

Test Report

No.T32120240597SN

Date: Apr 26, 2021

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MASKON LIMITED

RM 18, BLK E, 10/F, LEE SUM FACTORY BLDG, 21-25 NG FONG ST., SAN PO KONG,
KOWLOON, HONG KONG

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

MEDICAL FACE MASK

Case No. : CA321202436929
 Lot No. / Batch Code : NOT PROVIDED
 Sample Description : BEIGE MASK
 Country of Origin : HONG KONG
 Sample Receiving Date : MAR 24, 2021
 Testing Period : MAR 24, 2021 – APR 26, 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 ManagerSigned for and on behalf of
SGS Hong Kong Ltd.Wong Kin Man, Gilman
Technical Development ManagerSigned for and on behalf of
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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 : 200 pcs of complete product

Clause	Test Items/requirement
5	Requirements
5.1	General
5.1.1	Materials and construction

Test Result Summary

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.

PASS

Length: 17.3 cm
Width: 9.6 cm (Folded); 15.9 cm (Expanded)

5.1.2	Design
5.2	Performance requirements
5.2.2 ^A	Bacterial filtration efficiency (BFE)
5.2.3 ^A	Breathability (Differential Pressure)
5.2.4	Splash resistance
5.2.5 ^A	Microbial cleanliness (Bioburden)
5.2.6	Biocompatibility
5.2.7	Summary of performance requirements

> 98%
< 60 Pa/cm²
Penetration not seen at 16.0 kPa
≤ 30 cfu/g
Not Conducted as per client requested
See Table 1

6 Marking, labelling and packaging

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 *	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

- * 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:

- ^A 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%.

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

Test Side	: Beige colour without earloop (Inside)
Pre-Conditioning	: Minimum of 4 hours at 21±5°C and 85±5% R.H.
Dimensions of test specimen	: 173 mm x 94 mm
BFE Test Area	: 49 cm ²
BFE Flow Rate	: 28.3 l/min
Test bacteria	: Staphylococcus aureus ATCC 6538
Positive Control Average	: 2.4 x 10 ³ CFU
Negative Monitor Count	: < 1 CFU

Test Specimen	Percent BFE (%)
1	99.9
2	99.8
3	99.9
4	99.8
5	99.8

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

Test Side	: Beige colour without earloop (Inside)
Pre-Conditioning	: Minimum of 4 hours at 21±5°C and 85±5% R.H.
Test Area	: 4.9 cm ²
Flow Rate	: 8 l/min

Test Location	ΔP (Pa/cm ²)				
	Specimen 1	Specimen 2	Specimen 3	Specimen 4	Specimen 5
Top Centre	26.5	34.3	33.4	26.5	30.4
Centre	23.5	27.5	26.5	22.6	26.5
Bottom Centre	23.5	25.5	27.5	22.6	28.4
Centre Left	23.5	21.6	26.5	21.6	20.6
Centre Right	20.6	24.5	21.6	22.6	23.5
Average	23.5	26.7	27.1	23.2	25.9

Result 3 Splash resistance (ISO 22609:2004)

Test Side	: Beige colour with earloop (Outside)
Pre-Conditioning	: Minimum of 4 hours at 21±5°C and 85±5% R.H.
Test Condition	: 21±5°C and (85±10)% 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: Targeting-plate method was used.

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 and ISO 11737-1:2018

Test Results

SGS Sample No.:HKHC210300000958-101

Article Number	Mask Weight	Total Bioburden, cfu/mask	Total Bioburden, cfu/g
1	3.65g	9	2.47
2	3.65g	108	29.59
3	3.74g	51	13.64
4	3.64g	30	8.24
5	3.67g	99	26.98
6	3.64g	42	11.54
7	3.60g	21	5.83
8	3.64g	24	6.59
9	3.65g	24	6.58
10	3.65g	75	20.55
Mean:		48.3	13.2

Recovery Efficiency	Correction Factor
50.7%	2.0

Microbial Cleanliness (Bioburden): 26.0 cfu/g

Standard requirement#: ≤30 cfu/g

Note:

- Results reported on the submitted sample on an as received basis.
- cfu = Colony Forming Units
- Extraction method: by shaking at 250rpm for 5 minutes
- # 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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