

Hardline Laboratory

Report No. :
Page : 1 of 5
Date : JUL. 15, 2020

Medical Devices Co., Ltd.

PROVINCE, CHINA

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

Product Description: Disposable face mask for medical use

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
5. ASTM F2299:2017

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

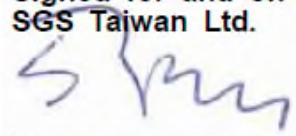
Date of Receipt : APR. 01, 2020

Testing Period : APR. 01, 2020 ~ MAY 12, 2020

Note:

1. 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.
2. The ASTM F2299:2017 testing was performed by Taiwan Textile Research Institute.

Signed for and on behalf of
SGS Taiwan Ltd.


Sturm Su
Asst. Manager



Test Method & Result:

1. ASTM F2101:2019:

Test Methods	Test Item	Test Results
1. Testing Sample Number: 2. Test surface : Outside 3. Test Area: 49 cm ² 4. Flow rate during testing: 28.3 Liter/min 5. Counts of positive control: 2673 CFU 6. Counts of negative control: 0 CFU 7. Average size: 3.3 μm	Bacterial filtration efficiency (BFE) %	01 98.1
		02 98.2
		03 98.1
		04 98.4
		05 97.6

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	1	1	1	6	37	4	50
02	0	0	0	3	40	4	47
03	0	0	0	1	49	1	51
04	0	0	3	4	35	0	42
05	2	1	2	6	49	3	63

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: 2. Test Flow Rate : 8.03 Liter/min 3. Pre-Conditioning: Minimum of 4 hours at (21±5) °C and (85±5) % relative humidity.	Differential pressure	01 3.53	34.60
		02 3.36	32.90
		03 3.48	34.11
		04 3.58	35.10
		05 3.42	33.56
		Avg.	3.47

This document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at <http://www.sgs.com.tw/Terms-and-Conditions> and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at <http://www.sgs.com.tw/Terms-and-Conditions>. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of client's instruction, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced, except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested.

3. ASTM F1862/F1862M-17:

Test Methods	Test Item		Test Article Number	Synthetic Blood Penetration
1. Testing Sample Number 2. Test Side : Outside 3. Pre-Conditioning : Minimum of 4 hours at (21±5) °C and (85±5) % relative humidity (RH) 4. Test Conditions : 23.9 °C and 47.4% RH	Synthetic Blood Penetration Resistance	120 mmHg (16.0 kPa) (As per client requested)	01-32	None Seen

4. 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 refurbishing, was not performed. 2. This 16 CFR Part 1610 standard specifies that 10 replicates are to be tested it, during preliminary testing, only 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 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 study. 3. Testing Sample Number : 	Flammability of Textiles (s)	01 DNI
		02 DNI
		03 DNI
		04 DNI
		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):

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

This document is issued by the Company subject to its General Conditions of Service printed overleaf, available on request or accessible at <http://www.sgs.com.tw/Terms-and-Conditions> and, for electronic format documents, subject to Terms and Conditions for Electronic Documents at <http://www.sgs.com.tw/Terms-and-Conditions>. Attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein. Any holder of this document is advised that information contained hereon reflects the Company's findings at the time of its intervention only and within the limits of client's instruction, if any. The Company's sole responsibility is to its Client and this document does not exonerate parties to a transaction from exercising all their rights and obligations under the transaction documents. This document cannot be reproduced, except in full, without prior written approval of the Company. Any unauthorized alteration, forgery or falsification of the content or appearance of this document is unlawful and offenders may be prosecuted to the fullest extent of the law. Unless otherwise stated the results shown in this test report refer only to the sample(s) tested.

5. ASTM F2299:2017

Test Methods	Test Item	Test Results	
Flow rate: 28.1 (Liter/min)	Sub-Micron Particulate Filtration Efficiency (%) (0.1 µm PSL)	01	95.27
		02	95.17
		03	95.26
		04	95.30
		05	95.11
		Ave	95.22

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.

- Picture(s) -



Photo A: Appearance of the sample

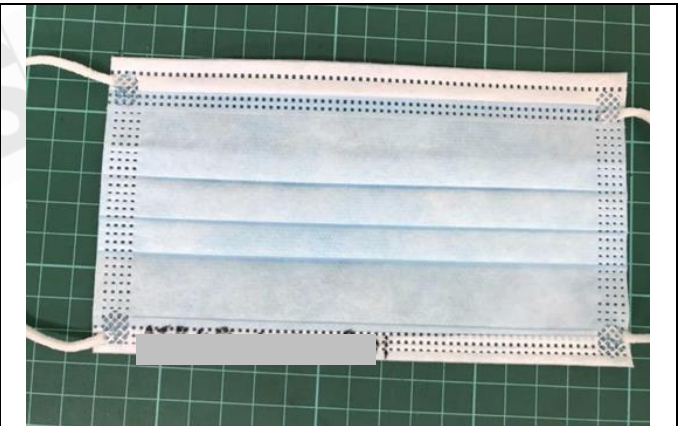


Photo B: Appearance of the sample

– Picture(s) –

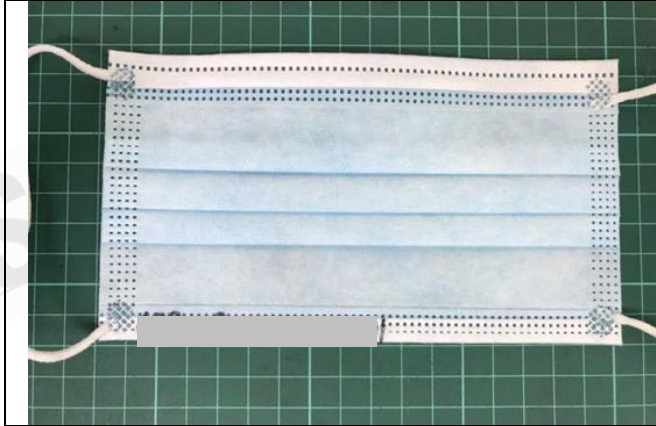


Photo C: Appearance of the sample

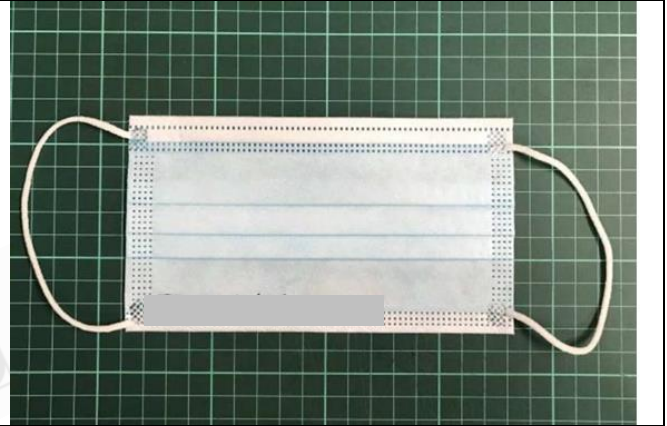


Photo D: Appearance of the sample



Photo E: Appearance of the sample

---End of Report---