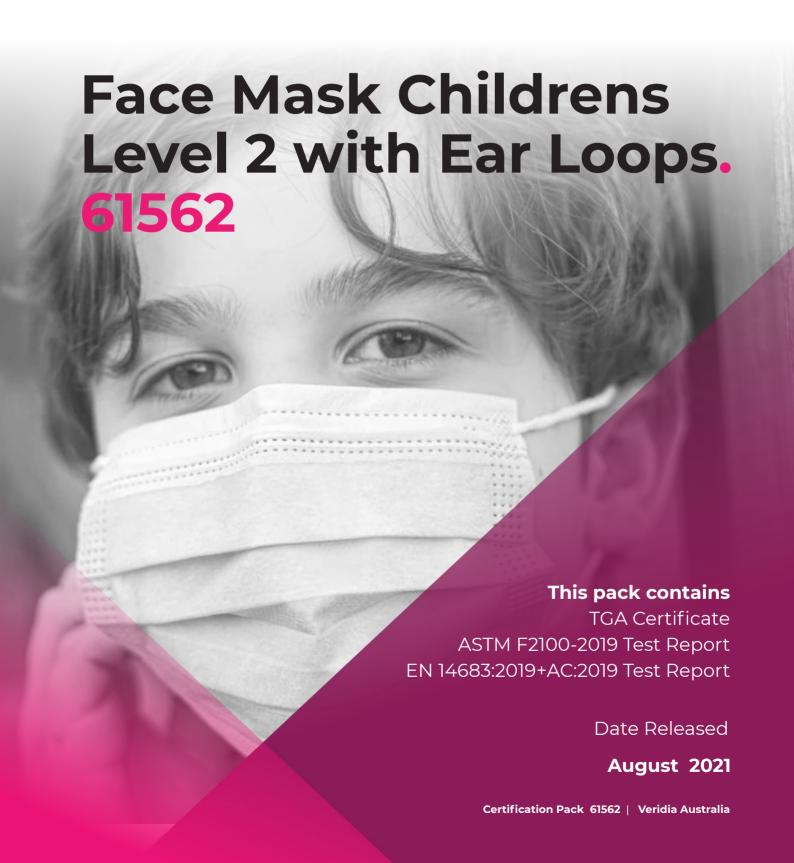
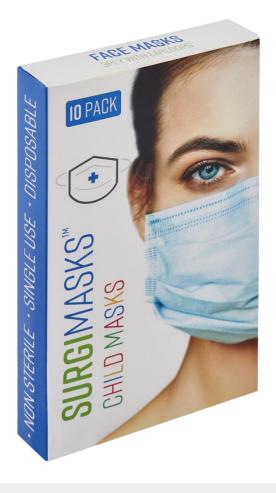


# Certification Pack.





## 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.
	<ul> <li>Single-use, disposable</li> <li>3-ply non-woven material, designed for child-sized face</li> <li>Elasticated ear loop and encased nose wire for fit and comfort</li> <li>TGA certified Level 2 rating</li> <li>High level of breathability, moisture resistance and bacterial filtration</li> </ul>
Colour	- Blue
Unit	- Pkt
Pack Qty	- 10
Carton Qty	- 50 Certification Pack 58993 Veridia Australia



## **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 (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

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Date: November 25,2020





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## Test Report SL52045300000101TX

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<sup>2</sup> Flow Rate : 28.3 L/min (1 ft<sup>3</sup>/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<sup>2</sup> Flow Rate : 8 l/min

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

#### Remark:

- 1) Performance Requirement: Level 1 Barrier: <5.0mm  $H_2$ O/cm², Level 2 Barrier: <6.0 mm  $H_2$ O/cm², Level 3 Barrier: <6.0 mm  $H_2$ O/cm²
- 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<sup>2</sup> Particle Size  $0.1 \mu m$ 

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:

- Performance Requirement: Level 1 Barrier≥95%, Level 2 Barrier≥98%, Level 3 Barrier≥98%
- The procedure incorporated a non-neutralized challenge. The non-neutralized aerosol is also specified in the FDA guidance document on surgical face masks.
- \* 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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**Test Report** 

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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:			Acce	eptable	



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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:			Acce	eptable	



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Test Report SL5204530

SL52045300000101TX Date: November 25,2020

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:			Acce	eptable	

#### 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)

<u>Sample</u> Α

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:**

Ignited, but extinguished



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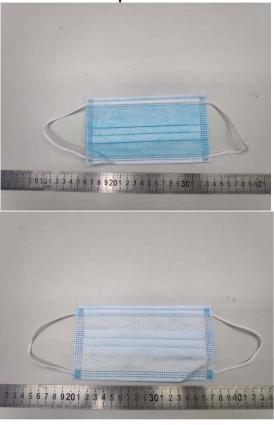


**Test Report** 

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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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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







**Test Report** 

SL52035272193001TX

Date: July 17,2020

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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<sup>2</sup>

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 < 1 CFU **Negative Monitor Count** Mean Particle Size  $3.0 \pm 0.3 \mu m$ 

Test bacteria Staphylococcus aureus ATCC 6538

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

## Remark:

- 1) Performance Requirement: Type I≥95%, Type II≥98%, Type IIR ≥98%
- 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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Test Report

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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<sup>2</sup> Flow Rate : 8 l/min

Specimen No.	Test Area No.	Different Pressure for each	The average value for each test
	4.4	tested area (Pa/cm²)	specimen (Pa/cm²)
	1-1	34.2	_
	1-2	34.8	-
1	1-3	30.1	35
	1-4	39.9	
	1-5	38.0	
	2-1	31.7	
	2-2	34.1	
2	2-3	29.4	33
	2-4	34.0	
	2-5	33.7	
	3-1	34.5	
	3-2	32.7	
3	3-3	28.1	33
	3-4	33.9	
	3-5	36.9	
	4-1	34.2	
	4-2	32.5	
4	4-3	30.2	34
	4-4	34.1	
	4-5	36.6	
	5-1	33.8	
	5-2	32.0	
5	5-3	34.6	32
_	5-4	29.7	1
	5-5	29.5	

#### Remark:

1) Performance Requirement: Type I<40 Pa/cm², Type II<40 Pa/cm², Type IIR<60 Pa/cm²

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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**Test Report** 

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**Date:July 17,2020** 

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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:			Acce	eptable	

#### 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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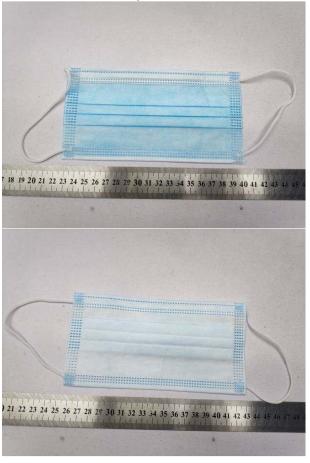
**Test Report** 

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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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