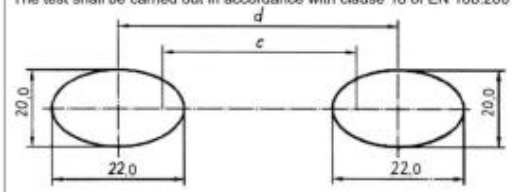
Test Conducted: Based on **BS EN 166-2001** Personal eye-protection —Specifications

Number of Tested Sample: _18_ piece(s)

Test Results: Details shown as following table

Clause	Test Method/Requirement	Result
6	**Design and manufacturing requirements**	
6.1	**General construction** Eye-protectors shall be free from projections, sharp edges or other defects which are likely to cause discomfort or injury during use.	Pass
6.2	**Materials** No parts of the eye-protector which are in contact with the wearer shall be made of materials which are known to cause any skin irritation.	NT
6.3	**Headbands** 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.	Pass
7	**Basic, particular and optional requirements**	
7.1	**Basic requirements**	
7.1.1	**Field of vision** The size of the field of vision is defined in conjunction with the appropriate head-form described in clause 17 of EN 168:2001. Eye-protectors shall exhibit a minimum field of vision defined by the two ellipses in Figure 1 when placed and centered at a distance of 25 mm from the surface of the eyes of the appropriate head-form. The horizontal axis shall be parallel to and 0,7 mm below the height of the line connecting the centres of the two eyes. The horizontal length of the ellipses shall be of 22,0 mm, the vertical width of the ellipses shall be 20,0 mm. The centre distance of the two ellipses shall be d = c + 6 mm, where c is the pupillary distance. The pupillary distance is 64 mm for the medium head-form and 54 mm for the small head-form, if not specified differently by the manufacture. The test shall be carried out in accordance with clause 18 of EN 168:2001. 	Pass
7.1.2	**Optical requirements**	

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Clause	Test Method/Requirement	Result
7.1.2.1	**Spherical, astigmatic and prismatic refractive powers** The refractive powers of oculars shall be measured by the reference methods specified in clause 3 of EN 167:2001. This clause refers also to an optional method for use in specific circumstances; the details of this method are given in annex A of EN 167:2001.	
7.1.2.1.1	**Unmounted oculars covering one eye** The refractive power characteristics of unmounted oculars covering one eye shall be measured by the method specified in 3.1 of EN 167:2001 (non-corrective oculars), and by the methods specified in EN ISO 8980-3 (corrective oculars). The permissible tolerances for oculars without corrective effect are given in Table 2. The permissible deviations for the vertex powers of oculars with corrective effect are specified in EN ISO 8980-1 and EN ISO 8980-2. Oculars that comply with EN ISO 8980-1 and EN ISO 8980-2 shall be categorised as class 1. For class 2, the deviations in vertex refractions may be 0,06 m-1 higher than for class 1. Table 2 — Permissible tolerances for refractive powers of unmounted oculars without corrective effect covering one eye	NA

Optical class	Spherical refractive power $(D_1 + D_2)/2$ m^{-1}	Astigmatic refractive power $\lvert D_1 - D_2 \rvert$ m^{-1}	Prismatic refractive power cm/m
1	± 0,06	0,06	0,12
2	± 0,12	0,12	0,12

NOTE D_1 and D_2 are the refractive powers in the two principal meridians.

7.1.2.1.2	**Mounted oculars and unmounted oculars covering both eyes** The refractive power characteristics of mounted oculars or unmounted oculars covering both eyes shall be measured by the method specified in 3.2 of EN 167:2001 at the visual centre of the ocular. The permissible tolerances for oculars without corrective effect are given in Table 3. The permissible deviations for vertex powers of oculars with corrective effect are as defined in 7.1.2.1.1. Deviations that would correspond to class 3 shall not be permitted. NOTE The difference in prismatic refractive power specified for an eye-protector depends not only on the prismatic refractive power of each ocular, but also on the position of the optical axis of the ocular in relation to the axis of vision, and therefore the shape of the frame. It is therefore necessary to use replacement oculars for which the difference in prismatic power remains within the permissible tolerance limits for the frame in question.	Pass See annex 1

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Clause	Test Method/Requirement	Result
	Table 3 — Permissible tolerances for refractive powers of mounted oculars without corrective effect and unmounted oculars without corrective effect covering both eyes	
7.1.2.1.3	**Cover plates** The refractive powers of cover plates shall comply with the tolerances for optical class 1 given in Tables 2 and 3.	NA
7.1.2.2	**Transmittance**	
7.1.2.2.1	**Oculars without filtering action** Oculars intended to protect the eyes against mechanical or chemical hazards only, and cover plates, shall have a luminous transmittance greater than 74,4 % when measured as given in clause 6 of EN 167:2001 (based on CIE source A (2856 K)).	Pass See annex 2
7.1.2.2.2	**Oculars with filtering action (filters) and housings for oculars with filtering action.** The transmittance of oculars with filtering action shall meet the requirements given in the specific standards relating to the various types of ocular (see 7.2.1). Goggles and face-shields which claim to provide protection against optical radiation shall provide at least the same level of protection against optical radiation as given by a filter of any scale number declared usable with the eyeprotector by the manufacturer or supplier. Testing shall be in accordance with clause 6 of EN 167:2001.	NA
7.1.2.2.3	**Variations in transmittance (Oculars without filtering action are exempt from this requirement)**	
7.1.2.2.3.1	**Oculars without corrective effect** Variations in luminous transmittance shall be measured in accordance with clause 7 of EN 167:2001. The relative variations of the luminous transmittance around the visual centre(s) P1 (and P2) shall not exceed the values of Table 4. The relative difference in luminous transmittance P3 between left and right eye shall not exceed the values of Table 4 or 20 % whichever is greater.	NA

Table 3 — Permissible tolerances for refractive powers of mounted oculars without corrective effect and unmounted oculars without corrective effect covering both eyes

Optical class	Spherical refractive power $(D_1 + D_2)/2$ m^{-1}	Astigmatic refractive power $\lvert D_1 - D_2 \rvert$ m^{-1}	Difference in prismatic refractive power cm/m		
			Horizontal		Vertical
			Base out	Base in	
1	±0,06	0,06	0,75	0,25	0,25
2	±0,12	0,12	1,00	0,25	0,25
3	+0,12 −0,25	0,25	1,00	0,25	0,25

NOTE D_1 and D_2 are the refractive powers in the two principal meridians. For optical class 3 the axes of the principal meridians shall be parallel within ± 10°

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Clause	Test Method/Requirement	Result
	Table 4 — Variations in luminous transmittance Luminous transmittance: less than % / up to %; Permissible relative variation % 100 / 17,8 / ± 5 17,8 / 0,44 / ± 10 0,44 / 0,023 / ± 15 0,023 / 0,0012 / ± 20 0,0012 / 0,000023 / ± 30	
7.1.2.2.3.2	**Oculars with corrective effect (prescription oculars)** The requirements of 7.1.2.2.3.1 shall also apply to prescription oculars, with the provision that variations in luminous transmittance which are due to thickness variations inherent in the design of the ocular are not taken into account, providing the luminous transmittance at no point deviates by more than a factor of 2,68 (one shade number) from its value at the visual centre. The IR and UV transmittance shall meet the requirements of the specified shade number at every point on the ocular.	NA
7.1.2.3	**Diffusion of light** The diffusion of light shall be measured in accordance with one of the reference methods specified in clause 4 of EN 167:2001. The maximum value of the reduced luminance factor shall be: $1{,}00\ \frac{cd}{m^2 \cdot lx}$ for welding filters; $0{,}75\ \frac{cd}{m^2 \cdot lx}$ for oculars used in eye-protectors against high speed particles; $0{,}50\ \frac{cd}{m^2 \cdot lx}$ for all other oculars.	Pass See annex 3
7.1.3	**Quality of material and surface** 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. The assessment shall be carried out in accordance with the method specified in clause 5 of EN 167:2001.	Pass
7.1.4	**Robustness**	
7.1.4.1	**Minimum robustness** This requirement relates only to cover plates and oculars with filtering effect and need not be assessed if these items are intended to meet the requirements for increased robustness or resistance to high speed particles, in which case the requirements of 7.1.4.2 or 7.2.2 shall be met. The requirement for minimum robustness is satisfied if the ocular withstands the application of a 22 mm nominal diameter steel ball with a force of (100 ± 2) N, when tested in accordance with clause 4 of EN 168:2001.	NA

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	On so testing the following defects shall not occur: 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.	
7.1.4.2	**Increased robustness**	
7.1.4.2.1	**Unmounted oculars** The oculars shall withstand the impact of a 22 mm nominal diameter steel ball, of 43 g minimum mass, striking the ocular at a speed of approximately 5,1 m/s, when tested in accordance with 3.1 of EN 168:2001. On so testing the following defects shall not occur: 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 struck by 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 that struck by the ball.	Pass
7.1.4.2.2	**Complete eye-protectors and frames** The complete eye-protector or frame shall withstand the lateral and frontal impacts of a steel ball striking at a specified speed. The diameter of the steel ball and the corresponding impact speed are given in Table 5. Table 5 — Requirements relating to increased robustness of complete eye-protectors Spectacles: Frontal impact, Lateral impact; Goggles: Frontal impact, Lateral impact; Face-shields Size, mass and speed of steel ball: 22 mm nominal diameter steel ball, of 43 g minimum mass, at a speed of approximately 5,1 m/s √ √ √ √ √ The test shall be in accordance with the method specified in 3.2 of EN 168:2001. If a spectacle is claimed to have lateral protection it shall not be possible for the ball to strike the lateral impactpoints without first striking the lateral protection. On so testing the following defects shall not occur: 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 struck by 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 that struck by the ball; c) ocular housing or frame fracture : an ocular housing or frame shall be considered to have failed if it separates into two or more pieces, or if it is no longer capable of holding an ocular in position, or if an unbroken ocular detaches from the frame, or if the ball passes through the housing or frame; d) lateral protection failure : the lateral protection shall be considered to have failed if it	Pass

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Clause	Test Method/Requirement	Result
	fractures through its entire thickness into two or more separate pieces, or if one or more particles become detached from the surface remote from the impact point, or if it allows the ball to penetrate completely, or if it partially or totally detaches from the eye-protector, or if its component parts become separated.	
7.1.5	**Resistance to ageing** NOTE Cover plates and glass oculars are exempt from these tests. The exemption does not apply to coated or laminated glass.	
7.1.5.1	**Stability at an elevated temperature** Assembled eye-protectors shall show no apparent deformation when tested by the method specified in clause 5 of EN 168:2001.	Pass
7.1.5.2	**Resistance to ultraviolet radiation (oculars only)** Oculars shall be subjected to the test for resistance to ultraviolet radiation in accordance with the method specified in clause 6 of EN 168:2001. At the end of the test, oculars shall meet the following requirements. a) The relative change of luminous transmittance shall not be greater than the values specified in Table 6. If for welding filters the relative change of the luminous transmittance is larger than the values specified in Table 6 but the actual value of luminous transmittance remains within the range specified by its shade number, a second irradiation is performed in accordance with clause 6 of EN 168:2001 on the same sample. The relative change of luminous transmittance due to the second irradiation shall not be greater than the values specified in Table 6 and the actual value of luminous transmittance shall remain within the range specified by its shade number; b) The value of the reduced luminance factor shall not exceed the permissible limits given in 7.1.2.3. Table 6 — Permissible relative change in luminous transmittance following the ultraviolet radiation test Luminous transmittance (less than / up to, %) — Permissible relative change (%) 100 / 17.8 — ± 5 17.8 / 8.44 — ± 10 8.44 / 0.333 — ± 15 0.333 / 0.0112 — ± 20 0.0112 / 0.000023 — ± 30	Pass See annex 4&5
7.1.6	**Resistance to corrosion** After having undergone the test for resistance to corrosion specified in clause 8 of EN 168:2001, all metal parts ofthe eye-protector shall display smooth surfaces, free from corrosion, when they are examined by a trained observer.	NA
7.1.7	**Resistance to ignition** Eye-protectors shall be tested in accordance with the method specified in clause 7 of EN 168:2001 and shall be considered to be satisfactory if no part of the eye-protector ignites or continues to glow after removal of the steel rod.	Pass
7.2	**Particular requirements**	
7.2.1	**Protection against optical radiation**	

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7.2.1.1	**Welding filters** – see EN 169.	NT
7.2.1.2	**Ultraviolet filters** – see EN 170.	NT
7.2.1.3	**Infrared filters** – see EN 171.	NT
7.2.1.4	**Sunglare filters for industrial use** – see EN 172.	NT
7.2.1.5	**Welding Filters with switchable luminous transmittance** - see EN 379.	NT
7.2.2	**Protection against high-speed particles** Eye-protectors intended to provide protection against high-speed particles shall withstand the impact of a 6 mm nominal diameter steel ball of 0,86 g minimum mass, striking the oculars and the lateral protection at one of the speeds given in Table 7. Eye-protectors for protection against high-speed particles shall also meet the requirements for increased robustness given in 7.1.4.2. Table 7 — Requirements relating to protection against high-speed particles Impact speed of ball Type of eye-protector / Low energy impact (F) $45^{+2.5}_{-4}$ m/s / Medium energy impact (B) $120^{+\frac{1}{2}}$ m/s / High energy impact(A) $190^{+\frac{1}{2}}$ m/s Spectacles: + / Not applicable / Not applicable Goggles: + / + / Not applicable Face-shields: + / + / + The test shall be in accordance with the method specified in clause 9 of EN 168:2001. It shall not be possible for the ball to strike the lateral impact point without first striking the lateral protection. On so testing the following defects shall not occur: 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 struck by 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 that struck by the ball; c) ocular housing or frame failure : an ocular housing or frame shall be considered to have failed if it separates into two or more pieces, or if it is no longer capable of holding an ocular in position, or if an unbroken ocular detaches from the frame, or if the ball passes through the housing or frame; d) lateral protection failure : the lateral protection shall be considered to have failed if it fractures through its entire thickness into two or more separate pieces, or if one or more particles becomes detached from the surface remote from the impact point, or if it allows the ball to penetrate completely, or if it partially or totally detaches from the eye-protector, or if its component parts become separated. NOTE Eye-protectors offering protection against high-speed particles must provide lateral protection (see 7.2.8).	NT
7.2.3	**Protection against molten metals and hot solids** Eye-protectors intended to provide protection against molten metals and hot solids	NT

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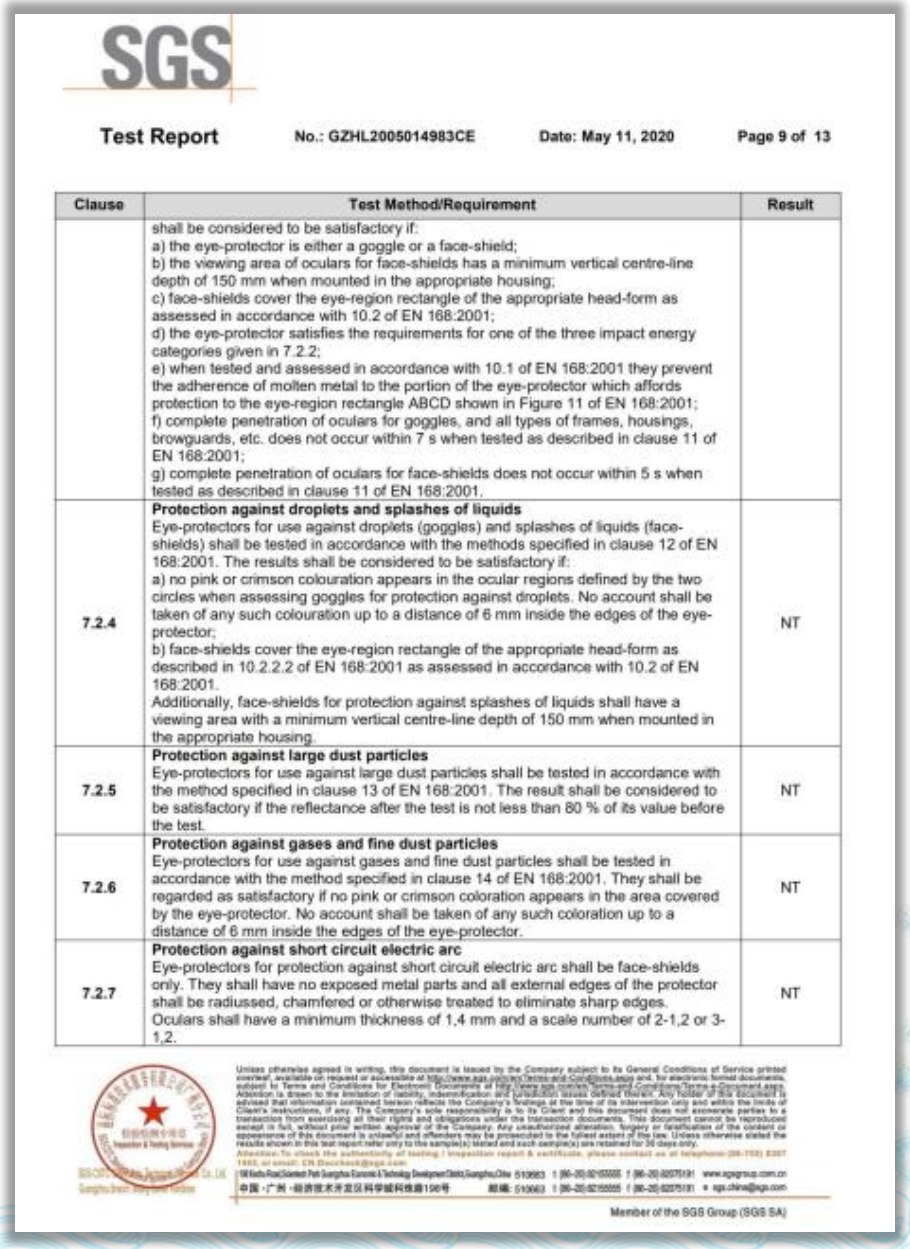

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Clause	Test Method/Requirement	Result
	shall be considered to be satisfactory if: a) the eye-protector is either a goggle or a face-shield; b) the viewing area of oculars for face-shields has a minimum vertical centre-line depth of 150 mm when mounted in the appropriate housing; c) face-shields cover the eye-region rectangle of the appropriate head-form as assessed in accordance with 10.2 of EN 168:2001; d) the eye-protector satisfies the requirements for one of the three impact energy categories given in 7.2.2; e) when tested and assessed in accordance with 10.1 of EN 168:2001 they prevent the adherence of molten metal to the portion of the eye-protector which affords protection to the eye-region rectangle ABCD shown in Figure 11 of EN 168:2001; f) complete penetration of oculars for goggles, and all types of frames, housings, browguards, etc. does not occur within 7 s when tested as described in clause 11 of EN 168:2001; g) complete penetration of oculars for face-shields does not occur within 5 s when tested as described in clause 11 of EN 168:2001.	
7.2.4	**Protection against droplets and splashes of liquids** Eye-protectors for use against droplets (goggles) and splashes of liquids (face-shields) shall be tested in accordance with the methods specified in clause 12 of EN 168:2001. The results shall be considered to be satisfactory if: 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. Additionally, face-shields for protection against splashes of liquids shall have a viewing area with a minimum vertical centre-line depth of 150 mm when mounted in the appropriate housing.	NT
7.2.5	**Protection against large dust particles** Eye-protectors for use against large dust particles shall be tested in accordance with the method specified in clause 13 of EN 168:2001. The result shall be considered to be satisfactory if the reflectance after the test is not less than 80 % of its value before the test.	NT
7.2.6	**Protection against gases and fine dust particles** Eye-protectors for use against gases and fine dust particles shall be tested in accordance with the method specified in clause 14 of EN 168:2001. They shall be regarded as satisfactory if no pink or crimson coloration appears in the area covered by the eye-protector. No account shall be taken of any such coloration up to a distance of 6 mm inside the edges of the eye-protector.	NT
7.2.7	**Protection against short circuit electric arc** Eye-protectors for protection against short circuit electric arc shall be face-shields only. They shall have no exposed metal parts and all external edges of the protector shall be radiussed, chamfered or otherwise treated to eliminate sharp edges. Oculars shall have a minimum thickness of 1,4 mm and a scale number of 2-1,2 or 3-1,2.	NT

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	Face-shields shall satisfy the requirements for area of coverage defined in clause 6.2.4 (b) and shall have a viewing area with a minimum vertical centre line depth of 150 mm when mounted in the appropriate housing. NOTE The specification of a minimum ocular thickness of 1,4 mm was derived from a series of tests in Germany on a range of materials, including polycarbonate, cellulose acetate and cellulose propionate. The distance of the material under test from the electric arc was a nominal 300 mm and the arc conditions were as follows : Current = 12 kA max. ; Voltage = 380 – 400 V ; Frequency = 50 Hz nominal ; Duration = 1 s max.	
7.2.8	**Lateral Protection** Eye-protectors claimed to provide lateral protection shall pass the lateral region coverage assessment detailed in clause 19 of EN 168:2001.	NT
7.3	**Optional requirements** Optional requirements are specified for additional characteristics of eye-protectors which may be found to be beneficial to the user for operational reasons.	NT
7.3.1	**Resistance to surface damage by fine particles** If oculars are described as resistant to surface damage by fine particles they shall have a reduced luminance factor of not more than τ_{v}^{ref} following the test specified in clause 15 of EN 168:2001. NOTE This procedure does not assess resistance to abrasion.	NT
7.3.2	**Resistance to fogging of oculars** If oculars are described as resistant to fogging they shall remain free from fogging for a minimum of 8 s when tested in accordance with clause 16 of EN 168:2001. NOTE This procedure does not assess resistance to fogging of the complete eye-protector.	NT
7.3.3	**Oculars with enhanced reflectance in the infrared** Oculars which are claimed to have enhanced reflectance in the infrared shall have a mean spectral reflectance greater than 60 % within the wavelength range 780 nm to 2 000 nm when measured in accordance with clause 8 of EN 167:2001.	NT
7.3.4	**Protection against high speed particles at extremes of temperature** Eye-protectors intended to provide protection against high-speed particles at extremes of temperature shall withstand the impact of a 6 mm nominal diameter steel ball of 0,86 g minimum mass, striking the oculars and the lateral protection at one of the speeds given in Table 7. The impacts are carried out after the eye-protectors have been conditioned at extremes of temperature ((55 ± 2) °C and (-5 ± 2) °C) using the method specified in clause 9 of EN 168:2001. It shall not be possible for the ball to strike the lateral impact point without first striking the lateral protection. On so testing the following defects shall not occur: 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 struck by 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 that struck by the ball;	NT

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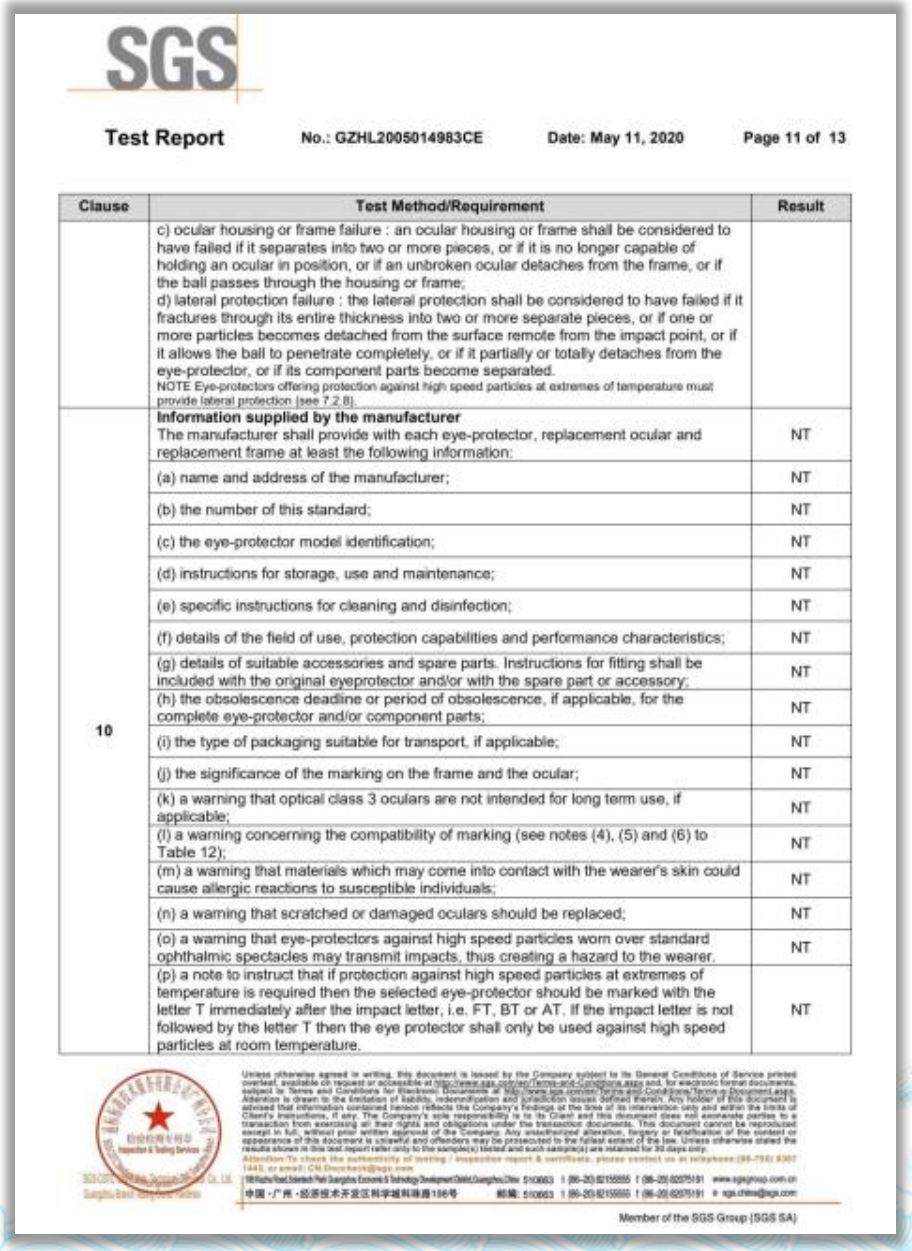

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Clause	Test Method/Requirement	Result
	c) ocular housing or frame failure : an ocular housing or frame shall be considered to have failed if it separates into two or more pieces, or if it is no longer capable of holding an ocular in position, or if an unbroken ocular detaches from the frame, or if the ball passes through the housing or frame; d) lateral protection failure : the lateral protection shall be considered to have failed if it fractures through its entire thickness into two or more separate pieces, or if one or more particles becomes detached from the surface remote from the impact point, or if it allows the ball to penetrate completely, or if it partially or totally detaches from the eye-protector, or if its component parts become separated. NOTE Eye-protectors offering protection against high speed particles at extremes of temperature must provide lateral protection (see 7.2.8).	
10	**Information supplied by the manufacturer** The manufacturer shall provide with each eye-protector, replacement ocular and replacement frame at least the following information:	NT
	(a) name and address of the manufacturer;	NT
	(b) the number of this standard;	NT
	(c) the eye-protector model identification;	NT
	(d) instructions for storage, use and maintenance;	NT
	(e) specific instructions for cleaning and disinfection;	NT
	(f) details of the field of use, protection capabilities and performance characteristics;	NT
	(g) details of suitable accessories and spare parts. Instructions for fitting shall be included with the original eyeprotector and/or with the spare part or accessory;	NT
	(h) the obsolescence deadline or period of obsolescence, if applicable, for the complete eye-protector and/or component parts;	NT
	(i) the type of packaging suitable for transport, if applicable;	NT
	(j) the significance of the marking on the frame and the ocular;	NT
	(k) a warning that optical class 3 oculars are not intended for long term use, if applicable;	NT
	(l) a warning concerning the compatibility of marking (see notes (4), (5) and (6) to Table 12);	NT
	(m) a warning that materials which may come into contact with the wearer's skin could cause allergic reactions to susceptible individuals;	NT
	(n) a warning that scratched or damaged oculars should be replaced;	NT
	(o) a warning that eye-protectors against high speed particles worn over standard ophthalmic spectacles may transmit impacts, thus creating a hazard to the wearer.	NT
	(p) a note to instruct that if protection against high speed particles at extremes of temperature is required then the selected eye-protector should be marked with the letter T immediately after the impact letter, i.e. FT, BT or AT. If the impact letter is not followed by the letter T then the eye protector shall only be used against high speed particles at room temperature.	NT

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Remark:
1. NA = Not applicable.
2. NT = Not tested as per client's request.
3. This test was subcontracted to Guangdong inspection& testing laboratory for ophthalmic optics products and Guangzhou inspection& testing laboratory for ophthalmic optics products.

Model: SW-0613

Annex 1: Refractive power test

Sample No.	Spherical power (m^{-1}) $(D_1+D_2)/2$		Astigmatic power (m^{-1}) $\|D_1-D_2\|$		Prismatic power (cm/m)			Assessment
					Horizontal		Vertical	
	Left	Right	Left	Right	Base out	Base in		
1	-0.04	-0.04	0.01	0.00	0.07	/	0.05	Pass
2	-0.03	-0.03	0.01	0.00	0.10	/	0.05	Pass
3	-0.04	-0.05	0.00	0.02	0.10	/	0.05	Pass

Annex 2: Transmittance test

Sample No.		Luminous transmittance	Assessment
4	Left	90.6%	Pass
	Right	90.6%	Pass
5	Left	91.0%	Pass
	Right	91.1%	Pass
6	Left	91.0%	Pass
	Right	90.7%	Pass

Annex 3: Diffusion of light test results:

Sample No.	Maximum reduced luminance coefficient			Assessment
	Left	Right	Requirements	
4	0.20	0.24	$100\frac{cd}{m^2 \cdot lx}$ for welding filters,	Pass
5	0.27	0.23	$270\frac{cd}{m^2 \cdot lx}$ for oculars used in eye protectors against high speed particles,	Pass
6	0.28	0.30	$500\frac{cd}{m^2 \cdot lx}$ for all other oculars.	Pass

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Annex 4: Resistance to ultraviolet radiation (oculars only) test results:

Sample No.	Maximum reduced ultraviolet radiation			Assessment
	Left	Right	Requirements	
4	0.0%	0.0%	Table 6 – Permissible relative change in luminous transmittance following the ultraviolet radiation test Luminous transmittance: less than % / up to % — Permissible relative change % 100 / 17.8 / ± 5 17.8 / 0.44 / ± 10 0.44 / 0.023 / ± 15 0.023 / 0.0012 / ± 20 0.0012 / 0.000023 / ± 30	Pass
5	-0.4%	-0.4%		Pass
6	-0.3%	-0.1%		Pass

Annex 5: Resistance to ultraviolet radiation (oculars only)-Diffusion of light test results:

Sample No.	Maximum reduced luminance coefficient			Assessment
	Left	Right	Requirements	
4	0.33	0.34	$100\frac{cd}{m^2 \cdot lx}$ for welding filters;	Pass
5	0.35	0.36	$0.75\frac{cd}{m^2 \cdot lx}$ for oculars used in eye protectors against high speed particles;	Pass
6	0.34	0.30	$0.20\frac{cd}{m^2 \cdot lx}$ for all other oculars.	Pass

Sample Photo(s):

Sample photo

End of Report

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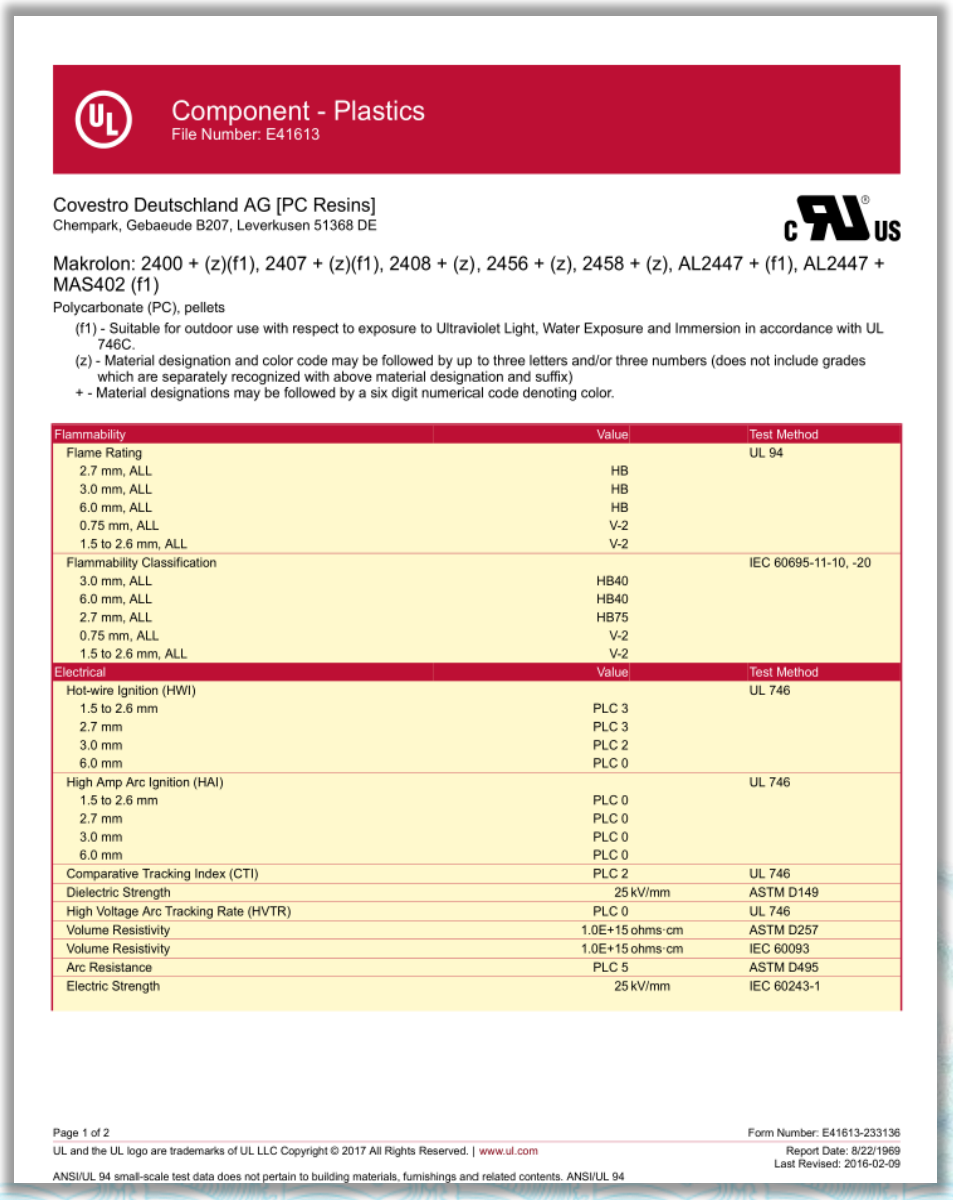
Test Report of the Material



Component - Plastics
File Number: E41613

Covestro Deutschland AG [PC Resins]
Chempark, Gebaeude B207, Leverkusen 51368 DE

c UL us

Makrolon: 2400 + (z)(f1), 2407 + (z)(f1), 2408 + (z), 2456 + (z), 2458 + (z), AL2447 + (f1), AL2447 + MAS402 (f1)

Polycarbonate (PC), pellets

(f1) - Suitable for outdoor use with respect to exposure to Ultraviolet Light, Water Exposure and Immersion in accordance with UL 746C.
(z) - Material designation and color code may be followed by up to three letters and/or three numbers (does not include grades which are separately recognized with above material designation and suffix)
+ - Material designations may be followed by a six digit numerical code denoting color.

Flammability	Value	Test Method
Flame Rating		UL 94
2.7 mm, ALL	HB	
3.0 mm, ALL	HB	
6.0 mm, ALL	HB	
0.75 mm, ALL	V-2	
1.5 to 2.6 mm, ALL	V-2	
Flammability Classification		IEC 60695-11-10, -20
3.0 mm, ALL	HB40	
6.0 mm, ALL	HB40	
2.7 mm, ALL	HB75	
0.75 mm, ALL	V-2	
1.5 to 2.6 mm, ALL	V-2	
Electrical	**Value**	**Test Method**
Hot-wire Ignition (HWI)		UL 746
1.5 to 2.6 mm	PLC 3	
2.7 mm	PLC 3	
3.0 mm	PLC 2	
6.0 mm	PLC 0	
High Amp Arc Ignition (HAI)		UL 746
1.5 to 2.6 mm	PLC 0	
2.7 mm	PLC 0	
3.0 mm	PLC 0	
6.0 mm	PLC 0	
Comparative Tracking Index (CTI)	PLC 2	UL 746
Dielectric Strength	25 kV/mm	ASTM D149
High Voltage Arc Tracking Rate (HVTR)	PLC 0	UL 746
Volume Resistivity	1.0E+15 ohms·cm	ASTM D257
Volume Resistivity	1.0E+15 ohms·cm	IEC 60093
Arc Resistance	PLC 5	ASTM D495
Electric Strength	25 kV/mm	IEC 60243-1

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Form Number: E41613-233136

Report Date: 8/22/1969
Last Revised: 2016-02-09

ANSI/UL 94 small-scale test data does not pertain to building materials, furnishings and related contents. ANSI/UL 94

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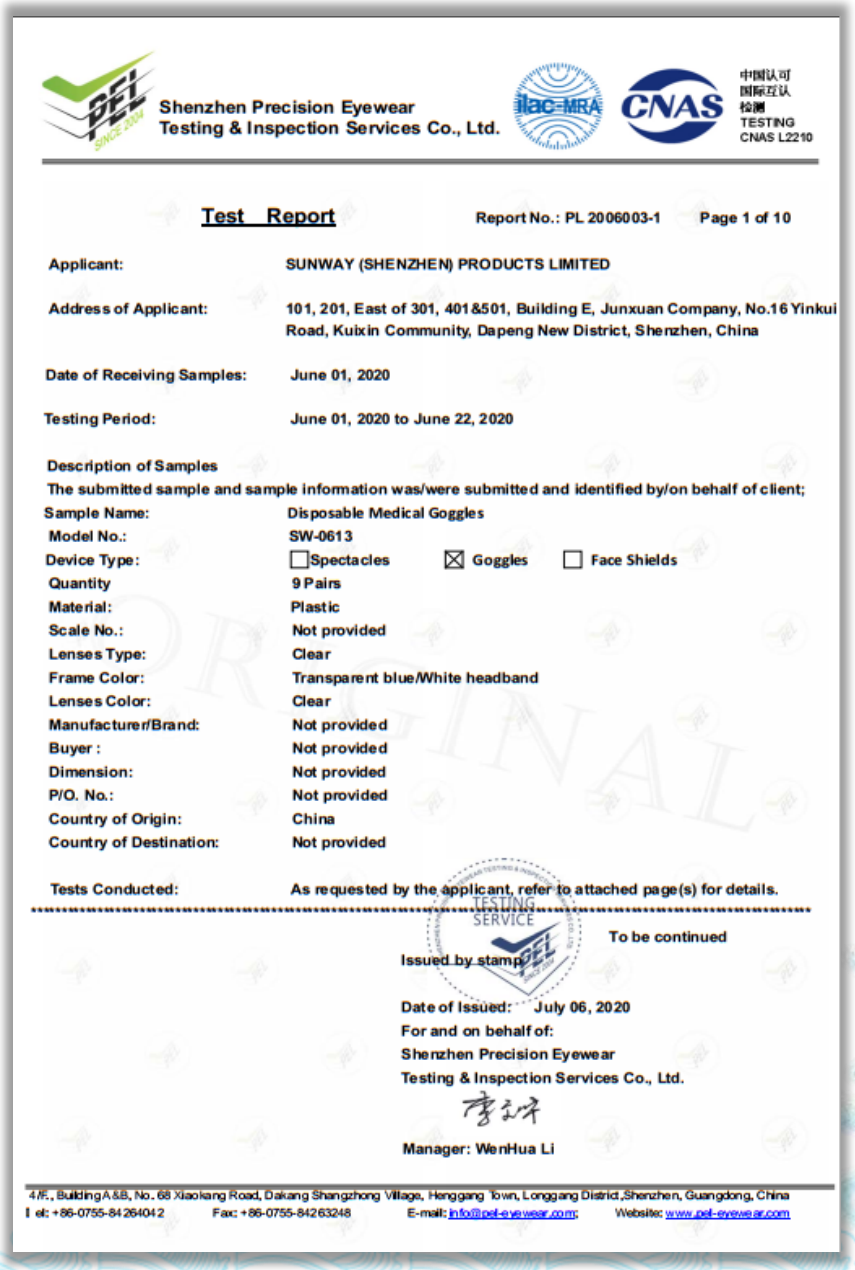

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Testing & Inspection Services Co., Ltd.

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Test Report Report No.: PL 2006003-1 Page 1 of 10

Applicant:	SUNWAY (SHENZHEN) PRODUCTS LIMITED
Address of Applicant:	101, 201, East of 301, 401&501, Building E, Junxuan Company, No.16 Yinkui Road, Kuixin Community, Dapeng New District, Shenzhen, China
Date of Receiving Samples:	June 01, 2020
Testing Period:	June 01, 2020 to June 22, 2020

Description of Samples

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

Sample Name:	Disposable Medical Goggles
Model No.:	SW-0613
Device Type:	☐ Spectacles ☒ Goggles ☐ Face Shields
Quantity	9 Pairs
Material:	Plastic
Scale No.:	Not provided
Lenses Type:	Clear
Frame Color:	Transparent blue/White headband
Lenses Color:	Clear
Manufacturer/Brand:	Not provided
Buyer :	Not provided
Dimension:	Not provided
P/O. No.:	Not provided
Country of Origin:	China
Country of Destination:	Not provided

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

TESTING SERVICE

To be continued

Issued by stamp

Date of Issued: July 06, 2020

For and on behalf of:

Shenzhen Precision Eyewear

Testing & Inspection Services Co., Ltd.

Manager: WenHua Li

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Conclusion:

Tested Samples	Required Standard(s)	Results
Submitted Samples	ANSI / ISEA Z87.1 - 2015 Occupation and Educational Personal Eye and Face Protection Devices, only test the related parameters, please refer to "Tests Conducted Summary" for details	☒Pass ☐Fail

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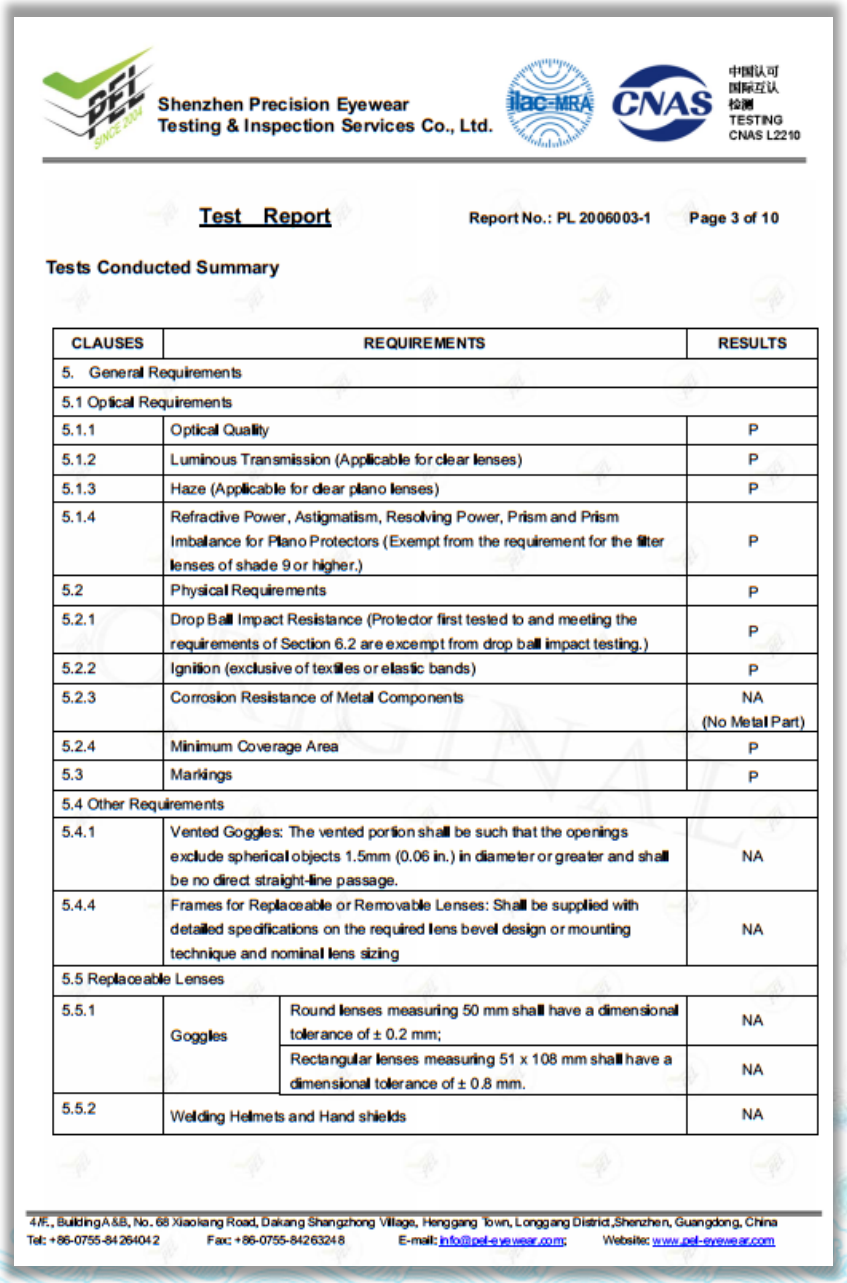

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Tests Conducted Summary

CLAUSES	REQUIREMENTS		RESULTS
5. General Requirements			
5.1 Optical Requirements			
5.1.1	Optical Quality		P
5.1.2	Luminous Transmission (Applicable for clear lenses)		P
5.1.3	Haze (Applicable for clear plano lenses)		P
5.1.4	Refractive Power, Astigmatism, Resolving Power, Prism and Prism Imbalance for Plano Protectors (Exempt from the requirement for the filter lenses of shade 9 or higher.)		P
5.2	Physical Requirements		P
5.2.1	Drop Ball Impact Resistance (Protector first tested to and meeting the requirements of Section 6.2 are exempt from drop ball impact testing.)		P
5.2.2	Ignition (exclusive of textiles or elastic bands)		P
5.2.3	Corrosion Resistance of Metal Components		NA (No Metal Part)
5.2.4	Minimum Coverage Area		P
5.3	Markings		P
5.4 Other Requirements			
5.4.1	Vented Goggles: The vented portion shall be such that the openings exclude spherical objects 1.5mm (0.06 in.) in diameter or greater and shall be no direct straight-line passage.		NA
5.4.4	Frames for Replaceable or Removable Lenses: Shall be supplied with detailed specifications on the required lens bevel design or mounting technique and nominal lens sizing		NA
5.5 Replaceable Lenses			
5.5.1	Goggles	Round lenses measuring 50 mm shall have a dimensional tolerance of ± 0.2 mm;	NA
		Rectangular lenses measuring 51 x 108 mm shall have a dimensional tolerance of ± 0.8 mm.	NA
5.5.2	Welding Helmets and Hand shields		NA

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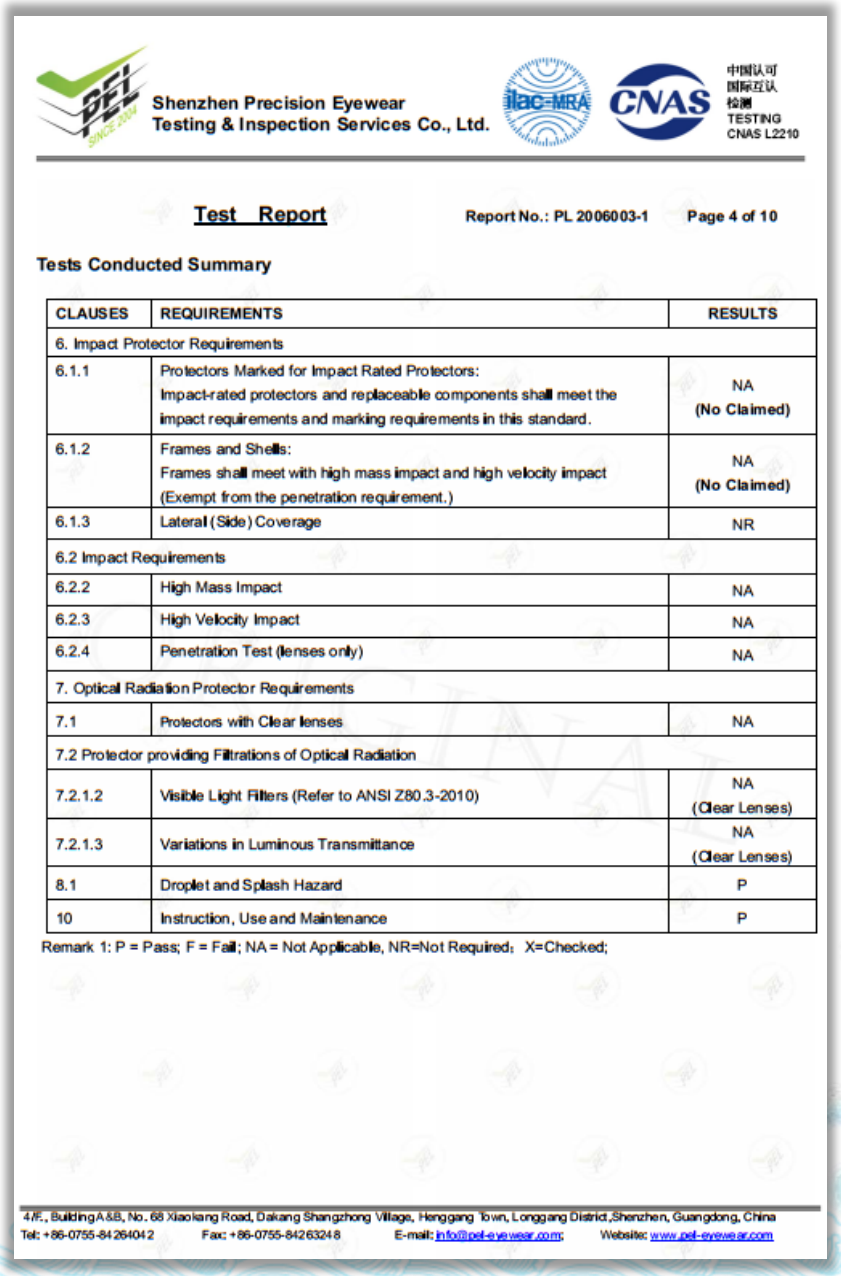

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Tests Conducted Summary

CLAUSES	REQUIREMENTS	RESULTS
6. Impact Protector Requirements		
6.1.1	Protectors Marked for Impact Rated Protectors: Impact-rated protectors and replaceable components shall meet the impact requirements and marking requirements in this standard.	NA (No Claimed)
6.1.2	Frames and Shells: Frames shall meet with high mass impact and high velocity impact (Exempt from the penetration requirement.)	NA (No Claimed)
6.1.3	Lateral (Side) Coverage	NR
6.2 Impact Requirements		
6.2.2	High Mass Impact	NA
6.2.3	High Velocity Impact	NA
6.2.4	Penetration Test (lenses only)	NA
7. Optical Radiation Protector Requirements		
7.1	Protectors with Clear lenses	NA
7.2 Protector providing Filtrations of Optical Radiation		
7.2.1.2	Visible Light Filters (Refer to ANSI Z80.3-2010)	NA (Clear Lenses)
7.2.1.3	Variations in Luminous Transmittance	NA (Clear Lenses)
8.1	Droplet and Splash Hazard	P
10	Instruction, Use and Maintenance	P

Remark 1: P = Pass; F = Fail; NA = Not Applicable, NR=Not Required; X=Checked;

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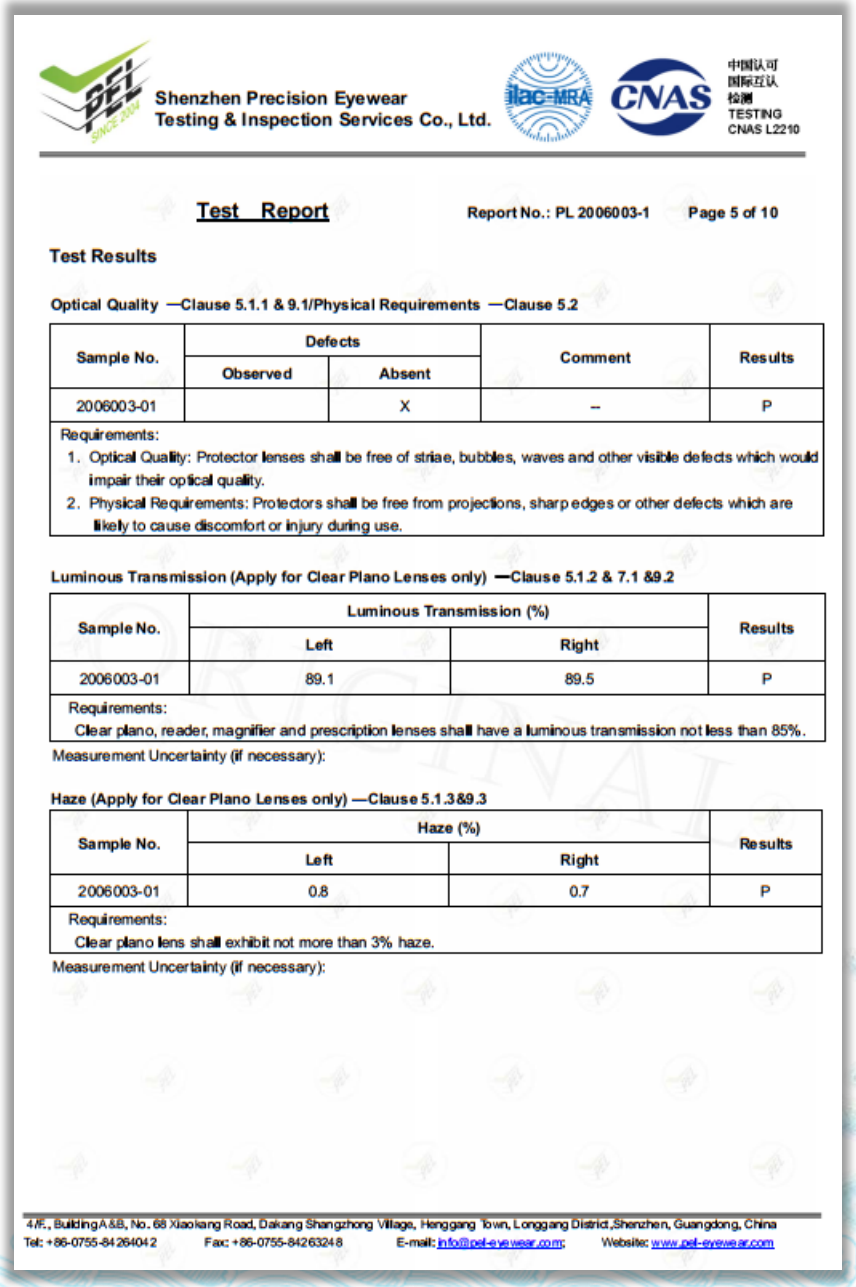

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Test Results

Optical Quality —Clause 5.1.1 & 9.1/Physical Requirements —Clause 5.2

Sample No.	Defects		Comment	Results
	Observed	Absent		
2006003-01		X	–	P

Requirements:
1. Optical Quality: Protector lenses shall be free of striae, bubbles, waves and other visible defects which would impair their optical quality.
2. Physical Requirements: Protectors shall be free from projections, sharp edges or other defects which are likely to cause discomfort or injury during use.

Luminous Transmission (Apply for Clear Plano Lenses only) —Clause 5.1.2 & 7.1 &9.2

Sample No.	Luminous Transmission (%)		Results
	Left	Right	
2006003-01	89.1	89.5	P

Requirements:
Clear plano, reader, magnifier and prescription lenses shall have a luminous transmission not less than 85%.

Measurement Uncertainty (if necessary):

Haze (Apply for Clear Plano Lenses only) —Clause 5.1.3&9.3

Sample No.	Haze (%)		Results
	Left	Right	
2006003-01	0.8	0.7	P

Requirements:
Clear plano lens shall exhibit not more than 3% haze.

Measurement Uncertainty (if necessary):

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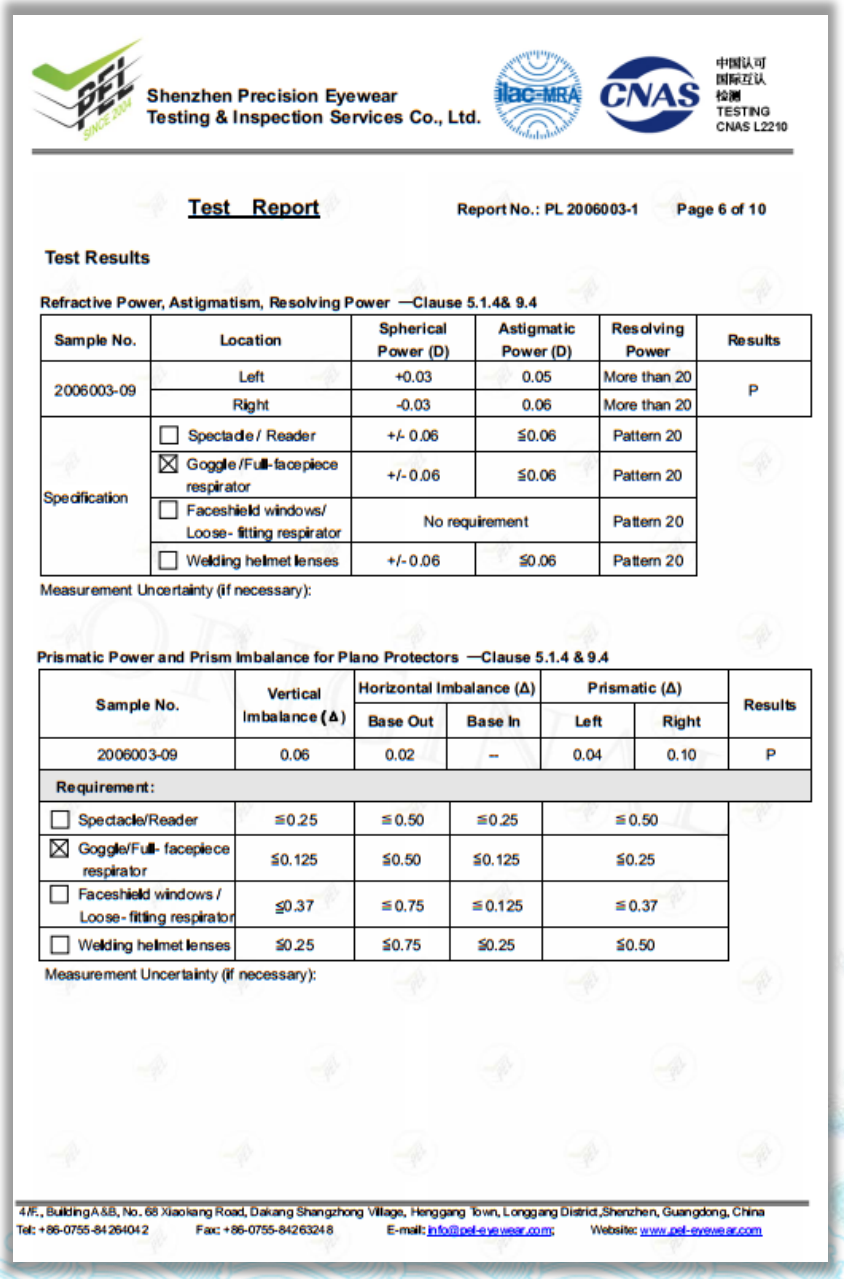

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Test Results

Refractive Power, Astigmatism, Resolving Power —Clause 5.1.4& 9.4

Sample No.	Location	Spherical Power (D)	Astigmatic Power (D)	Resolving Power	Results
2006003-09	Left	+0.03	0.05	More than 20	P
	Right	-0.03	0.06	More than 20	
Specification	☐ Spectacle / Reader	+/- 0.06	≤0.06	Pattern 20	
	☒ Goggle /Full-facepiece respirator	+/- 0.06	≤0.06	Pattern 20	
	☐ Faceshield windows/ Loose- fitting respirator	No requirement		Pattern 20	
	☐ Welding helmet lenses	+/- 0.06	≤0.06	Pattern 20	

Measurement Uncertainty (if necessary):

Prismatic Power and Prism Imbalance for Plano Protectors —Clause 5.1.4 & 9.4

Sample No.	Vertical Imbalance (Δ)	Horizontal Imbalance (Δ)		Prismatic (Δ)		Results
		Base Out	Base In	Left	Right	
2006003-09	0.06	0.02	--	0.04	0.10	P
Requirement:						
☐ Spectacle/Reader	≤0.25	≤0.50	≤0.25	≤0.50		
☒ Goggle/Full- facepiece respirator	≤0.125	≤0.50	≤0.125	≤0.25		
☐ Faceshield windows / Loose- fitting respirator	≤0.37	≤0.75	≤0.125	≤0.37		
☐ Welding helmet lenses	≤0.25	≤0.75	≤0.25	≤0.50		

Measurement Uncertainty (if necessary):

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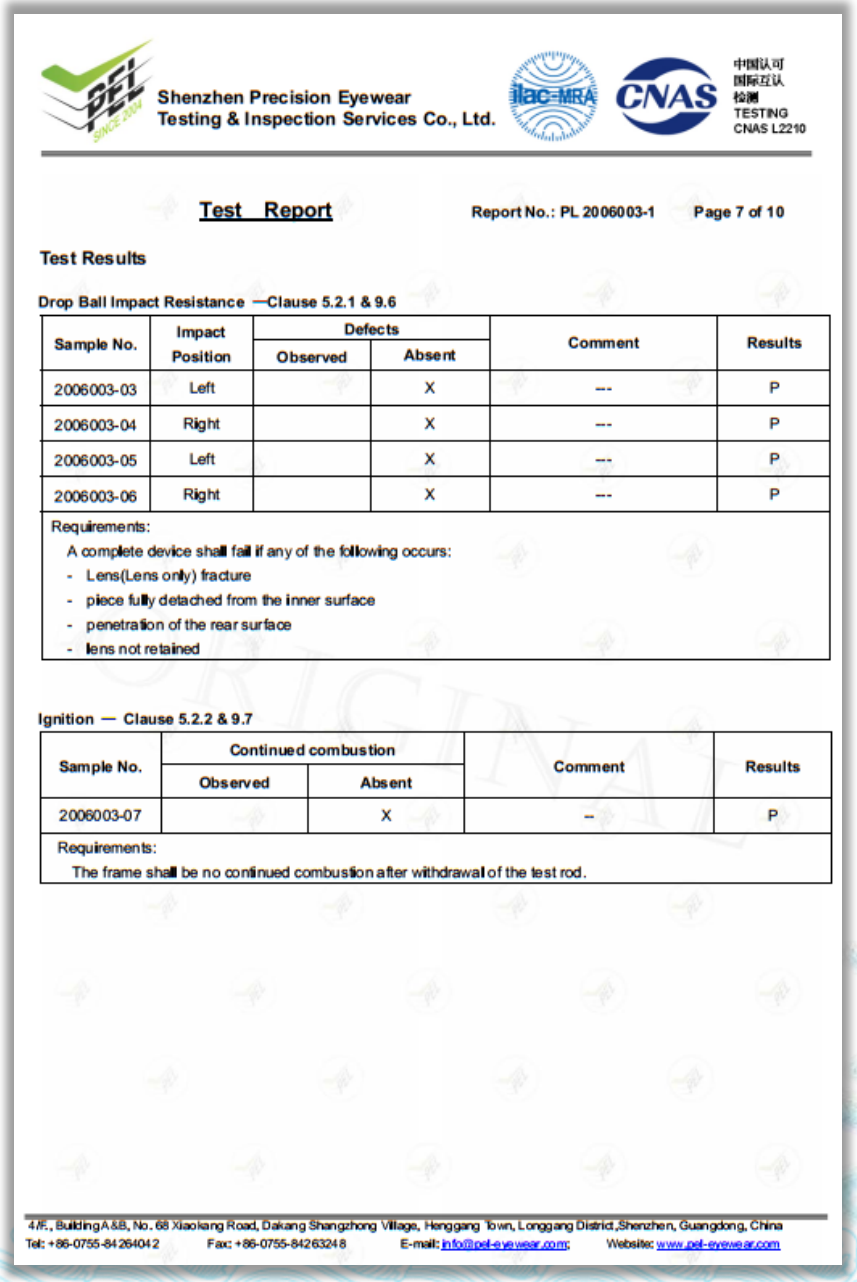

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Test Results

Drop Ball Impact Resistance —Clause 5.2.1 & 9.6

Sample No.	Impact Position	Defects		Comment	Results
		Observed	Absent		
2006003-03	Left		X	---	P
2006003-04	Right		X	---	P
2006003-05	Left		X	---	P
2006003-06	Right		X	---	P

Requirements:
A complete device shall fail if any of the following occurs:
- Lens(Lens only) fracture
- piece fully detached from the inner surface
- penetration of the rear surface
- lens not retained

Ignition — Clause 5.2.2 & 9.7

Sample No.	Continued combustion		Comment	Results
	Observed	Absent		
2006003-07		X	–	P

Requirements:
The frame shall be no continued combustion after withdrawal of the test rod.

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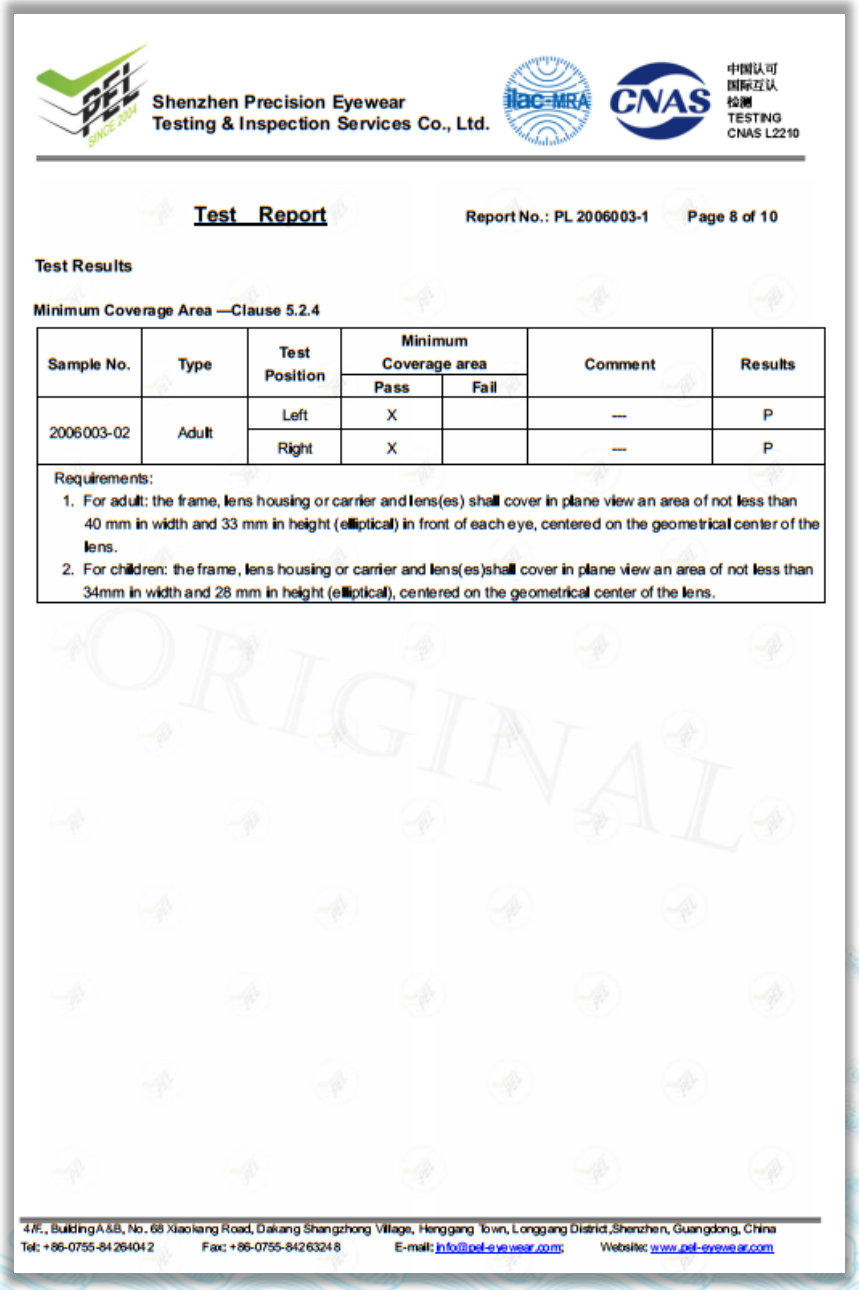

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Test Results

Minimum Coverage Area —Clause 5.2.4

Sample No.	Type	Test Position	Minimum Coverage area		Comment	Results
			Pass	Fail		
2006003-02	Adult	Left	X		---	P
		Right	X		---	P

Requirements:

1. For adult: the frame, lens housing or carrier and lens(es) shall cover in plane view an area of not less than 40 mm in width and 33 mm in height (elliptical) in front of each eye, centered on the geometrical center of the lens.
2. For children: the frame, lens housing or carrier and lens(es)shall cover in plane view an area of not less than 34mm in width and 28 mm in height (elliptical), centered on the geometrical center of the lens.

ORIGINAL

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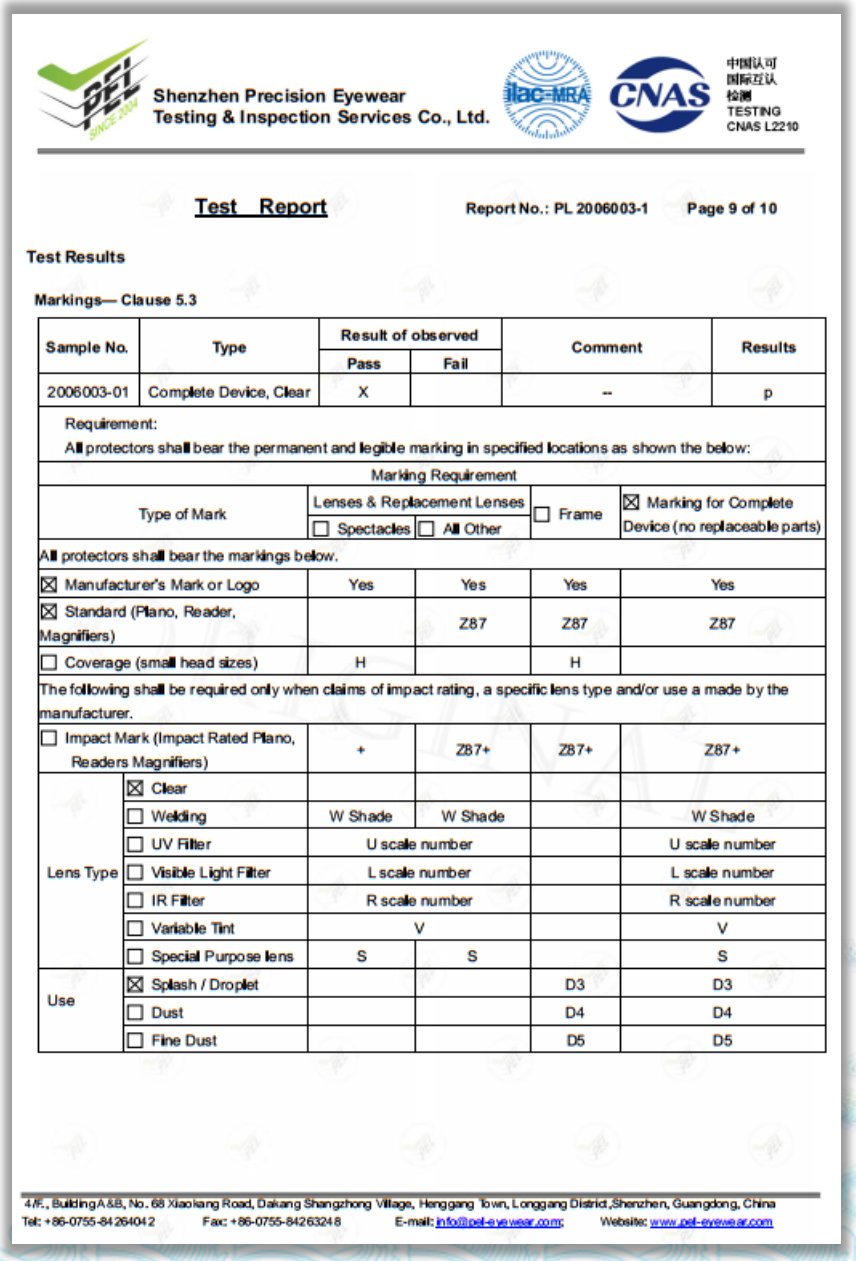

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Test Results

Markings— Clause 5.3

Sample No.	Type	Result of observed		Comment	Results
		Pass	Fail		
2006003-01	Complete Device, Clear	X		--	p

Requirement:
All protectors shall bear the permanent and legible marking in specified locations as shown the below:

Marking Requirement				
Type of Mark	Lenses & Replacement Lenses ☐ Spectacles ☐ All Other		☐ Frame	☒ Marking for Complete Device (no replaceable parts)
All protectors shall bear the markings below.				
☒ Manufacturer's Mark or Logo	Yes	Yes	Yes	Yes
☒ Standard (Plano, Reader, Magnifiers)		Z87	Z87	Z87
☐ Coverage (small head sizes)	H		H	
The following shall be required only when claims of impact rating, a specific lens type and/or use a made by the manufacturer.				
☐ Impact Mark (Impact Rated Plano, Readers Magnifiers)	+	Z87+	Z87+	Z87+
Lens Type ☒ Clear				
Lens Type ☐ Welding	W Shade	W Shade		W Shade
Lens Type ☐ UV Filter	U scale number			U scale number
Lens Type ☐ Visible Light Filter	L scale number			L scale number
Lens Type ☐ IR Filter	R scale number			R scale number
Lens Type ☐ Variable Tint	V			V
Lens Type ☐ Special Purpose lens	S	S		S
Use ☒ Splash / Droplet			D3	D3
Use ☐ Dust			D4	D4
Use ☐ Fine Dust			D5	D5

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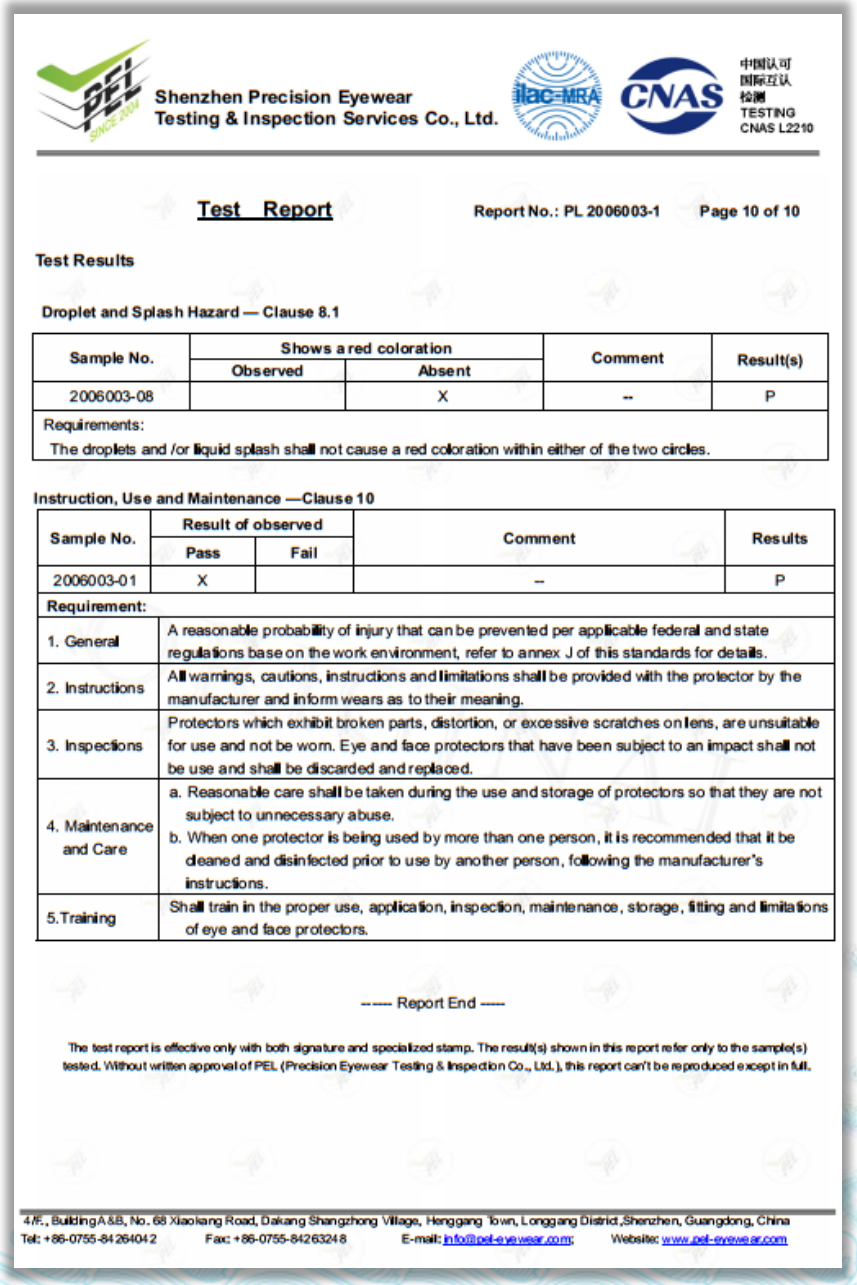
Tel: +86-0755-84264042 Fax: +86-0755-84263248 E-mail: info@pei-eyewear.com; Website: www.pei-eyewear.com

SUNWAY

SUNWAY (SHENZHEN) PRODUCTS LIMITED

Test Report



Shenzhen Precision Eyewear Testing & Inspection Services Co., Ltd.

ilac-MRA CNAS 中国认可 国际互认 检测 TESTING CNAS L2210

Test Report Report No.: PL 2006003-1 Page 10 of 10

Test Results

Droplet and Splash Hazard — Clause 8.1

Sample No.	Shows a red coloration		Comment	Result(s)
	Observed	Absent		
2006003-08		X	--	P
Requirements: The droplets and /or liquid splash shall not cause a red coloration within either of the two circles.				

Instruction, Use and Maintenance —Clause 10

Sample No.	Result of observed		Comment	Results
	Pass	Fail		
2006003-01	X		--	P
Requirement:				
1. General	A reasonable probability of injury that can be prevented per applicable federal and state regulations base on the work environment, refer to annex J of this standards for details.			
2. Instructions	All warnings, cautions, instructions and limitations shall be provided with the protector by the manufacturer and inform wears as to their meaning.			
3. Inspections	Protectors which exhibit broken parts, distortion, or excessive scratches on lens, are unsuitable for use and not be worn. Eye and face protectors that have been subject to an impact shall not be use and shall be discarded and replaced.			
4. Maintenance and Care	a. Reasonable care shall be taken during the use and storage of protectors so that they are not subject to unnecessary abuse. b. When one protector is being used by more than one person, it is recommended that it be cleaned and disinfected prior to use by another person, following the manufacturer's instructions.			
5.Training	Shall train in the proper use, application, inspection, maintenance, storage, fitting and limitations of eye and face protectors.			

----- Report End -----

The test report is effective only with both signature and specialized stamp. The result(s) shown in this report refer only to the sample(s) tested. Without written approval of PEL (Precision Eyewear Testing & Inspection Co., Ltd.), this report can't be reproduced except in full.

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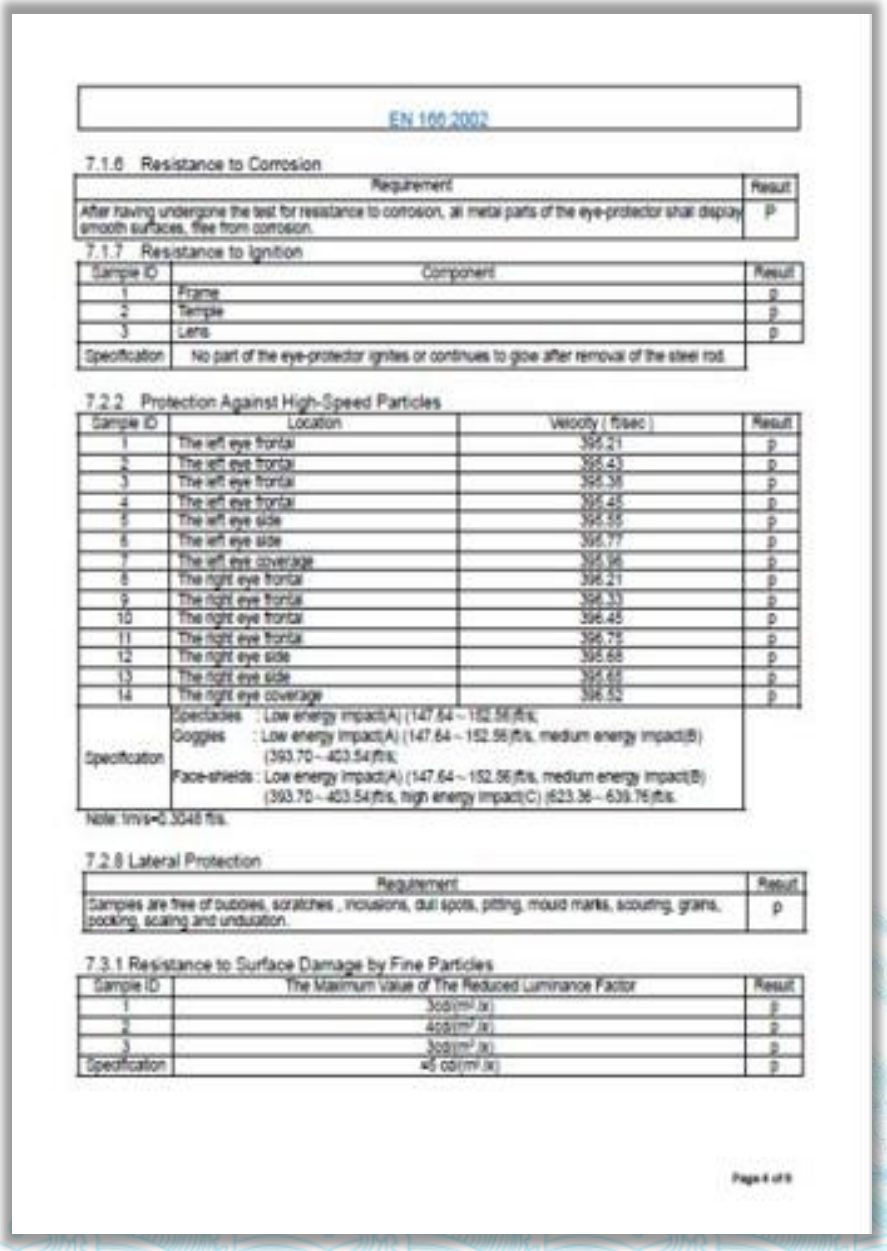
Tel: +86-0755-84264042 Fax: +86-0755-84263248 E-mail: info@pel-eyewear.com; Website: www.pel-eyewear.com

SUNWAY

SUNWAY (SHENZHEN) PRODUCTS LIMITED

Test Report



EN 166:2002

7.1.6 Resistance to Corrosion

Requirement	Result
After having undergone the test for resistance to corrosion, all metal parts of the eye-protector shall display smooth surfaces, free from corrosion.	P

7.1.7 Resistance to Ignition

Sample ID	Component	Result
1	Frame	P
2	Temple	P
3	Lens	P
Specification	No part of the eye-protector ignites or continues to glow after removal of the steel rod.	

7.2.2 Protection Against High-Speed Particles

Sample ID	Location	Velocity (ft/sec)	Result
1	The left eye frontal	396.21	P
2	The left eye frontal	396.43	P
3	The left eye frontal	396.38	P
4	The left eye frontal	396.45	P
5	The left eye side	396.55	P
6	The left eye side	396.77	P
7	The left eye coverage	396.96	P
8	The right eye frontal	396.21	P
9	The right eye frontal	396.33	P
10	The right eye frontal	396.45	P
11	The right eye frontal	396.75	P
12	The right eye side	396.68	P
13	The right eye side	396.65	P
14	The right eye coverage	396.52	P
Specification	Spectacles : Low energy impact(A) (147.64～152.56 ft/s; Goggles : Low energy impact(A) (147.64～152.56 ft/s, medium energy impact(B) (393.70～403.54 ft/s; Face-shields : Low energy impact(A) (147.64～152.56 ft/s, medium energy impact(B) (393.70～403.54 ft/s, high energy impact(C) (623.36～639.76 ft/s.		

Note: 1m/s=3.3048 ft/s.

7.2.8 Lateral Protection

Requirement	Result
Samples are free of bubbles, scratches , inclusions, dull spots, pitting, mould marks, scouring, grains, pocking, scaling and undulation.	P

7.3.1 Resistance to Surface Damage by Fine Particles

Sample ID	The Maximum Value of The Reduced Luminance Factor	Result
1	3cd/(m²·lx)	P
2	4cd/(m²·lx)	P
3	3cd/(m²·lx)	P
Specification	≤5 cd/(m²·lx)	P

Page 4 of 9

SUNWAY

SUNWAY (SHENZHEN) PRODUCTS LIMITED

Test Report

EN 166:2002

7.3.2 Resistance to Fogging of Oculars

Sample ID	Minimum Seconds	Result
1	9 seconds	p
2	9 seconds	p
3	9 seconds	p
Specification	≥ 8 seconds	p

7.3.3 Oculars with enhanced reflectance in the infrared

Sample ID	Spectral reflectance	Result
1	68%	p
2	68%	p
3	69%	p
Specification	> 60%	p

7.3.4 Protection Against High-Speed Particles at Extremes of Temperature

Sample ID	Temperature	Location	Velocity (ft/s)	Result
1	(55±2)℃	left eye frontal	395.42	p
2		left eye frontal	396.21	p
3		left eye side	398.32	p
4		right eye frontal	396.82	p
5		right eye frontal	395.53	p
6		right eye side	395.46	p
7		left eye coverage	395.64	p
8		right eye coverage	396.76	p
9	(-5±2)℃	left eye frontal	148.62	p
10		left eye frontal	149.68	p
11		left eye side	148.64	p
12		right eye frontal	148.95	p
13		right eye frontal	149.21	p
14		right eye side	149.80	p
15		left eye coverage	149.11	p
16		right eye coverage	149.33	p
Specification	Spectacles : Low energy impact(A) (147.64～152.56 ft/s; Goggles : Low energy impact(A) (147.64～152.56 ft/s, medium energy impact(B) (393.70～403.54 ft/s; Face-shields : Low energy impact(A) (147.64～152.56 ft/s, medium energy impact(B) (393.70～403.54 ft/s, high energy impact(C) (623.36～639.76 ft/s.			

Note: 1m/s=0.3048 ft/s.

Page 5 of 6

SUNWAY

SUNWAY (SHENZHEN) PRODUCTS LIMITED

Test Report

PHoto 1

Certificates of the Company

统一社会信用代码
91440300799201478B

营业执照

(副本)

名　　称　深圳市山而威户外装备科技有限公司

类　　型　有限责任公司

成立日期　2007年04月02日

法定代表人　李光曦

住　　所　深圳市大鹏新区葵涌街道葵新社区银葵路16号君轩公司E栋厂房101、301东、401、501

重要提示
1. 商事主体的经营范围由章程确定。经营范围中属于法律、法规规定应当经批准的项目，取得许可审批文件后方可开展相关经营活动。
2. 商事主体经营范围和许可审批项目等有关企业信用事项及年报信息和其他信用信息，请登录左下角的国家企业信用信息公示系统或扫描右上方的二维码查询。
3. 各类商事主体每年须于成立周年之日起两个月内，向商事登记机关提交上一自然年度的年度报告。企业应当按照《企业信息公示暂行条例》第十条的规定向社会公示企业信息。

登记机关　深圳市市场监督管理局

2019 年 09 月 05 日

国家企业信用信息公示系统网址：http://www.gsxt.gov.cn

国家市场监督管理总局监制

SUNWAY

SUNWAY (SHENZHEN) PRODUCTS LIMITED

Certificates of the Company

第二类医疗器械经营备案凭证

备案编号：粤深食药监械经营备 202033323 号

企业名称	深圳市山而威户外装备科技有限公司
法定代表人	李光曦
企业负责人	李光曦
经营方式	批零兼营
住　　所	深圳市大鹏新区葵涌街道葵新社区银葵路 16 号君轩公司 E 栋厂房 101、301 东、401、501
经营场所	深圳市大鹏新区葵涌街道葵新社区银葵路 16 号君轩公司 E 栋厂房 101、301 东、401、501
库房地址	深圳市大鹏新区葵涌街道葵新社区银葵路 16 号君轩公司 E 栋厂房 101、301 东、401、501
经营范围	2002 年分类目录（二类）：6801，6802，6803，6804，6805，6806，6807，6808，6809，6810，6812，6813，6815，6816，6820，6821，6822，6823，6824，6825，6826，6827，6828，6830，6831，6832，6833，6834，6840（诊断试剂不需低温冷藏运输贮存），6841，6845，6846，6854，6855，6856，6857，6858，6863，6864，6865，6866，6870，6877，以上类别中包含的植入和介入类产品除外，以上类别中包含的角膜接触镜、助听器产品除外 2017 年分类目录（二类）：01，02，03，04，05，06，07，08，09，10，11，12，13，14，15，16，17，18，19，20，21，22，以上类别中包含的植入和介入类产品除外，以上类别中包含的角膜接触镜、助听器产品除外

深圳市市场监督管理局

备案部门（公章）

备案日期：2020 年 03 月 11 日

SUNWAY

SUNWAY (SHENZHEN) PRODUCTS LIMITED

Certificates of the Company

医疗器械网络销售信息公示

关闭

企业信息

企业名称	深圳市山而威户外装备科技有限公司	社会信用代码	91440300799201478B
法定代表人	李光曙	企业负责人	李光曙
住所	深圳市大鹏新区葵涌街道葵新社区银葵路16号君轩公司E栋厂房101、301东、401、501	经营场所或生产场所	深圳市大鹏新区葵涌街道葵新社区银葵路16号君轩公司E栋厂房101、301东、401、501
库房地址	深圳市大鹏新区葵涌街道葵新社区银葵路16号君轩公司E栋厂房101、301东、401、501	备案编号	粤深械网备202003110316
医疗器械生产（经营）许可证或备案凭证编号	粤深食药监械经营备202033323号	主体业态（可多选）	☐医疗器械生产 ☐医疗器械批发 ☐医疗器械零售 ☑医疗器械批零兼营
*经营范围	2002年分类目录（二类）：6801，6802，6803，6804，6805，6806，6807，6808，6809，6810，6812，6813，6815，6816，6820，6821，6822，6823，6824，6825，6826，6827，6828，6830，6831，6832，6833，6834，6840（诊断试剂不需低温冷藏运输贮存），6841，6845，6846，6854，6855，6856，6857，6858，6863，6864，6865，6866，6870，6877，以上类别中包含的植入和介入类产品除外，以上类别中包含的角膜接触镜、助听器产品除外[br]2017年分类目录（二类）：01，02，03，04，05，06，07，08，09，10，11，12，13，14，15，16，17，18，19，20，21，22，以上类别中包含的植入和介入类产品除外，以上类别中包含的角膜接触镜、助听器产品除外		
联系人姓名	李光曙	联系人电话	13695180593

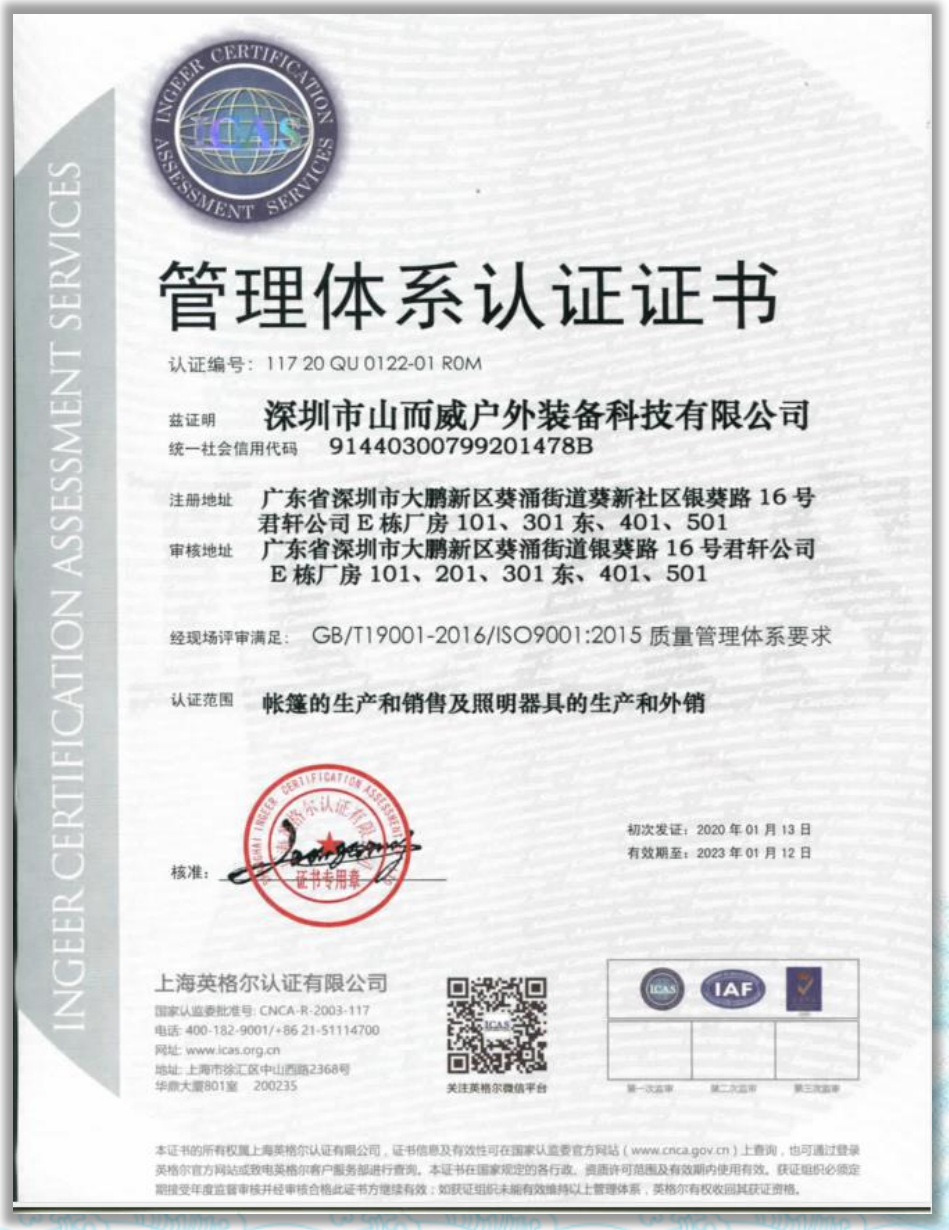
销售类型

医疗器械网络销售类型	☐自建类 ☑入驻类	申请日期：	2020-03-11
网站名称		网络客户端应用程序名	
网站域名		网站IP地址	
电信业务经营许可证编号		非经营性互联网信息服务备案编号	
服务器存放地址		互联网药品信息服务资格证书编号（自建类必填）	
医疗器械网络交易服务第三方平台名称	浙江天猫网络有限公司 浙江淘宝网络有限公司 杭州阿里巴巴广告有限公司 叮当快药科技集团有限公司 深圳市腾讯计算机系统有限公司	医疗器械网络交易服务第三方平台备案凭证编号	（浙）网械平台备字【2018】第00002号 （浙）网械平台备字【2018】第00004号 （浙）网械平台备字【2018】第00001号 （京）网械平台备字【2018】第00006号 （粤）网械平台备字【2019】第00003号
变更信息			

SUNWAY

SUNWAY (SHENZHEN) PRODUCTS LIMITED

Certificates of the Company



INGEER CERTIFICATION ASSESSMENT SERVICES

INGEER CERTIFICATION ASSESSMENT SERVICES

ICAS

管理体系认证证书

认证编号：117 20 QU 0122-01 R0M

兹证明　深圳市山而威户外装备科技有限公司

统一社会信用代码　91440300799201478B

注册地址　广东省深圳市大鹏新区葵涌街道葵新社区银葵路 16 号君轩公司 E 栋厂房 101、301 东、401、501

审核地址　广东省深圳市大鹏新区葵涌街道银葵路 16 号君轩公司 E 栋厂房 101、201、301 东、401、501

经现场评审满足：GB/T19001-2016/ISO9001:2015 质量管理体系要求

认证范围　帐篷的生产和销售及照明器具的生产和外销

核准：

证书专用章

初次发证：2020 年 01 月 13 日

有效期至：2023 年 01 月 12 日

上海英格尔认证有限公司

国家认监委批准号：CNCA-R-2003-117

电话：400-182-9001/+86 21-51114700

网址：www.icas.org.cn

地址：上海市徐汇区中山西路2368号华鼎大厦801室　200235

关注英格尔微信平台

ICAS　IAF

第一次监审　第二次监审　第三次监审

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SUNWAY (SHENZHEN) PRODUCTS LIMITED

Certificates of the Company

INGEER CERTIFICATION ASSESSMENT SERVICES

MANAGEMENT SYSTEM CERTIFICATE

Certificate No.: 117 20 QU 0122-01 R0M

This is to certify the quality management systems of

Sunway (Shenzhen) Products Limited

Unified Social Credit Code 91440300799201478B

Registered Address 101, East of 301, 401, 501, E Building, Junxuan Company, 16# Yinkui Road, Kuixin Community, Kuichong Street, Dapeng New District, Shenzhen, Guangdong, China

Auditing Address 101, 201, East of 301, 401, 501, E Building, Junxuan Company, 16# Yinkui Road, Kuichong Street, Dapeng New District, Shenzhen, Guangdong, China

has been assessed and registered as meeting the requirements of

GB/T19001-2016/ISO9001:2015

Scope of approval

Production and Sales of Tents, Production and Export of Lighting Fixtures

Signed by:

First Certification: 13 Jan. 2020

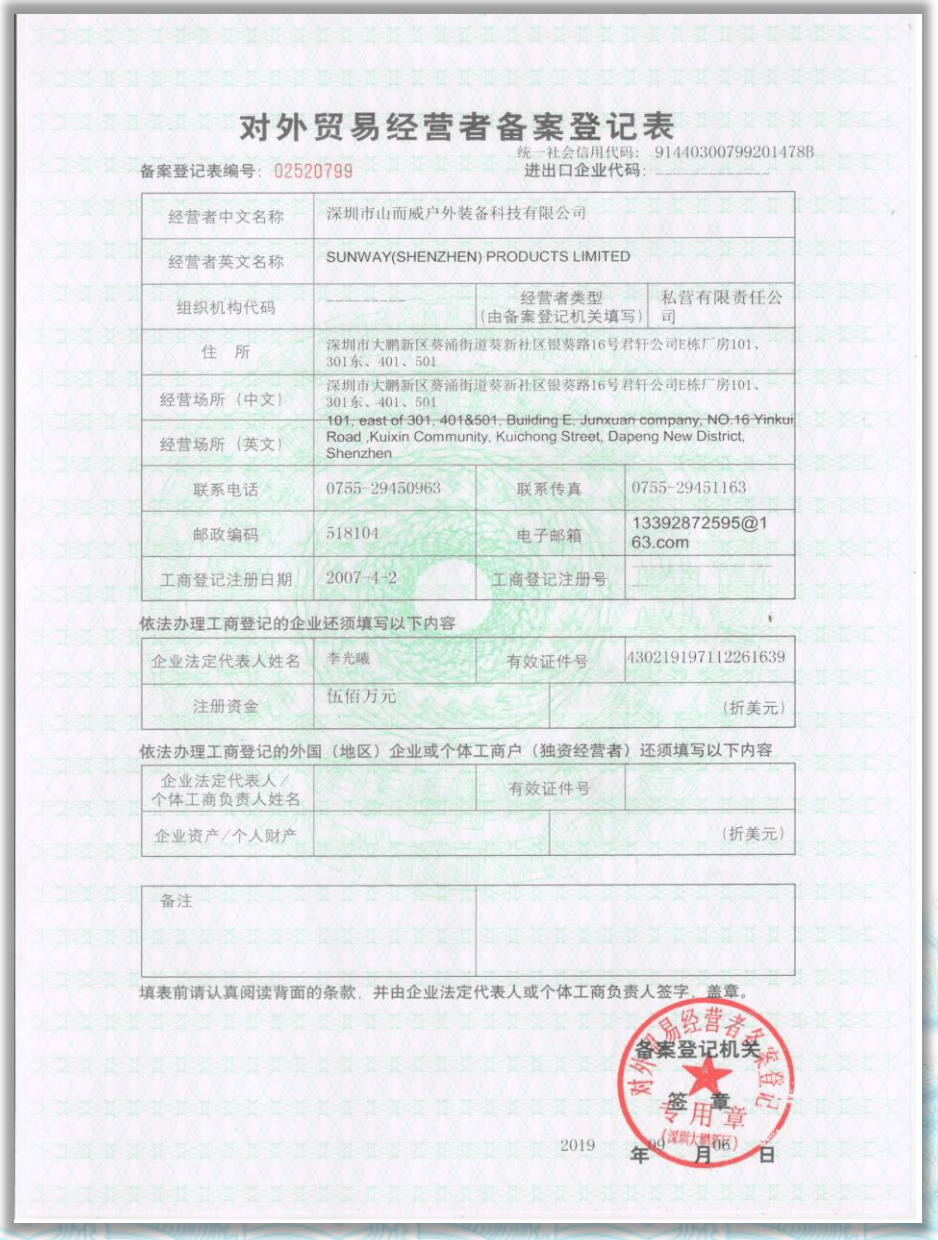
Expiry Date: 12 Jan. 2023

Shanghai Ingeer Certification Assessment Co.,Ltd.

IAF

SUNWAY (SHENZHEN) PRODUCTS LIMITED

Certificates of the Company



对外贸易经营者备案登记表

备案登记表编号：02520799　　统一社会信用代码：91440300799201478B　　进出口企业代码：

经营者中文名称	深圳市山而威户外装备科技有限公司		
经营者英文名称	SUNWAY(SHENZHEN) PRODUCTS LIMITED		
组织机构代码		经营者类型（由备案登记机关填写）	私营有限责任公司
住　所	深圳市大鹏新区葵涌街道葵新社区银葵路16号君轩公司E栋厂房101、301东、401、501		
经营场所（中文）	深圳市大鹏新区葵涌街道葵新社区银葵路16号君轩公司E栋厂房101、301东、401、501		
经营场所（英文）	101, east of 301, 401&501, Building E, Junxuan company, NO.16 Yinkui Road ,Kuixin Community, Kuichong Street, Dapeng New District, Shenzhen		
联系电话	0755-29450963	联系传真	0755-29451163
邮政编码	518104	电子邮箱	13392872595@163.com
工商登记注册日期	2007-4-2	工商登记注册号	

依法办理工商登记的企业还须填写以下内容

企业法定代表人姓名	李光曦	有效证件号	430219197112261639
注册资金	伍佰万元		（折美元）

依法办理工商登记的外国（地区）企业或个体工商户（独资经营者）还须填写以下内容

企业法定代表人／个体工商负责人姓名		有效证件号	
企业资产／个人财产			（折美元）

备注	

填表前请认真阅读背面的条款，并由企业法定代表人或个体工商负责人签字、盖章。

备案登记机关　签　章

2019　年　09　月　06　日

SUNWAY

SUNWAY (SHENZHEN) PRODUCTS LIMITED

Packaging Information

No.	Unit Package	Qty（Pcs）/Carton	Measurement			N.W. (KGS)	G.W. (KGS)
			Length (cm)	Width (cm)	Height (cm)		
1	3pcs/box	200pcs	52.00	39.00	35.00	14.00	15.00

合格证CERTIFICATION

【产品名称】护目镜(非医用)
【N a m e】 Protective Goggles
【规格型号】SW-0613
【M o d e l】SW-0613
【主要成分】PVC 70%、PC 23%、松紧带 7%
【Main components】70% PVC、23% PC、7% Elastic Rope
【执行标准】GB14866-2006
【 Standard 】GB14866-2006
【包装规格】1副/袋
【Packing Spec.】1set/bag
【有效期】2年
【Validity】2 years
【生产日期】2020年5月10日
【Production Date】2020.05.10
【批次号】202005
【Production LOT】202005
【生产商】深圳市山而威户外装备科技有限公司
【Manufacturer】Sunway (Shenzhen) Products Limited
【生产地址】深圳市大鹏新区葵涌街道葵新社区银葵路16号
【Address】君轩公司E栋厂房101、201、301东、401、501
101, 201, east of 301, 401&501,Building E, junxuan Company, No.16 Yikui Road, Kuixin Community, Kuichong street, Dapeng new district, Shenzhen.

深圳市山而威户外装备科技有限公司 检验合格章

SUNWAY

SUNWAY (SHENZHEN) PRODUCTS LIMITED

Factory Photos

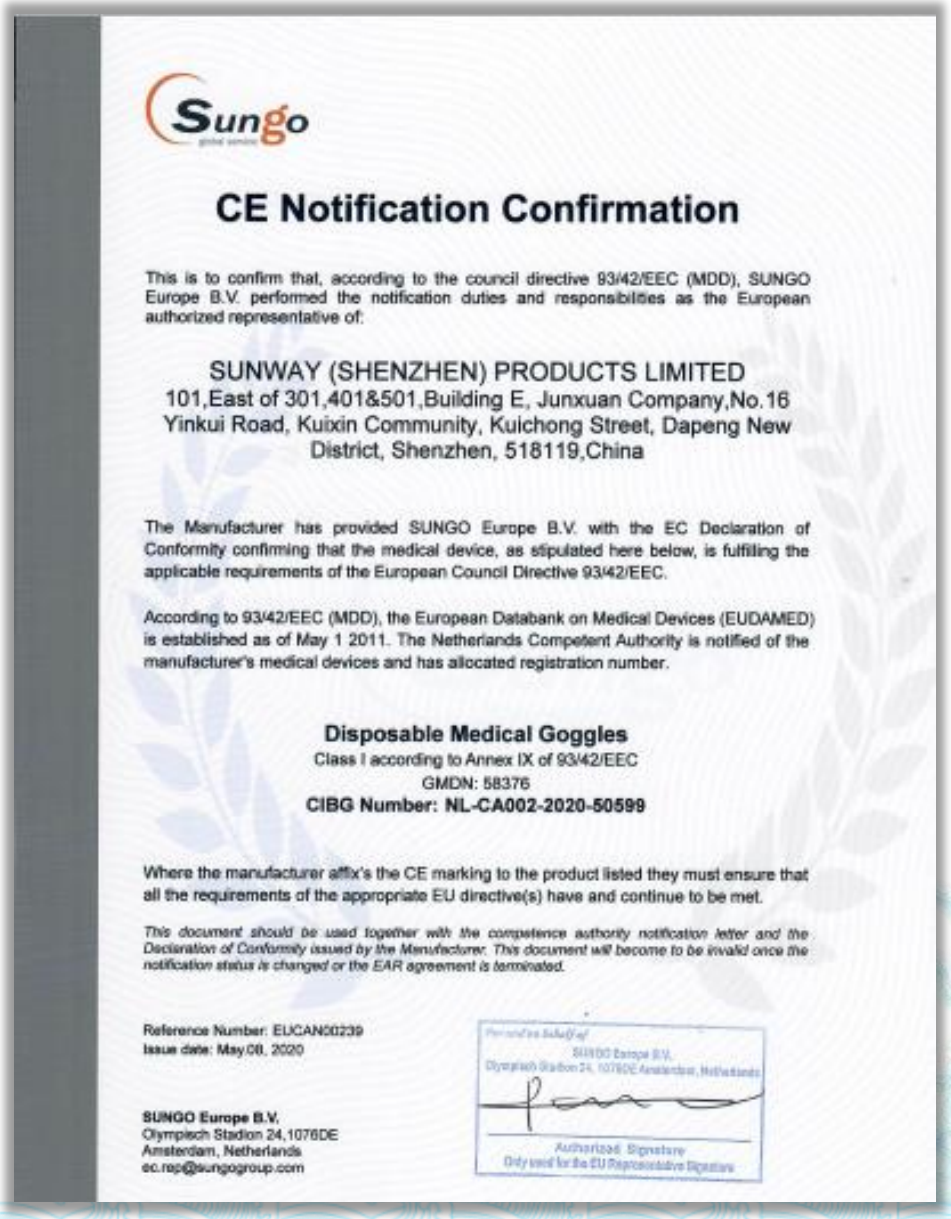
SUNWAY (SHENZHEN) PRODUCTS LIMITED

GMP Photos

Photo of the Company

SUNWAY (SHENZHEN) PRODUCTS LIMITED

CE Notification Confirmation



Sungo

CE Notification Confirmation

This is to confirm that, according to the council directive 93/42/EEC (MDD), SUNGO Europe B.V. performed the notification duties and responsibilities as the European authorized representative of:

SUNWAY (SHENZHEN) PRODUCTS LIMITED
101,East of 301,401&501,Building E, Junxuan Company,No.16 Yinkui Road, Kuixin Community, Kuichong Street, Dapeng New District, Shenzhen, 518119,China

The Manufacturer has provided SUNGO Europe B.V. with the EC Declaration of Conformity confirming that the medical device, as stipulated here below, is fulfilling the applicable requirements of the European Council Directive 93/42/EEC.

According to 93/42/EEC (MDD), the European Databank on Medical Devices (EUDAMED) is established as of May 1 2011. The Netherlands Competent Authority is notified of the manufacturer's medical devices and has allocated registration number.

Disposable Medical Goggles
Class I according to Annex IX of 93/42/EEC
GMDN: 58376
CIBG Number: NL-CA002-2020-50599

Where the manufacturer affix's the CE marking to the product listed they must ensure that all the requirements of the appropriate EU directive(s) have and continue to be met.

This document should be used together with the competence authority notification letter and the Declaration of Conformity issued by the Manufacturer. This document will become to be invalid once the notification status is changed or the EAR agreement is terminated.

Reference Number: EUCAN00239
Issue date: May 08, 2020

SUNGO Europe B.V.
Olympisch Stadion 24,1076DE
Amsterdam, Netherlands
ec.rep@sungogroup.com

Authorized Signature
Only used for the EU Representative Signature

SUNWAY (SHENZHEN) PRODUCTS LIMITED

CE Claim of Conformity

CIBG
Ministerie van Volksgezondheid, Welzijn en Sport

> Retouradres Postbus 16114 2500 BC Den Haag

SUNGO Europe B.V.
T.a.v. de heer Luo
Olympisch Stadion 24
1076 DE Amsterdam

Farmatec

Bezoekadres:
Hoftoren
Rijnstraat 50
2515 XP Den Haag

T 070 340 6161

http://hulpmiddelen.farmatec.nl

Inlichtingen bij:
J.I. van de Leuv

medische_hulpmiddelen@minvws.nl

Ons kenmerk:
CIBG-20201509

Bijlagen
-

Uw aanvraag
17 april 2020

Correspondentie uitsluitend richten aan het retouradres met vermelding van de datum en het kenmerk van deze brief.

Datum: 6 mei 2020
Betreft: aanmelding medische hulpmiddelen klasse I

Geachte heer Luo,

Graag bevestig ik hierbij de ontvangst op 17 april 2020 van de mededeling ex artikel 5 van het Besluit medische hulpmiddelen (BMH) dat bedrijf SUNWAY (SHENZHEN) PRODUCTS LIMITED met Europees gemachtigde SUNGO Europe B.V. onderstaande medische hulpmiddelen, ingedeeld in risicoklasse I, aflevert. De producten zijn onder volgend kenmerk geregistreerd. Ik verzoek u om in alle verdere correspondentie betreffende een of meer van deze producten het bijbehorende kenmerk te vermelden.

Disposable Medical Face Mask
(geen merknaam) (NL-CA002-2020-50600)
Disposable Medical Goggles
(geen merknaam) (NL-CA002-2020-50599)
Disposable Medical Protective Gowns
(geen merknaam) (NL-CA002-2020-50598)

Toekomstige wijzigingen in bovengenoemde gegevens – waaronder een eventuele wijziging van de indeling in risicoklasse in verband met wijzigingen van Europese regelgeving inzake de classificatie van medische hulpmiddelen, en aan voortschrijdend wetenschappelijk inzicht (zie art.9, lid 3 van Europese Richtlijn 93/42/EEG) – dient u te zijner tijd mede te delen.

Volledigheidshalve wijs ik u erop dat het - ongeacht uw mededeling – verboden is een medisch hulpmiddel ter aflevering voorhanden te hebben, dan wel af te leveren indien niet aan de voor dat medisch hulpmiddel geldende regels gesteld bij of krachtens de Wet op de Medische Hulpmiddelen (WMH) wordt voldaan. Met name wijzen wij u op de Nederlandse-taaleis, de eisen voor het ter beschikking houden van de technische documentatie en de plicht tot het hebben van een Post Market Surveillance- en vigilantiesysteem.

Pagina 1 van 2

CE Claim of Conformity

Tevens wijs ik u er voor de goede orde nog op dat de registratie van uw mededeling betreffende de aflevering van de bovengenoemde producten slechts een administratieve handeling betreft. Deze ontvangstbevestiging behelst dan ook geen besluit betreffende de kwalificatie van de desbetreffende producten als medisch hulpmiddel in de zin van art. 1 WMH, noch betreffende de indeling in risicoklasse I.

De Minister voor Medische Zorg en Sport,
namens deze,

Afdelingshoofd
Farmatec

Dr. M.J. van de Velde

Dhr. M.J. van de Velde

Pagina 2 van 2

SUNWAY (SHENZHEN) PRODUCTS LIMITED

FDA

Certification of FDA Registration Service

This document provides notification of the registration number assigned to the client's establishment.

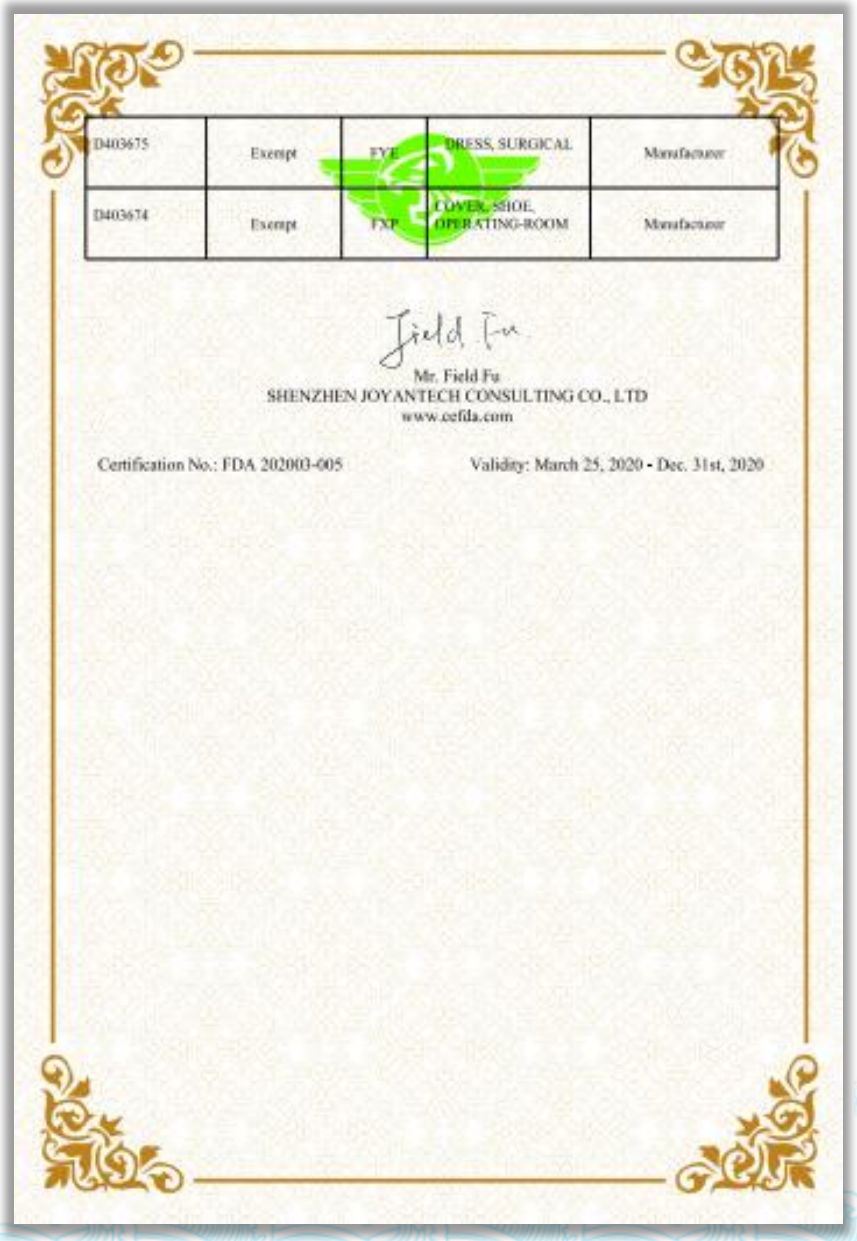
Establishment: SUNWAY (SHENZHEN) PRODUCTS LIMITED
Address: E Building,Junxuan company,16# Yinkui Road, Kuixin community, Kuichong street,Dapeng New District, Shenzhen, Guangdong, 518119, CHINA

Owner/Operator No.: 10064363
Registration No.: 3014331592

Listing No.	Premarket Submission No.	Product Codes	Device Name	Activities
D378901	Exempt	MSH	Respirator, surgical	Manufacturer
D378898	Exempt	LYU	ACCESSORY, SURGICAL APPAREL	Manufacturer
D403677	Exempt	FXO	SUIT, SURGICAL	Manufacturer
D403676	Exempt	OEA	Non-surgical isolation gown	Manufacturer
D403678	Exempt	KHA	MASK, SCAVENGING	Manufacturer
D403673	Exempt	FYF	CAP, SURGICAL	Manufacturer

SUNWAY (SHENZHEN) PRODUCTS LIMITED

FDA



D403675	Exempt	FYE	DRESS, SURGICAL	Manufacturer
D403674	Exempt	FXP	COVER, SHOE, OPERATING-ROOM	Manufacturer

Field Fu

Mr. Field Fu
SHENZHEN JOYANTECH CONSULTING CO., LTD
www.cefda.com

Certification No.: FDA 202003-005 Validity: March 25, 2020 - Dec. 31st, 2020

SUNWAY (SHENZHEN) PRODUCTS LIMITED

FDA

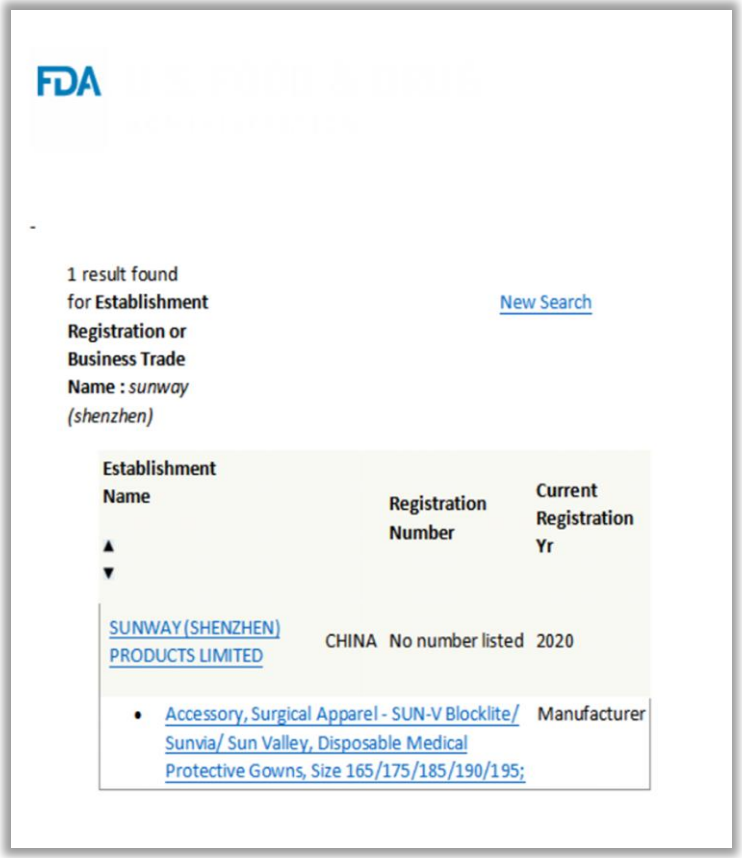
Business Trade Name : *sunway (shenzhen)*
Establishment Registration or FEI Number : *3014331592*

New Search[6]

Establishment Name [7] [8]	Registration Number	Current Registration Yr
SUNWAY (SHENZHEN) PRODUCTS LIMITED[9] CHINA	3014331592	2020
• accessory, surgical apparel - Accessory,Surgical Apparel; SUN-V Blocklite/ Sunvia/ Sun Valley, Disposable Medical Protective Gowns, size 165/175/185/190/195; SUN-V Blocklite/ Sunvia/ Sun Valley, Disposable Protective Clothing, size 165/175/185/190/195; SUN-V Blocklite/ Sunvia/ Sun Valley, Medical Disposable Goggles [10]		Manufacturer
• respirator, surgical - SUN-V Blocklite/ Sunvia/ Sun Valley, Disposable Medical Face Mask [11]		Manufacturer
• cap, surgical - Cap,Surgical [12]		Manufacturer
• cover, shoe, operating-room - Cover,Shoe,Operating-Room [13]		Manufacturer
• dress, surgical - Dress,Surgical [14]		Manufacturer
• non-surgical isolation gown - Non-Surgical Isolation Gown [15]		Manufacturer
• suit, surgical - Suit,Surgical [16]		Manufacturer
• mask, scavenging - Face mask; Protective mask KN95 [17]		Manufacturer

SUNWAY (SHENZHEN) PRODUCTS LIMITED

FDA



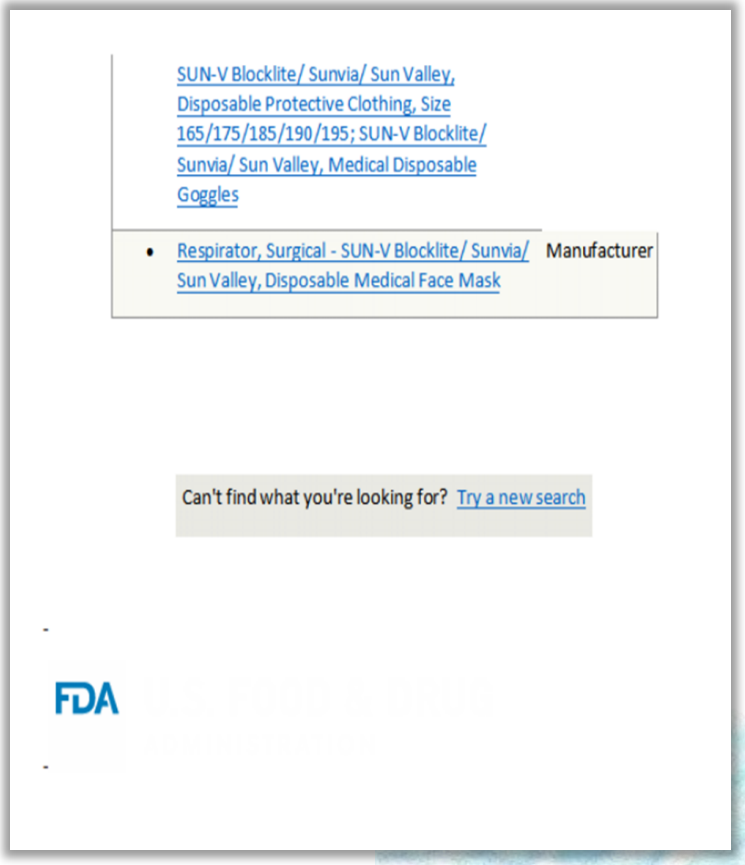
FDA U.S. Food & Drug Administration

1 result found for **Establishment Registration or Business Trade Name :** *sunway (shenzhen)*

New Search

Establishment Name		Registration Number	Current Registration Yr
SUNWAY (SHENZHEN) PRODUCTS LIMITED	CHINA	No number listed	2020

- Accessory, Surgical Apparel - SUN-V Blocklite/ Sunvia/ Sun Valley, Disposable Medical Protective Gowns, Size 165/175/185/190/195; — Manufacturer



SUN-V Blocklite/ Sunvia/ Sun Valley, Disposable Protective Clothing, Size 165/175/185/190/195; SUN-V Blocklite/ Sunvia/ Sun Valley, Medical Disposable Goggles

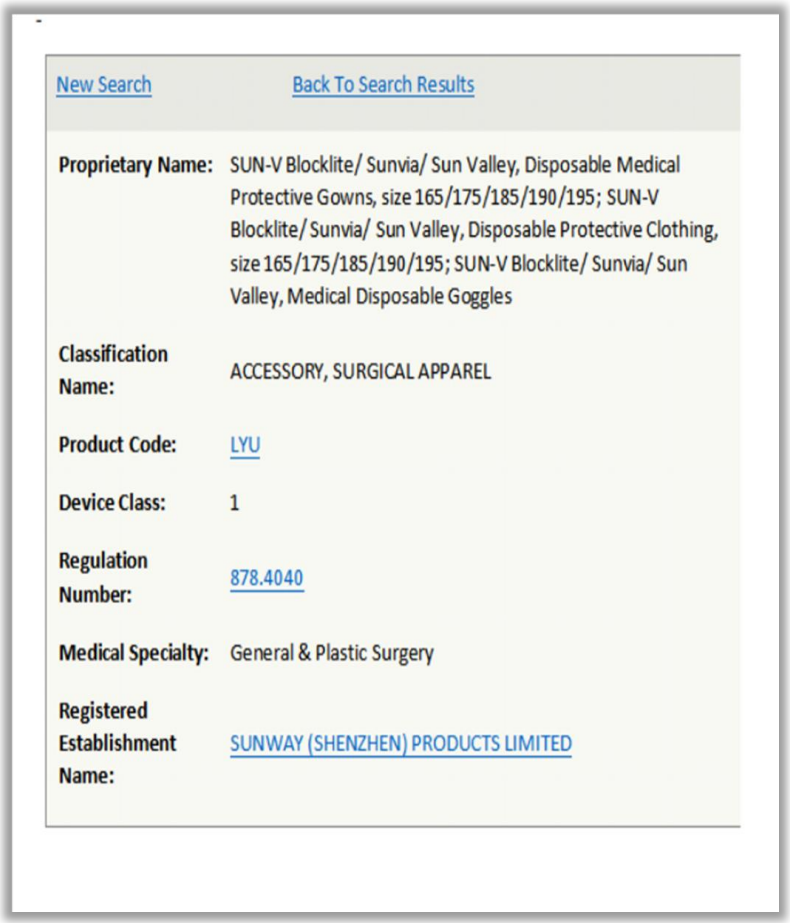
- Respirator, Surgical - SUN-V Blocklite/ Sunvia/ Sun Valley, Disposable Medical Face Mask — Manufacturer

Can't find what you're looking for? Try a new search

FDA U.S. Food & Drug Administration

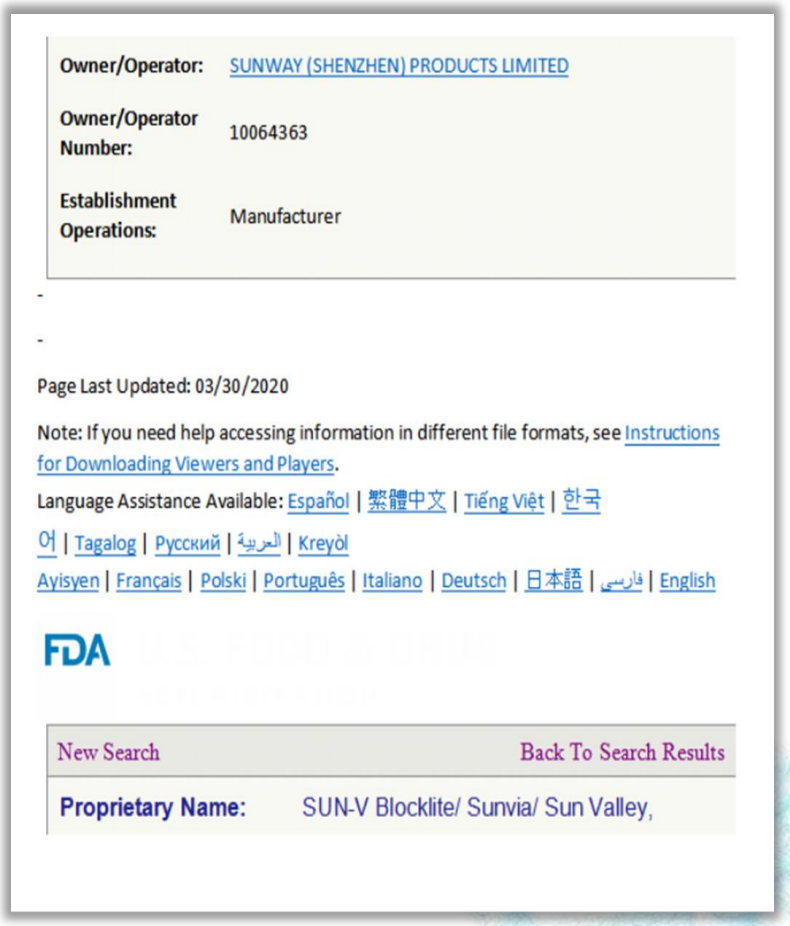
SUNWAY (SHENZHEN) PRODUCTS LIMITED

FDA



New Search Back To Search Results

Proprietary Name:	SUN-V Blocklite/ Sunvia/ Sun Valley, Disposable Medical Protective Gowns, size 165/175/185/190/195; SUN-V Blocklite/ Sunvia/ Sun Valley, Disposable Protective Clothing, size 165/175/185/190/195; SUN-V Blocklite/ Sunvia/ Sun Valley, Medical Disposable Goggles
Classification Name:	ACCESSORY, SURGICAL APPAREL
Product Code:	LYU
Device Class:	1
Regulation Number:	878.4040
Medical Specialty:	General & Plastic Surgery
Registered Establishment Name:	SUNWAY (SHENZHEN) PRODUCTS LIMITED



Owner/Operator:	SUNWAY (SHENZHEN) PRODUCTS LIMITED
Owner/Operator Number:	10064363
Establishment Operations:	Manufacturer

Page Last Updated: 03/30/2020

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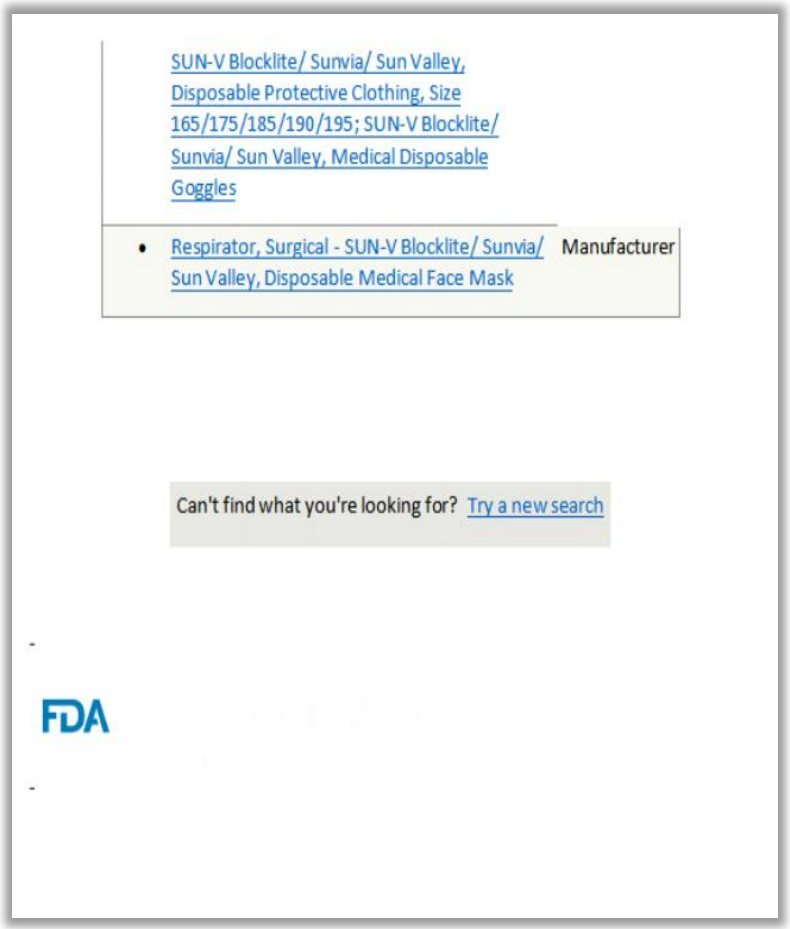
FDA

New Search Back To Search Results

Proprietary Name: SUN-V Blocklite/ Sunvia/ Sun Valley,

FDA


SUN-V Blocklite/ Sunvia/ Sun Valley, Disposable Protective Clothing, Size 165/175/185/190/195; SUN-V Blocklite/ Sunvia/ Sun Valley, Medical Disposable Goggles
Respirator, Surgical - SUN-V Blocklite/ Sunvia/ Sun Valley, Disposable Medical Face Mask
Manufacturer
Can't find what you're looking for? Try a new search
FDA