

– Picture(s) –



Photo A: Appearance of the sample
- T-1090821-02



Photo B: Appearance of the sample
- BFE-1090824004

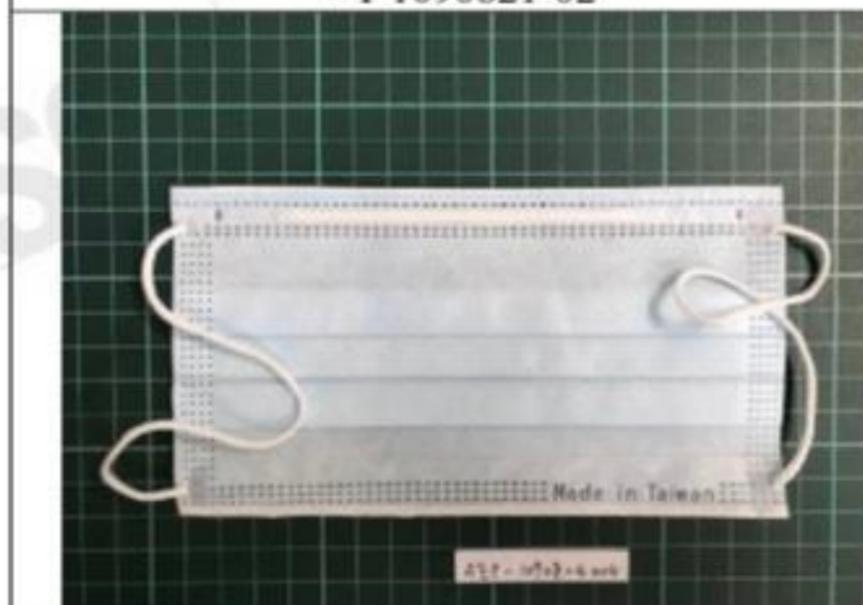


Photo C: Appearance of the sample
- AEP-1090824004



Photo D: Appearance of the sample
- SBP-1090824001

---End of Report---

Note :

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

- Picture(s) -



Photo A: Appearance of the sample
- BFE-1090824005

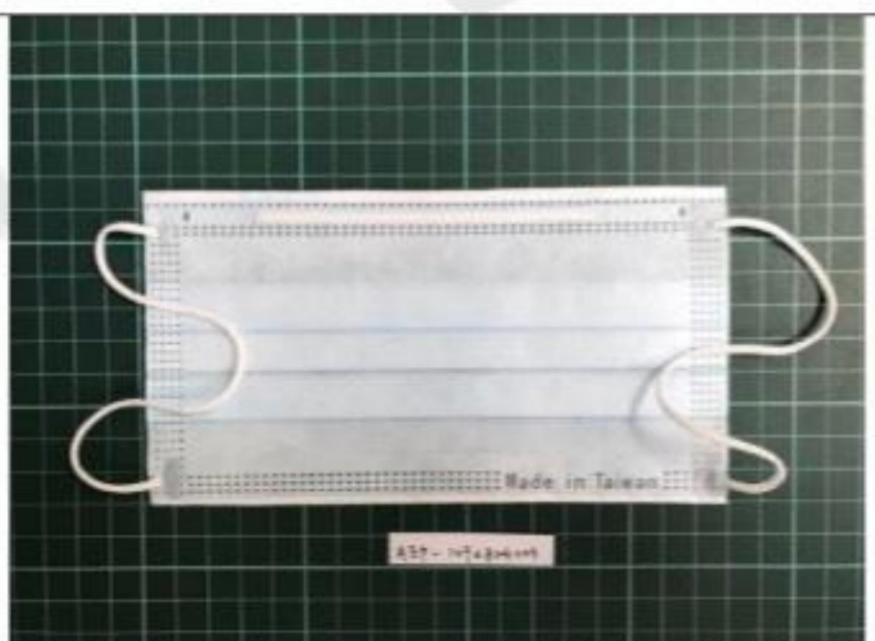


Photo B: Appearance of the sample
- AEP-1090824005

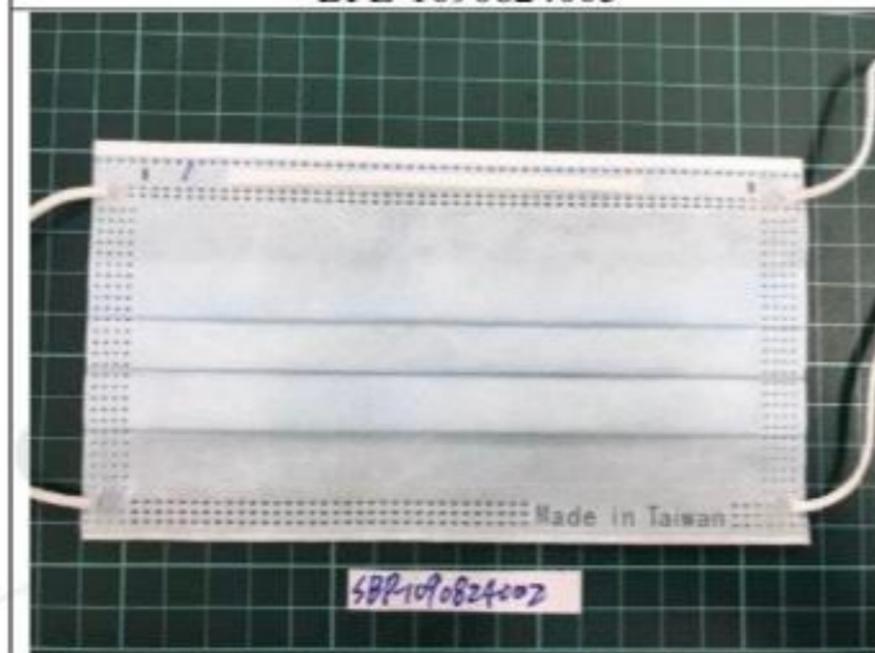


Photo C: Appearance of the sample
- SBP-1090824002



Photo D: Appearance of the sample
- TFT-1090824001

---End of Report---

Results:

Sample No.	Aerobic (CFU/Sample)	Fungal (CFU/Sample)	Anaerobic (CFU/Sample)
#1	336	266	348
#2	8	12	< 3
#3	2	4	2
#4	16	16	< 3
#5	20	10	4
#6	< 3	12	< 3
#7	116	108	40
#8	294	262	50
#9	486	524	96
#10	6	6	< 3
Average (CFU/Sample)	128.4	122	54.0
*Average (CFU/g)	41.4 (CFU/g)	39.4 (CFU/g)	17.4 (CFU/g)
Negative Control	0	0	0

Remarks: 1. SIP= 0.5, SIP (Sample Item Portion) is the portion of sample under analysis.

1.0 represents a full piece. Above data has been calculated by SIP.

2. < 3= No organisms detected.

3. CFU =Colony Forming Units.

4. *: Average weight for single mask is 3.1 g; average (CFU/g) is obtained from average (CFU/Sample) ÷ 3.1 g.

2. EN 14683:2019 Annex B:

Test Methods	Test Item	Test Results
1. Testing Sample Number: 5 2. Sample Dimensions : ~9.5 cm x ~17.2 cm 3. Test surface : Inside 4. Test Area: 49 cm ² 5. Flow rate during testing: 28.3 Liter/min 6. Counts of positive control: 2670 CFU 7. Counts of negative control: 0 CFU 8. Average size: 3.1 µm 9. Sample Model: BFE-1090824004	Bacterial filtration efficiency (BFE) (%)	01 99.5
		02 99.8
		03 99.5
		04 99.6
		05 99.8

Test Method & Result:

1. ASTM F2101:2019

Test Methods	Test Item	Test Results
1. Testing Sample Number: 5 2. Test surface : Inside 3. Test Area: 49 cm ² 4. Flow rate during testing: 28.3 Liter/min 5. Counts of positive control: 2298 CFU 6. Counts of negative control: 0 CFU 7. Average size: 2.9 μm 8. Sample Model: BFE-1090824005	Bacterial filtration efficiency (BFE) (%)	01 99.8
		02 >99.9
		03 99.7
		04 99.5
		05 99.7

6 Stage Sample No.	Colonies count of each stage						Total colony count (CFU)
	Stage 1 (7 μm)	Stage 2 (4.7 μm)	Stage 3 (3.3 μm)	Stage 4 (2.1 μm)	Stage 5 (1.1 μm)	Stage 6 (0.65 μm)	
01	0	0	0	0	3	2	5
02	0	0	0	0	1	1	2
03	0	0	0	1	4	3	8
04	0	0	0	0	5	7	12
05	0	0	0	0	5	2	7

2. EN 14683:2019 Annex C

Test Methods	Test Item	Test Results (mm H ₂ O/cm ²)	Test Results (Pa/cm ²)
1. Testing Sample Number: 5 2. Test Flow Rate : 8.08 Liter/min 3. Pre-Conditioning: Minimum of 4 hours at (21±5) °C and (85±5) % relative humidity. 4. Sample Model: AEP-1090824005	Differential pressure	01 3.86	37.83
		02 3.82	37.44
		03 4.39	43.02
		04 3.87	37.93
		05 3.90	38.22
		Avg. 3.97	38.89

Test Method & Result:

1. ISO 11737-1:2018 (E):

Test Article:

The following information of the test article was supplied by the sponsor.

Name: MEDICAL MASK

Lot No.: N/A

Model No.: N/A

Article No.: T-1090821-02

Purpose:

The purpose of the study was to evaluate the total number of viable microorganisms on a medical device before sterilization.

Materials:

Test Article: MEDICAL MASK

Other Materials:

Tryptic Soy Agar (TSA)

Peptone water

Sample bag

References:

The test was conducted based upon the following reference:

ISO11737-1:2018(E) Sterilization of health care products-Microbiological methods-Part1: Estimation of population of microorganisms on products.

Method:

Test Procedure: (SOP: EA-WI-013)

Test article's packing was aseptically opened in the laminar flow hood. Test article was cut into small pieces and transferred to sample bag containing 150 ml peptone water. Test article was extracted by ultrasonic bath and then tested for aerobic, anaerobic, and fungal counts using the membrane filtration method. Three 0.45 μ m membranes with 50 ml filtered extract were placed individually onto Tryptic Soy Agar (TSA) plates for aerobic, fungal and anaerobic counts. A negative control with only peptone water was performed to ensure that the test results were reliable. The aerobic and anaerobic were incubated at 30~35 °C for 7 days, while fungal were incubated at 20~ 25 °C for 7 days.

Hardline Laboratory

Report No. : HL80419/2020

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Date : OCT. 20, 2020

WAN CHOU TONG INT. CO. LTD.

1F, No.1, Lane 364, Wu-Shing St., Taipei, Taiwan (R.O.C.)

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

Product Description: MEDICAL MASK
Style/Item No.: WA-109001
Manufacturer/Vendor: WAN CHOU TONG INT. CO. LTD.
Country of Origin: TAIWAN

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

Test Requested:

1. ASTM F2101:2019
2. EN 14683:2019 Annex C
3. ASTM F1862/F1862M-17
4. 16 CFR Part 1610

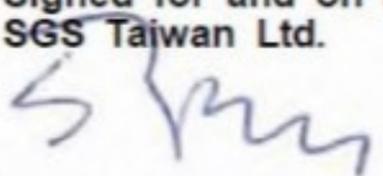
Test Method & Result: ---See following sheet(s)---

Date of Receipt: AUG. 20, 2020

Testing Period: AUG. 20, 2020 ~ OCT. 20, 2020

Note: The ASTM F2101:2019, EN 14683:2019 Annex C, ASTM F1862/F1862M-17 and 16 CFR Part 1610 tests were performed by O.S.H. CO., LTD. Respirator Test Center.

Signed for and on behalf of
SGS Taiwan Ltd.


Sturm Su
Asst. Manager

