

Report No.: HLB0306/2020

Page of

Date DEC. 11, 2020

## SHUO TING PRECISION IND., CO., LTD. (Second Factory)

40743 No. 83, Sec. 1, Changan Rd., Xitun Dist., Taichung City 407, Taiwan

The following merchandise was submitted and identified by the applicant as:

**Product Description:** Medical Face Mask

We have tested the submitted sample(s) as requested and the following results were obtained:

Test Requested: 1. ASTM F2101:2019

2. ASTM F2299:2017

3. EN 14683:2019 Annex C

4. ASTM F1862/F1862M-17

5. 16 CFR Part 1610

Test Method & Result: ---See following sheet(s)---

Date of Receipt: NOV. 16, 2020

**Testing Period:** NOV. 16, 2020 ~ DEC. 11, 2020

The EN 14683:2019 Annex C, ASTM F1862/F1862M-17 and 16 CFR Part 1610 tests Note: were performed by O.S.H. CO., LTD. Respirator Test Center.

The ASTM F2101:2019 and ASTM F2299:2017 tests were performed by SGS Hong Kong Ltd.

> Signed for and on bel Taiwan Ltd.

Sturm Su Asst. Manager

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SGS Taiwan Ltd.
No.127, Wu Kung Road, New Taipei Industrial Park, New Taipei City, Taiwan /新北市新北產業園區五工路 127 號

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Report No.: HLB0306/2020

Page

## **Test Method & Result:** 1. ASTM F2101:2019

Test Item: Bacterial Filtration Efficiency Test Side: Side without strips (Inside)

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

Dimensions of test specimen: 176 mm x 97 mm

BFE Test Area: 49 cm<sup>2</sup>

BFE Flow Rate: 28.3 l/min

Test Bacteria: Staphylococcus aureus ATCC 6538

Mean Particle Size : 2.8 μm

Positive Control Average : 2.2 x 10<sup>3</sup> CFU

Negative Monitor Count : < 1 CFU Sample Model: T32020310793SN

Test Specimen	Percent BFE (%)		
1	99.6		
2	99.6		
3	99.5		
4	99.6		
5	99.7		

Note: Plate count total for each stage can be provided upon request.

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Report No.: HLB0306/2020

Page : 3 of 6

#### 2. ASTM F2299:2017:

Test Item: Particulate Filtration Efficiency

Test Side: Side with strips (Outside)

Pre-Conditioning: Minimum of 4 hours at (21±3) °C and (30-50±5) % R.H.

Test Condition :  $(21\pm3)$  °C and  $(50\pm5)$  % R.H.

Test Area: 41.61 cm<sup>2</sup>

Face Velocity: 18.18 cm/s

Particle Size: 0.1 µm

Average Filtration Efficiency: 98.78%

Standard Deviation: 0.15

Sample Model: T32020310793SN

Test Specimen	Pressure Drop (inH <sub>2</sub> O)	<b>Test Article Counts</b>	Average Control Counts	Filtration Efficiency (%)
1	0.465	1662	146485	98.87
2	0.476	1647	126852	98.70
3	0.380	1194	106428	98.88
4	0.467	1641	113893	98.56
5	0.495	1290	117959	98.91

<u>Note</u>: The procedure incorporated a non-neutralized challenge. The non-neutralized aerosol is also specified in the FDA guidance document on surgical face masks.

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Report No.: HLB0306/2020

Page of

## 3. EN 14683:2019 Annex C:

Test Methods	Test Item		Test Results (mm H <sub>2</sub> O/cm <sup>2</sup> )	Test Results (Pa/cm <sup>2</sup> )
1. Testing Sample Number: 5		01	4.58	44.88
2. Test Flow Rate: 8.05 Liter/min		02	4.44	43.51
3. Pre-Conditioning: Minimum of 4 hours at (21±5) °C and (85±5) % relative	Differential	03	4.56	44.69
	pressure	04	4.12	40.38
humidity.		05	4.76	46.65
4. Sample Model: AEP-1091119001		Avg.	4.49	44.02

# 4. ASTM F1862/F1862M-17:

Test Methods	Test Item		Test Item		Test Article Number	Synthetic Blood Penetration
<ol> <li>Testing Sample Number: 32</li> <li>Test Side: Outside</li> </ol>	Cynthatia	00 11	01-06 \ 09 \ 11-32	None Seen		
3. Pre-Conditioning : Minimum of 4 hours at (21±5) °C	Blood (10.7 kPa	(10.7 kPa)	01-00 (0) (11-32	None Seen		
and (85±5) % relative humidity (RH) 4. Test Conditions : 26.2 °C and	Penetration Resistance	(As per client requested)	07-08 \ 10	Yes		
40.4% RH 5. Sample Model: SBP-1091119001		,	3. 33 23	100		

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Report No.: HLB0306/2020 Page

5. 16 CFR Part 1610:

	Test Methods	Test Item		Test Results
1.	16 CFR Part 1610 Step 1: Testing in the original state. Step 2: Refurbishing and testing after	C	01	DNI
2.	10 replicates are to be tested it, during preliminary testing, only		02	DNI
	1 test article exhibits flame spread and it is less than 3.5 seconds or the test articles exhibit an average flame spread less than 3.5 seconds. Five replicates are to be tested if no flame spread is observed upon preliminary testing, if only 1 test article exhibits	Flammability of Textiles (s)	03	DNI
	flame spread and it is equal to or greater than 3.5 seconds, or if the average flame spread is equal to or greater than 3.5 seconds. In accordance with the standard, 5 replicates were tested for this		04	DNI
3. 4.	study. Testing Sample Number: 5 Sample Model: TFT-1091119001		05	DNI

### Note:

- 1. This test report is the test result issued by the testing institution as requested by the consignor.
- 2. DNI = Test Article did not ignite
- 3. Test Criteria for Specimen Classification (See 16 CFR Part 1610.7):

1		
Class	Plain Surface Textile Fabric	
1	Burn time $\geq 3.5$ seconds	
2	Not applicable to plain surface textile fabrics	
3	Burn time <3.5 seconds	

### Note:

- The test report merely reflects the test results of the consigned matters of the client and is not a certification.
- The content of this report is invalid if it is not presented as the entire report.

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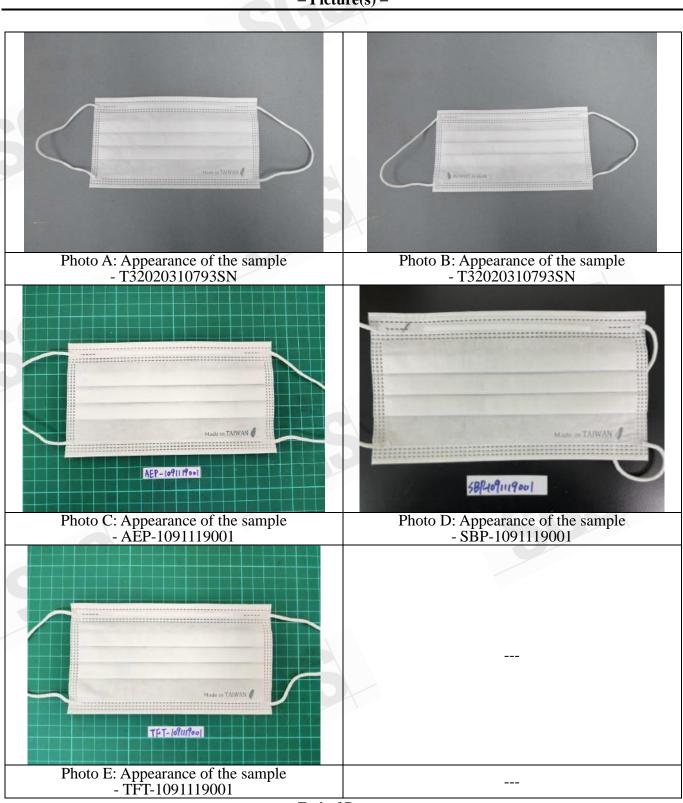
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Report No.: HLB0306/2020 Page : 6 of

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### ---End of Report---

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