



VERIDIA

Certification Pack.

Face Shield With Flip Screen.

25970



This pack contains

TGA Certificate
Anti-Fog Test Report
Eye Protection Test Report
EU Certificate

Date Released

February 2021



PE Face Shield is made of PE material providing ultimate clarity, be designed for procedures and environments where the risk of exposure to blood and/or bodily fluids through splashing is possible.

Can be used together with a Surgical/Non-surgical mask & Goggle if required.

Reusable Face Shield with Flip Screen

25970

Colour	White
Features	<ul style="list-style-type: none"> Fully transparent protective mask, anti-fog, anti-splash, isolation mask, full face protection. One size fits all. Resistant to fogging. Clear for maximum visibility. Can be used together with others PPE (such as mask/goggle). Lightweight and comfortable to wear, quick and easy to put on. Elastic band can be adjusted according to your need.
Standard(s)	Restriction of Hazardous Substances (RoHS) Test Report No. VNHL2002001653HG by SGC FDA 21 CFR 177.1630 Test Report No. CANEC200644060 by SGS
TGA Approved	ARTG ID: 340227
Recommendation	This mask is totally foamless making it suitable to clean/sterilise after each shift and use again the next day.
Country Of Origin	Vietnam



Australian Government
Department of Health
Therapeutic Goods Administration

Record Summary	340227 IP Supply Pty Ltd - Face splash shield, reusable
Sponsor	IP Supply Pty Ltd
Therapeutic Type	Medical Device
Product Category	Included Class 1
ARTG Start Date	27/07/2020
Postal Address	Unit 8 4A Bachell Avenue, Lidcombe, NSW, 2141 Australia
Billing Address	Unit 8 4A Bachell Avenue, Lidcombe, NSW, 2141 Australia
Product Type	Medical Device - Class 1 - Included
Status	Active
Approval Area	Medical Devices

Conditions

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Manufacturers

Name	Address	Certificate number(s)
MINH MAN PRINTING CO LTD	14/5 Bau Bang 13 Ward Tan Binh District Ho Chi Minh , Thanh Pho , 72110 Vietnam	

Products

1 . Face splash shield, reusable

Product Type	Single Device Product	Status	Current
		Effective Date	27/07/2020
GMDN	64779 Face splash shield, reusable		
Functional Description	Not included on record		
Intended Purpose	Uses of FACE SHIELD - Block direct shot, virus, dirt in the air - The shield is made from polyester film, compliance for medical device, ROHS environmental standard, safety for users, does not affect the wearer's vision, does not cause dew when talking. - Does not cause skin irritation in direct contact - The polymer film has temperature resistance over 100o C which is easily cleaned with hot water, scratch-resistant, reusable - Appropriate for children and adults.		

Variant Information

Device Information

Record Summary

Record Summary

Specific Conditions

No Specific Conditions included on Record



Test Report

No. CANEC2006440601

Date: 11 May 2020

Page 1 of 3

HX PRODUCTION LIMITED

HZ PACKFILM LIMITED

NO. 14, QUNHUA ROAD, WEST SIDE, WEST CIRCLE ROAD, JIANGMEN, GUANGDONG, CHINA

NO. 71, SONGNIAN ROAD, SIX JOINT PINGDI, LONGGUAN, SHENZHEN, CHINA

The following sample(s) was/were submitted and identified on behalf of the clients as : PET FILM

SGS Job No. : CP20-020419 - GZ

Client Ref. Info. : Be used for:TCC/UY Series/UY4200/UY4300/SC/XF/XFK/
RF/GW/EBG/EBA/F/V/HL/ST/BEF/RF-SILVER/RF-WHITE/HCGG-AF

Date of Sample Received : 06 May 2020

Testing Period : 06 May 2020 - 11 May 2020

Test Requested : Selected test(s) as requested by client.

Test Method : Please refer to next page(s).

Test Results : Please refer to next page(s).

Result Summary :

Test Requested	Conclusion
FDA 21 CFR 177.1630-Chloroform-soluble extractive residues	PASS

Conclusion : The tested parameters comply with the requirement stated in Food and Drug Administration Regulations.

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

Ivy Ren

Approved Signatory



SGS-CSTC Standards Technical Services Co., Ltd.
Guangzhou Branch Testing Center Chemical Laboratory.

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Attention: To check the authenticity of testing /inspection report & certificate, please contact us at telephone: (86-755) 8307 1443, or email: CN.Doccheck@sgs.com

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Test Report

No. CANEC2006440601

Date: 11 May 2020

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Test Results :

Test Part Description :

Specimen No.	SGS Sample ID	Description	Material (claimed by the client)
SN1	CAN20-064406.001	Colorless transparent sheet	PET

FDA 21 CFR 177.1630—Chloroform-soluble extractive residues

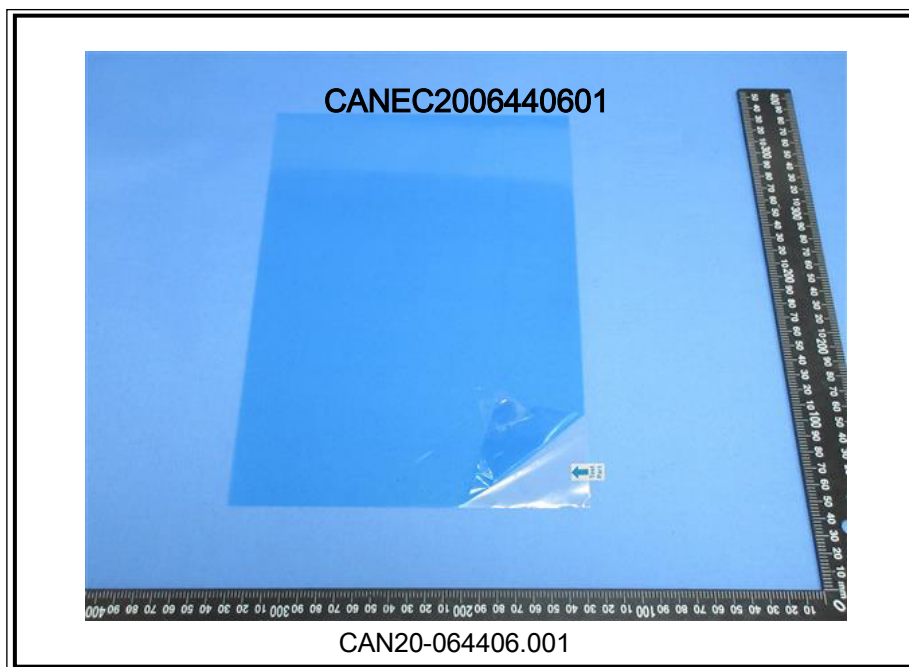
Test Method : With reference to US FDA 21 CFR 177.1630.

<u>Simulant Used</u>	<u>Time</u>	<u>Temperature</u>	<u>Max. Permissible Limit</u>	<u>Result of 001</u>	<u>Comment</u>
Distilled Water	24.0hr(s)	120°F	0.5mg/sq. in	<0.1mg/sq. in	PASS
n-Heptane	24.0hr(s)	120°F	0.5mg/sq. in	<0.1mg/sq. in	PASS
8% Ethanol	24.0hr(s)	120°F	0.5mg/sq. in	<0.1mg/sq. in	PASS

Notes :

mg/inch²= milligram per square inch

Sample photo:



SGS authenticate the photo on original report only



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Guangzhou Branch Testing Center Chemical Laboratory.

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Test Report

No. CANEC2006440601

Date: 11 May 2020

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*** End of Report ***



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Guangzhou Branch Testing Center Chemical Laboratory

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PZA Nürnberg
 Testing Centre Eye-Protection
 Tillystraße 2
 90431 Nürnberg

Test Report

No. 1254-PZA-20
 Rev. 0

Contact person: Dr. Andreas Winbauer
 phone: +49 911 655-3034
 fax: +49 911 655-3033
 e-mail: andreas.winbauer@dincertco.de

Accredited by the Deutsche
 Akkreditierungsstelle GmbH (DAkkS)
 D-PL-11125-01

Customer

MINH MAN PRINTING CO., LTD
 14/5 Bau Bang Street
 Ward 13, Tan Binh District
 HO CHI MINH CITY
 VIETNAM

Test report contains	Main part and 1 annex
Number of pages	5
Product	Face shield
Arrival of samples	2020-06-12
Period of testing	2020-07-15 to 2020-07-21
Reference Standard	DIN EN 166 : 2002-04
Remarks	Special testing sequence

This test report relates to the mentioned test samples. Without the permission of the DIN CERTCO test centre Nürnberg this test report is not permitted to be duplicated in extracts. This test report does not entitle to carry any certification mark.

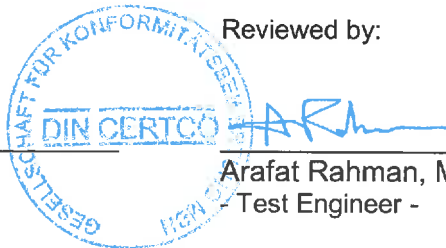
Nürnberg, 2020-07-21

Compiled by:



Dr. Andreas Winbauer
 - Head of Testing Laboratory -

Reviewed by:



Arafat Rahman, M. Sc.
 - Test Engineer -



Test objects, tests and results

Based on the tables as written in the standard DIN EN 166, the main part assigns the test samples to the named tests. Each individual test result is documented in the annexes according to the named standards.

Signs and symbols:

- + meet the requirements
- ***do not meet the requirements***
- / not tested or not applicable
- Ab interruption of the testing sequence


The uncertainty of optical measurements corresponds to the required one in DIN EN 167.

Unless stated otherwise, the measurements were carried out in the main viewing point of the samples and, in the case of lenses with corrective power, at the applicable reference point.

Test Report No. 1254-PZA-20

Main Part: Page 3 of 3

Samples and summary of all test results

Type:	Face shield, type "FM3"					
Test mark:	12541-PZA-20					
Number of delivered parts: 16			Number of test samples: 16			
						
Test- sequence	Requirements	according to		Tests according to		Sample 0254-1 to 0254-16
		DIN EN	Clause	DIN EN	Clause	
1	User information	166	10	166	10	+
2	Design and manufacturing requirements	166	6	166	6	+
3	Lateral protection	166	7.2.8	168	19	+
4	Field of vision	166	7.1.1	168	18	+
5	Diffusion of light	166	7.1.2.3	167	4	+
6	Spherical refractive power and astigmatic refractive power	166	7.1.2.1	167	3	+
7	Prismatic refractive power	166	7.1.2.1	167	3	+
8	Transmittance	166	7.1.2.2	167	6	+
9	Increased robustness	166	7.1.4.2	168	3	+
10	Resistance to ignition	166	7.1.7	168	7	+
11	Protection against splashes of liquids	166	7.2.4b	168	10.2	+
Individual results of each test sample see annex 1						

Marking:

Frame:	CE G-CERTi system service GKVN-0317-MD ISO 13485:2016 Face Shield Direct Splash Protection Warning: Use only against liquids or dust. This shield is not impact resistant. Do not use as protection against open flame or sparks Made in Vietnam
Oculars:	None

Test Report No. 1254-PZA-20

Annex 1: Page 1 of 2

ANNEX 1

Type:	Face shield, type "FM3"
Test mark:	12541-PZA-20

Description of the type

Condition of the test item at delivery:	Undamaged	
Frame:	Material:	Plastics, metal, textile
	Colour:	White, black, blue
Oculars:	Material:	Plastics
	Colour:	Untinted
	Centre thickness:	0.4 mm
	Dimension:	340 mm x 208 mm
User information:	Available and complete, including additional information	
Design and manufacturing requirements:	Fulfill the requirements	

Diffusion of light, refractive powers, transmittance, lateral protection and field of vision

Test↓	Sample →		0254-1	0254-2	0254-3
Reduced luminance coefficient	R	$\frac{\text{cd/m}^2}{\text{lx}}$	0.06	0.17	0.16
	L		0.05	0.19	0.21
Spherical power	R	dpt	0.00	0.00	+0.01
	L		0.00	0.00	+0.01
Astigmatic power	R	dpt	0.01	0.01	0.01
	L		0.01	0.01	0.01
Difference in prismatic effect horizontal		cm/m	0.13 Base out	0.10 Base out	0.10 Base out
Difference in prismatic effect vertical		cm/m	0.00	0.00	0.00
Optical class			1	1	1
Luminous transmittance τ_{v1} based on CIE source A	R	%	92.9	92.8	92.7
	L		92.7	92.4	92.5
Lateral protection			+	+	+
Field of vision			+	+	+

Test Report No. 1254-PZA-20

Annex 1: Page 2 of 2

Type:	Face shield, type "FM3"
Test mark:	12541-PZA-20

Increased robustness

Ambient temperature: (23±5)° C

Sample	Impact point	Comments
0254-4	1	+
0254-5	1	+
0254-6	2	+
0254-7	2	+
0254-8	3	+
0254-9	4	+
0254-10	1	+
0254-11	1, 4	+, +
0254-12	2	+
0254-13	2, 3	+, +

 Impact point 1: left eye frontal
 Impact point 2: right eye frontal

 Impact point 3: left eye side
 Impact point 4: right eye side

Resistance to ignition

Test ↓	Sample →	0254-7	0254-8	0254-9
Resistance to ignition		+	+	+

Protection against splashes of liquids

Test ↓	Sample →	0254-14	0254-15	0254-16
Comments		+	+	+



EU Type-Examination Certificate

Holder	MINH MAN PRINTING CO., LTD 14/5 Bau Bang Street Ward 13, Tan Binh District Ho Chi Minh City VIETNAM
Registration No.	C6514MMP/R0
Product	Face shield
Type, Model	FM3
Testing basis	Certification Scheme Eye Protection: Category II-Products acc. to PPE-Directive/ Regulation (2017-03)
Test reports/Test marks	12541-PZA-20
Marking of the product	Detailed marking see annex
Validity period	2020-07-24 to 2021-07-23
Conformity	DIN CERTCO confirms that the prototype complies with the essential health and safety requirements according to the Annex II of Regulation (EU) 2016/425 on personal protective equipment. This assessment was based on the test samples submitted by the manufacturer or authorised representative, the technical documentation and the test report of the test laboratory.

Any previous versions of this EU Type-Examination Certificate hereby cease to be valid.

Please see the annex for further information.

2020-07-24

Dipl.-Wi.-Ing. (FH) Sören Scholz
Notified Body 0196



ANNEX

Page 1 of 2

Certificate	C6514MMP/R0 dated 2020-07-24
Manufacturer's Identification	MMP
Marking of the product	MMP CE
Product specification	<p>Mechanical strength: increased robustness S (23°C) Optical class: 1 Protection against droplets and splashes of liquids: 3</p> <p>Ocular Material: Polyester Colour: Untinted Centre thickness: 0.4 mm</p> <p>Frame Material: PP, fabric, metal button Colour: White/black/blue</p>
Additional product information	<p>The eye protection device meets the basic health and safety requirements of the PPE regulation. It does not offer any protection against mechanical impacts. The eye protection device protects against droplets and splashes of liquids. This reduces the risk of droplet infection. Due to its design, full protection against viruses, bacteria or other biological agents is only given to a limited extent. The eye protection device can be combined with facemasks. The eye protection device shall be disposed of after use. Reuse is at the discretion of the user.</p> <p>Marking of the product: The label (including the manufacturer's code) is not required on the product itself, but shall be applied to each packaging unit.</p> <p>Scope of testing: DIN EN 166:2002-04 Clauses 6.1 / 6.2 / 6.3 / 7.1.1 + 7.2.8 / 7.1.2 / 7.1.7 / 7.2.4 / 10</p>
Regulations/Liabilities	This EU Type-Examination Certificate is the property of DIN CERTCO and may be withdrawn if the conditions on which its issue was based are no longer met.



ANNEX

Page 2 of 2

Certificate

C6514MMP/R0 dated 2020-07-24

The information leaflet (instructions for use) for the specified eye protection product must be written in the official language of the country of destination and include, among other things, the following details of the Notified Body:

DIN CERTCO Gesellschaft für
Konformitätsbewertung mbH
Alboinstraße 56
12103 BERLIN
GERMANY

Identification number of the Notified Body: 0196

As far as possible, the product must be marked with a type, batch or serial number or other element allowing its identification.

As far as possible, the product must be marked with the name and postal address of the manufacturer or, if the manufacturer is not based in the European Economic Area, the name and contact address of an authorised representative or importer based in the European Economic Area.

The product or its packaging must be indelibly and unambiguously marked with the month and year of manufacture and/or the month and year of obsolescence.

It is not permitted to mark the product with the identification number 0196.

All changes to the product, the technical documentation or to the quality assurance system must be notified to DIN CERTCO in writing.

The General Terms and Conditions of DIN CERTCO apply.

