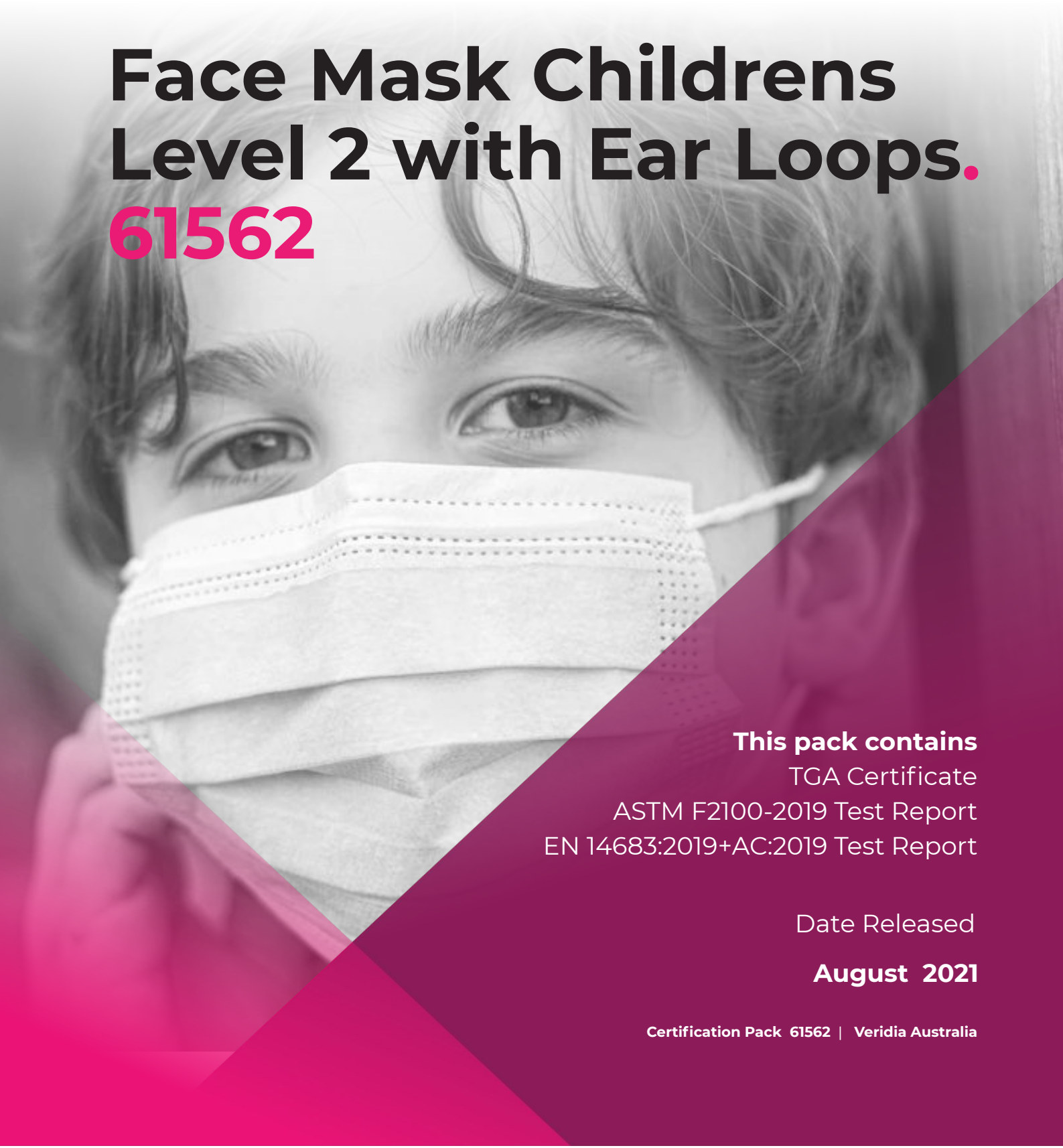
VERIDIA

Certification Pack.

Face Mask Childrens Level 2 with Ear Loops.

61562



This pack contains

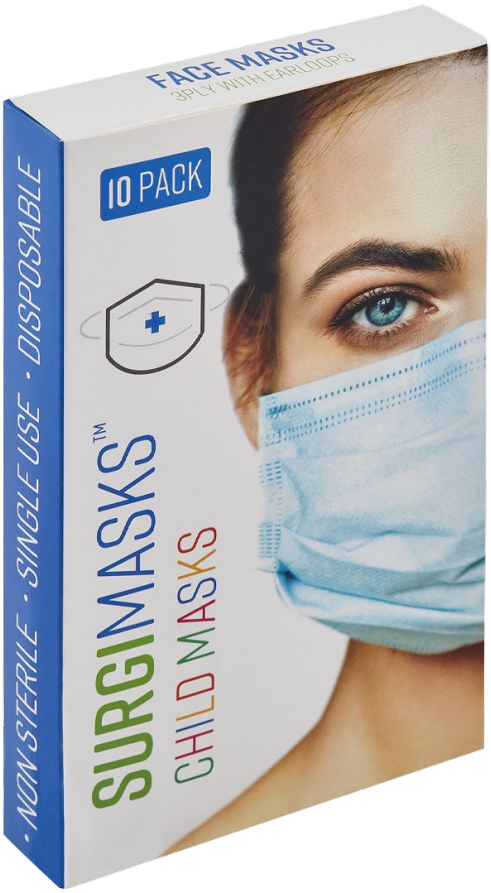
TGA Certificate

ASTM F2100-2019 Test Report

EN 14683:2019+AC:2019 Test Report

Date Released

August 2021



Face Mask Childrens Level 2 with Ear Loops (10) **61562**

Features	Designed especially for smaller faces, our 3-ply kid-sized disposable face masks with ear loops, offer extra high levels of bacteria filtration, liquid resistance, breathability and comfort. Ideal for any clinical, hospital and care setting as defensive protection against bacteria and viruses, and to reduce vapour diffusion. • Single-use, disposable • 3-ply non-woven material, designed for child-sized face • Elasticated ear loop and encased nose wire for fit and comfort • TGA certified Level 2 rating • High level of breathability, moisture resistance and bacterial filtration
Colour	- Blue
Unit	- Pkt
Pack Qty	- 10
Carton Qty	- 50

Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	339834	Medical Industries Australia Hold Co Pty Ltd - Mask, surgical, single use

ARTG entry for	Medical Device Included Class 1
Sponsor	Medical Industries Australia Hold Co Pty Ltd
Postal Address	2 Imperata Close, Kemps Creek, NSW, 2178 Australia
ARTG Start Date	20/07/2020
Product Category	Medical Device Class 1
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
Hebei Shenda Pharmaceutical Co Ltd	No 27 Donghai Road Cangzhou Development Zone, Hebei, China

Products

1 . Mask, surgical, single use

Product Type	Single Device Product	**Effective Date**	20/07/2020
GMDN	35177 Mask, surgical, single use		
Intended Purpose	This is disposable device made from fabric or other material placed over the nose and mouth by medical personnel or non-medical personnel to prevent the transmission of airborne organisms and potential contaminants during surgical or examination of a patient.		

Specific Conditions

No Specific Conditions included on Record

Public Summary

XIANTAO TONGDA NON-WOVEN PRODUCTS CO.,LTD
NO.28,PENGCHANG ROAD,433018,XIANTAO

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

Sample Description	:	(A)3 ply surgical face mask
Composition	:	(A)Non woven & Melt blown
Sample Color	:	(A)Blue
Lot No.	:	001
Manufacturer	:	XIANTAO TONGDA NON-WOVEN PRODUCTS CO.,LTD
Test Performed	:	Selected test(s) as requested by applicant
Sample Receiving Date	:	Oct 12, 2020
Testing Period	:	Oct 14, 2020 - Nov 25, 2020
Test Result(s)	:	Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s).

Signed for and on behalf of
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd Testing Center

Sara Guo (Account Executive)

Helen Xuan (Authorized Signatory)

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Test Result

ASTM F2100-2019 Standard Specification for Performance of Materials Used in Medical Face Masks

Section 6 Requirement

Section 6.1 Bacterial Filtration Efficiency (BFE)
(ASTM F2101- 2019)

Sample A

Test Side	:	Inside
Test Area	:	Approximately 60 cm^2
Flow Rate	:	28.3 L/min (1 ft^3/min)
Pre-Conditioning	:	Minimum of 4 hours at 21±5°C (70±10°F) and 85±5% R.H.
Positive Control Average	:	2572 CFU
Negative Monitor Count	:	< 1 CFU
Mean Particle Size(Pre)	:	2.80μm
Mean Particle Size(Post)	:	2.76μm
Test bacteria	:	Staphylococcus aureus ATCC 6538

Test Item	Specimen No.	Plate Count Total for Each Stage	Result(%)
Bacterial Filtration Efficiency (BFE), %	1	4 CFU	99.8%
	2	1 CFU	99.9%
	3	2 CFU	99.9%
	4	1 CFU	99.9%
	5	1 CFU	99.9%

Remark: Performance Requirement: Level 1 Barrier≥95%, Level 2 Barrier≥98%, Level 3 Barrier≥98%

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Section 6.1 Differential Pressure

(EN 14683 :2019+AC:2019 Annex C)

Sample: A

Test number and location : Randomly test in different location (1 around and 4 away from the centric point) on each of the 5 masks

Pre-Conditioning : Minimum of 4 hours at 21±5°C (70±10°F) and 85±5% R.H.

Test Area : 4.9 cm^2

Flow Rate : 8 l/min

Specimen No.	Test Area No.	Different Pressure for each tested area (mm H_2O/cm^2)	The average value for each test specimen (mm H_2O/cm^2)
1	1-1	3.99	3.9
	1-2	3.67	
	1-3	3.93	
	1-4	3.94	
	1-5	4.00	
2	2-1	3.96	3.8
	2-2	3.82	
	2-3	3.86	
	2-4	3.84	
	2-5	3.29	
3	3-1	3.12	3.7
	3-2	3.76	
	3-3	4.04	
	3-4	3.73	
	3-5	3.85	
4	4-1	3.15	3.8
	4-2	3.87	
	4-3	3.92	
	4-4	4.02	
	4-5	4.00	
5	5-1	3.69	3.8
	5-2	3.72	
	5-3	3.68	
	5-4	4.06	
	5-5	3.93	

Remark:

1) Performance Requirement: Level 1 Barrier: <5.0mm H_2O/cm^2, Level 2 Barrier: <6.0 mm H_2O/cm^2, Level 3 Barrier: <6.0 mm H_2O/cm^2
2) The number of specimens that shall be tested is minimum 5, but can be greater and shall be increased if necessary to allow for an AQL (Acceptable Quality Level) of 4%.

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Section 6.1 Sub-micron particulate filtration efficiency(PFE)*
(ASTM F2299/F2299M-03 (Reapproved 2017))

Sample: A

Test Side	:	Blue colour (Outside)
Area Tested	:	41.61 cm^2
Particle Size	:	0.1 μm
Pre-Conditioning	:	Minimum of 4 hours at 21±3°C and 30-50±5% R.H.
Test Condition	:	21±3°C and 50±5% R.H.
Standard Deviation	:	0.002

Test Specimen	Test Article Counts	Average Control Counts	Filtration Efficiency (%)
1	395	98517	99.60
2	894	91626	99.02
3	487	93957	99.48
4	316	90440	99.65
5	497	88787	99.44

Remark:
1) Performance Requirement: Level 1 Barrier≥95%, Level 2 Barrier≥98%, Level 3 Barrier≥98%
2) The procedure incorporated a non-neutralized challenge. The non-neutralized aerosol is also specified in the FDA guidance document on surgical face masks.
3) * Tests denoted with an * in this test report have been carried out by SGS Hong Kong Hardline laboratory, this test is under ISO 17025 Accredited.

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Section 6.1 Resistance to Penetration by Synthetic Blood
(ASTM F1862/F1862M-2017)

Sample: A
Test Blood Pressure : Level 1 Barrier-80mmHg
Test volume of synthetic blood : 2 mL
Pre-Conditioning : Minimum of 4 hours at 21±5°C (70±10°F) and 85±5% R.H.
Distance of the mask to the tip of cannula : 30.5cm (12.0 in.)

Test Specimen#	Penetration on inside surface	Conclusion	Test Specimen#	Penetration on inside surface	Conclusion
1	None Seen	Pass	17	None Seen	Pass
2	None Seen	Pass	18	None Seen	Pass
3	None Seen	Pass	19	None Seen	Pass
4	None Seen	Pass	20	None Seen	Pass
5	None Seen	Pass	21	None Seen	Pass
6	None Seen	Pass	22	None Seen	Pass
7	None Seen	Pass	23	None Seen	Pass
8	None Seen	Pass	24	None Seen	Pass
9	None Seen	Pass	25	None Seen	Pass
10	None Seen	Pass	26	None Seen	Pass
11	None Seen	Pass	27	None Seen	Pass
12	None Seen	Pass	28	None Seen	Pass
13	None Seen	Pass	29	None Seen	Pass
14	None Seen	Pass	30	None Seen	Pass
15	None Seen	Pass	31	None Seen	Pass
16	None Seen	Pass	32	None Seen	Pass
Number of Pass:		32			
Overall result:		Acceptable			

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Test Blood Pressure : Level 2 Barrier-120mmHg
Test volume of synthetic blood : 2 mL
Pre-Conditioning : Minimum of 4 hours at 21±5°C (70±10°F) and 85±5% R.H.
Distance of the mask to the tip of cannula : 30.5cm (12.0 in.)

Test Specimen#	Penetration on inside surface	Conclusion	Test Specimen#	Penetration on inside surface	Conclusion
1	None Seen	Pass	17	None Seen	Pass
2	None Seen	Pass	18	None Seen	Pass
3	None Seen	Pass	19	None Seen	Pass
4	None Seen	Pass	20	None Seen	Pass
5	None Seen	Pass	21	None Seen	Pass
6	None Seen	Pass	22	None Seen	Pass
7	None Seen	Pass	23	None Seen	Pass
8	None Seen	Pass	24	None Seen	Pass
9	None Seen	Pass	25	None Seen	Pass
10	None Seen	Pass	26	None Seen	Pass
11	None Seen	Pass	27	None Seen	Pass
12	None Seen	Pass	28	None Seen	Pass
13	None Seen	Pass	29	None Seen	Pass
14	None Seen	Pass	30	None Seen	Pass
15	None Seen	Pass	31	None Seen	Pass
16	None Seen	Pass	32	None Seen	Pass
Number of Pass:		32			
Overall result:		Acceptable			

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Test Blood Pressure : Level 3 Barrier-160mmHg
Test volume of synthetic blood : 2 mL
Pre-Conditioning : Minimum of 4 hours at 21±5°C (70±10°F) and 85±5% R.H.
Distance of the mask to the tip of cannula : 30.5cm (12.0 in.)

Test Specimen#	Penetration on inside surface	Conclusion	Test Specimen#	Penetration on inside surface	Conclusion
1	None Seen	Pass	17	None Seen	Pass
2	None Seen	Pass	18	None Seen	Pass
3	None Seen	Pass	19	Seen	Fail
4	None Seen	Pass	20	None Seen	Pass
5	Seen	Fail	21	None Seen	Pass
6	None Seen	Pass	22	None Seen	Pass
7	None Seen	Pass	23	None Seen	Pass
8	None Seen	Pass	24	None Seen	Pass
9	None Seen	Pass	25	None Seen	Pass
10	None Seen	Pass	26	None Seen	Pass
11	None Seen	Pass	27	None Seen	Pass
12	None Seen	Pass	28	None Seen	Pass
13	None Seen	Pass	29	None Seen	Pass
14	None Seen	Pass	30	None Seen	Pass
15	Seen	Fail	31	None Seen	Pass
16	None Seen	Pass	32	None Seen	Pass
Number of Pass:		29			
Overall result:		Acceptable			

Remark:
1) Test was conducted within 1min after removal from conditioning chamber.
2) An acceptable quality limit of 4.0% is met for a single sampling plan when 29 or more of the 32 tested specimens show pass results.

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Section 6.2 Flammability
(16 CFR Part 1610 - 2008)

Sample : **A**
Fabric Surface : Smooth
Test Specimen Direction : Length

	As Received
	Burn Code
(1)	IBE
(2)	IBE
(3)	IBE
(4)	IBE
(5)	IBE

Flammability Classification: Class 1

Requirement: Class 1 for Level 1/ Level 2/ Level 3

Conclusion: Pass

Remarks
Class 1 Normal Flammability
Class 1 textiles exhibit normal flammability and are acceptable for use in clothing.

Burn Code Description:
IBE = Ignited, but extinguished

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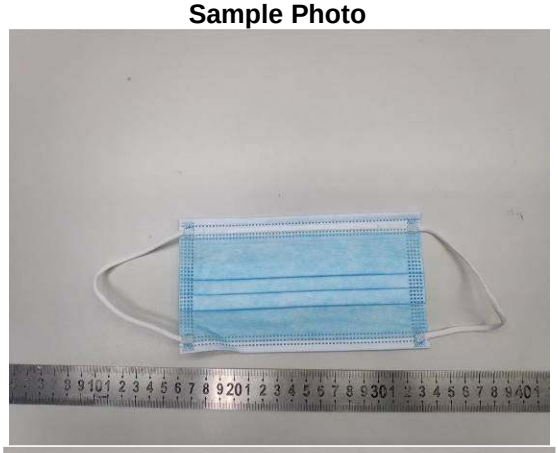
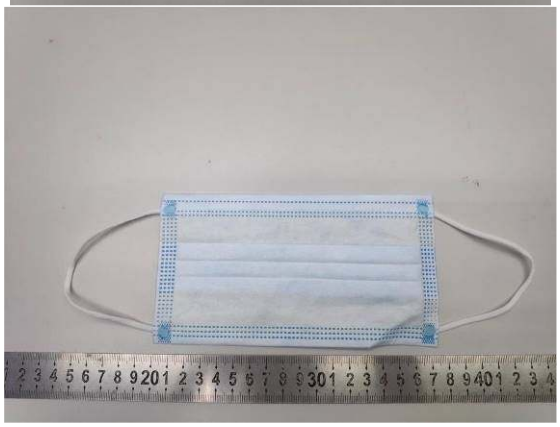
Sample Photo





The statement of conformity in this test report is only based on measured values by the laboratory and does not take their uncertainties into consideration.

End of Report

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XIANTAO TONGDA NON-WOVEN PRODUCTS CO., LTD
NO.28, PENGCHANG ROAD, 433018, XIANTAO

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

Sample Description	:	(A)3 ply surgical face mask
Composition	:	(A)Non woven & Melt blown
Sample Color	:	(A)Blue
Roll/ Lot No.	:	200315
Test Performed	:	Selected test(s) as requested by applicant
Sample Receiving Date	:	Jul 03, 2020
Testing Period	:	Jul 03, 2020 - Jul 17, 2020
Test Result(s)	:	Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s).

Signed for and on behalf of
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd Testing Center

Sara Guo (Account Executive)

Helen Xuan (Authorized Signatory)

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Test Result

EN 14683:2019+AC:2019 Medical Face Masks-Requirements and Test Methods

Clause 5.2 Performance Requirement

Clause 5.2.2 Bacterial Filtration Efficiency (BFE)
(EN 14683:2019+AC:2019 Annex B)

Sample: A

Test Side	:	Inside
Test Area	:	Approximately 60 cm^2
Flow Rate	:	28.3 L/min
Pre-Conditioning	:	Minimum of 4 hours at 21±5°C and 85±5% R.H.
Dimensions of test specimen	:	175 mm x 155 mm
Positive Control Average	:	2448.5 CFU
Negative Monitor Count	:	< 1 CFU
Mean Particle Size	:	3.0 ±0.3μm
Test bacteria	:	Staphylococcus aureus ATCC 6538

Test Item	Specimen No.	Result
Bacterial Filtration Efficiency (BFE)	1	99.9%
	2	99.9%
	3	99.9%
	4	99.9%
	5	99.9%

Remark:
1) Performance Requirement: Type I≥95%, Type II≥98%, Type IIR ≥98%
2) The number of specimens that shall be tested is minimum 5, but can be greater and shall be increased if necessary to allow for an AQL(Acceptable Quality Level) of 4%.

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Clause 5.2.3 Breathability

(EN 14683 :2019+AC:2019 Annex C)

Sample: A

Test Side : Randomly test in different location (1 around and 4 away from the centric point) on each of the 5 masks

Pre-Conditioning : Minimum of 4 hours at 21±5°C and 85±5% R.H.

Test Area : 4.9 cm^2

Flow Rate : 8 l/min

Specimen No.	Test Area No.	Different Pressure for each tested area (Pa/cm^2)	The average value for each test specimen (Pa/cm^2)
1	1-1	34.2	35
	1-2	34.8	
	1-3	30.1	
	1-4	39.9	
	1-5	38.0	
2	2-1	31.7	33
	2-2	34.1	
	2-3	29.4	
	2-4	34.0	
	2-5	33.7	
3	3-1	34.5	33
	3-2	32.7	
	3-3	28.1	
	3-4	33.9	
	3-5	36.9	
4	4-1	34.2	34
	4-2	32.5	
	4-3	30.2	
	4-4	34.1	
	4-5	36.6	
5	5-1	33.8	32
	5-2	32.0	
	5-3	34.6	
	5-4	29.7	
	5-5	29.5	

Remark:

1) Performance Requirement: Type I<40 Pa/cm^2, Type II<40 Pa/cm^2, Type IIR<60 Pa/cm^2
2) The number of specimens that shall be tested is minimum 5, but can be greater and shall be increased if necessary to allow for an AQL(Acceptable Quality Level) of 4%.

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Clause 5.2.4 Splash Resistance
(ISO 22609 :2004)

Sample: A
Test Blood Pressure : 16.0kPa
Pre-Conditioning : Minimum of 4 hours at 21±5°C and 85±5% R.H.
Distance of the mask to the tip of cannula : 300±10mm

Test Specimen#	Penetration on inside surface	Conclusion	Test Specimen#	Penetration on inside surface	Conclusion
1	None Seen	Pass	17	None Seen	Pass
2	None Seen	Pass	18	None Seen	Pass
3	None Seen	Pass	19	None Seen	Pass
4	None Seen	Pass	20	None Seen	Pass
5	None Seen	Pass	21	None Seen	Pass
6	None Seen	Pass	22	None Seen	Pass
7	None Seen	Pass	23	None Seen	Pass
8	None Seen	Pass	24	None Seen	Pass
9	None Seen	Pass	25	None Seen	Pass
10	None Seen	Pass	26	None Seen	Pass
11	None Seen	Pass	27	Seen	Fail
12	None Seen	Pass	28	None Seen	Pass
13	None Seen	Pass	29	None Seen	Pass
14	Seen	Fail	30	None Seen	Pass
15	None Seen	Pass	31	None Seen	Pass
16	None Seen	Pass	32	None Seen	Pass
Number of Pass:		30			
Overall result:		Acceptable			

Remark:
1) Performance Requirement Type I: N/A, Type II: N/A, Type IIR: ≥16.0kPa
2) Test was conducted within 60s after removal from conditioning chamber.
3) An acceptable quality limit of 4.0% is met for a single sampling plan when 29 or more of the 32 tested specimens show pass results.

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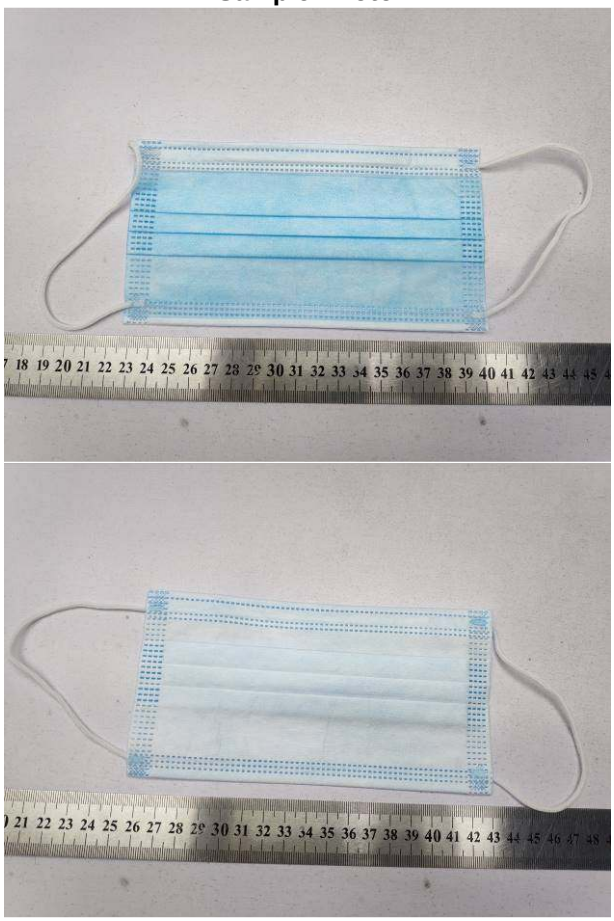
Sample Photo



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End of Report

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