



Test Report

No.T32120260177SN

Date: May 20, 2021

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SAVEWO LIMITED

1/F., 266-270 TEXACO ROAD, TSUEN WAN, N.T., HONG KONG

The following samples were submitted and identified by/on behalf of the client as:

SMILE

Case No. : CA321202529029
Lot No. / Batch Code : NOT PROVIDED
Sample Description : WHITE MASK WITH PLASTIC FILM
Style / Item No. : SMILE
Quantity Submitted : 150 PCS
Supplier : SAVEWO LIMITED
Manufacturer : SAVEWO LIMITED
Country of Origin : HONG KONG
Sample Receiving Date : APR 21, 2021
Testing Period : APR 21 TO MAY 20, 2021

Test Requested	Conclusion
EN 14683:2019+AC:2019 Medical face masks - Requirements and test methods (Excluded Clause 5.2.6 and Clause 6)	PASS (Type IIR)

***** FOR FURTHER DETAILS, PLEASE REFER TO THE FOLLOWING PAGE(S) *****

Signed for and on behalf of
SGS Hong Kong Ltd.

Au Kam Chi, Gigi
Technical Manager

Signed for and on behalf of
SGS Hong Kong Ltd.

Wong Kin Man, Gilman
Technical Development Manager

Signed for and on behalf of
SGS Hong Kong Ltd.

Tsang Chuk Hai
Senior Microbiologist

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EN 14683:2019+AC:2019 Medical face masks - Requirements and test methods

Scope : This document specifies construction, design, performance requirements and test methods for medical face masks intended to limit the transmission of infective agents from staff to patients during surgical procedures and other medical settings with similar requirements. A medical face mask with an appropriate microbial barrier can also be effective in reducing the emission of infective agents from the nose and mouth of an asymptomatic carrier or a patient with clinical symptoms. This European Standard is not applicable to masks intended exclusively for the personal protection of staff.

Number of Specimen : 150 pcs of complete product

<u>Clause</u>	<u>Test Items/requirement</u>	<u>Test Result Summary</u>
5	<u>Requirements</u>	
5.1	General	
5.1.1	Materials and construction	PASS The mask is composed of a filter layer that is bonded between layers of fabric. The mask was not disintegrated, split or tear during intended use, and no objectionable matter was observed by visual assessment.
5.1.2	Design	PASS Length: 21.8 cm; 17.0 cm (Expanded) Width: 8.5 cm (Folded); 10.5 cm (Expanded)
5.2	Performance requirements	
5.2.2^	Bacterial filtration efficiency (BFE)	> 98%
5.2.3^	Breathability (Differential Pressure)	< 60 Pa/cm ²
5.2.4	Splash resistance	Penetration not seen at 16.0 kPa
5.2.5^	Microbial cleanliness (Bioburden)	≤ 30 cfu/g
5.2.6	Biocompatibility	Not Conducted as per client requested
5.2.7	Summary of performance requirements	See Table 1
6	<u>Marking, labelling and packaging</u>	Not Conducted as per client requested

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EN 14683:2019+AC:2019 Medical face masks - Requirements and test methods

Table 1 Performance requirements for medical face masks

Characteristics	Type I ^a	Type II	Type IIR
Bacterial filtration efficiency (BFE), %	≥ 95	≥ 98	≥ 98
Differential pressure, Pa/cm ²	< 40	< 40	< 60
Splash resistance (kPa) [#]	Not Required	Not Required	≥ 16.0
Microbial cleanliness (cfu/g)	≤ 30	≤ 30	≤ 30

^a Type I medical face masks should only be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations. Type I masks are not intended for use by healthcare professionals in an operating room or in other medical settings with similar requirements.

[#] - 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.

Note:

[^] Results of compliance for tests requested is justified according to decision rule based on the non-binary statement with guard band (is equal to the expanded measurement uncertainty with a 95% coverage probability, $w = U_{95}$) as stated in ILAC-G8:09/2019 Clause 4.2.3.

“Pass - The measured values were observed in tolerance at the points tested. The specific false accept risk is up to 2.5%.”

“Fail - One or more measured values were observed out of tolerance at the points tested”. The specific false reject risk is up to 2.5%.

Result 1 Bacterial filtration efficiency (BFE) (EN14683:2019+AC:2019 Appendix B)

Test Side : Inside
 Pre-Conditioning : Minimum of 4 hours at 21±5°C and 85±5% R.H.
 Dimensions of test specimen : 215 mm x 150 mm
 BFE Test Area : 49 cm²
 BFE Flow Rate : 28.3 l/min
 Test bacteria : Staphylococcus aureus ATCC 6538
 Positive Control Average : 2.6 x 10³ CFU
 Negative Monitor Count : < 1 CFU

Test Specimen	Percent BFE (%)
1	99.9
2	99.9
3	99.9
4	99.9
5	99.9

Result 2 Determination of Breathability (EN14683:2019+AC:2019 Appendix C Differential pressure)

Test Side : Inside
 Pre-Conditioning : Minimum of 4 hours at 21±5°C and 85±5% R.H.
 Test Area : 4.9 cm²
 Flow Rate : 8 l/min

Test Location	ΔP (mm H ₂ O/cm ²)				
	Specimen 1	Specimen 2	Specimen 3	Specimen 4	Specimen 5
Top Centre	40.2	40.2	39.2	37.3	42.2
Centre Left	43.2	40.2	38.3	41.2	40.2
Centre Right	47.1	41.2	41.2	46.1	47.1
Bottom Left	40.2	40.2	40.2	40.2	38.3
Bottom	39.2	38.3	39.2	38.3	41.2
Bottom Right	39.2	39.2	40.2	37.3	41.2
Average	41.5	39.9	39.7	40.1	41.7

Result 3 Splash resistance (ISO 22609:2004)

Test Side : Outside
 Pre-Conditioning : Minimum of 4 hours at 21±5°C and 85±5% R.H.
 Test Condition : 21±5°C and 85±5% R.H.
 Test Pressure : 16.0 kPa (120 mmHg)
 No of Test Specimen Tested : 32
 No of Test Specimen Passed : 32

Test Specimen #	Synthetic Blood Penetration
1-32	None Seen

Note:

1. Targeting-plate method was used.
2. Sample was tested in the stage of spreading the pleats out when mounted on the test fixture.

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Result 4 Microbial cleanliness (Bioburden)(EN 14683:2019+AC:2019 Annex D)

Test Methods

Bioburden

The analyses were performed according to EN 14683:2019+AC:2019 Annex D and ISO 11737-1:2018

Test Results

SGS Sample No.:HKHC200400001275-101

Article Number	Mask Weight	Total Bioburden, cfu/mask	Total Bioburden, cfu/g
1	8.14g	<3	<0.37
2	8.16g	6	0.74
3	8.22g	42	5.11
4	8.17g	3	0.37
5	8.22g	9	1.09
Mean:		<12.6	<1.5

Recovery Efficiency	Correction Factor
62.2%	1.6

Microbial Cleanliness (Bioburden): < 2.5 cfu/g

Standard requirement#: ≤30 cfu/g

Note:

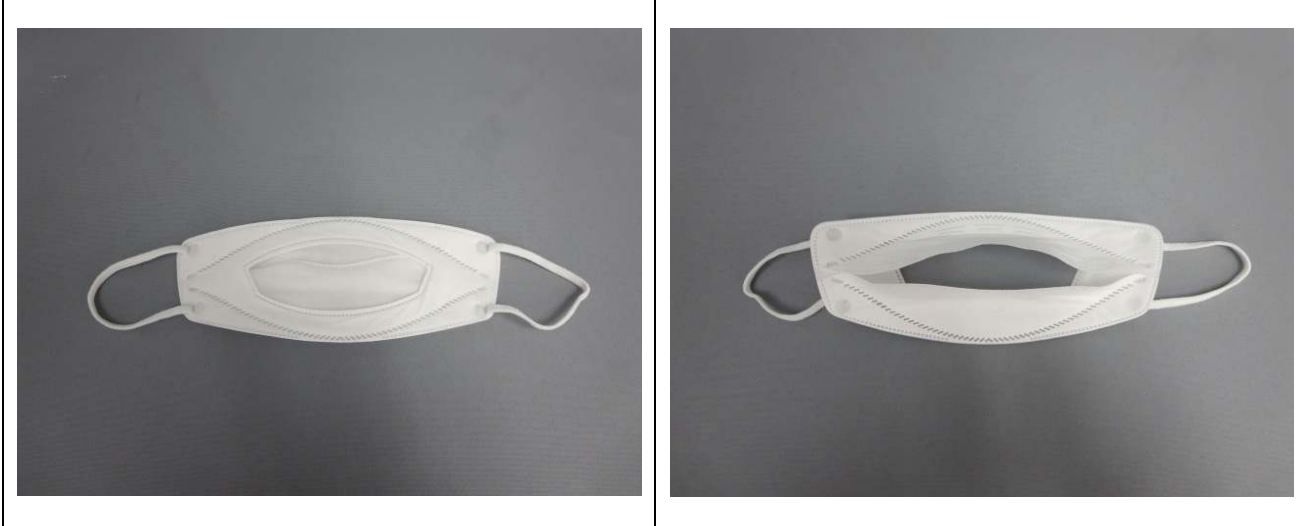
1. Results reported on the submitted sample on an as received basis.
2. < = less than
3. cfu = Colony Forming Units
4. Extraction method: by stomacher at 250rpm for 5 minutes
5. # EN 14683:2019+AC:2019 - Medical face masks - Requirements and test methods – Performance requirements for medical face masks – Microbial cleanliness

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Sample Photo:

Sample Picture (As received)



SGS authenticate the photo on original report only

*** End of Report ***

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