

Test Report

No.T32120270317SN

Date: Jun 28, 2021

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10A LIMITED

RMS 1001-1005, 10/F, NANYANG PLAZA, 57 HUNG TO RD., KWUN TONG, KLN., HONG KONG

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

10A NANOGO FACE MASK LOTUS SLIM B401/S

Case No. : CA321202717389
 Lot No. / Batch Code : G1C
 Sample Description : WHITE MASK
 Style / Item No. : FM3D-M-LOT-B401/S
 Quantity Submitted : 100 PCS
 Manufacturer : 10A LIMITED
 Country of Origin : HONG KONG
 Sample Receiving Date : JUN 11, 2021
 Testing Period : JUN 11 TO JUN 28, 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.



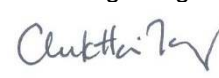
Au Kam Chi, Gigi
Technical Manager

Signed for and on behalf of
SGS Hong Kong Ltd.



Wong Kin Man, Gilman
Technical Development Manager

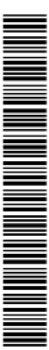
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Tsang Chuk Hai
Senior Microbiologist

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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 : 100 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: 10.1 cm (Folded); 12.5 cm (Expanded) Width: 15.6 cm (Folded); 13.5 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%.

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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 : 204 mm x 155 mm
 BFE Test Area : 49 cm²
 BFE Flow Rate : 28.3 l/min
 Test bacteria : Staphylococcus aureus ATCC 6538
 Positive Control Average : 2.3 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 (Pa/cm ²)				
	Specimen 1	Specimen 2	Specimen 3	Specimen 4	Specimen 5
Top Centre	43.2	38.3	34.3	37.3	37.3
Centre	47.1	42.2	47.1	48.1	47.1
Bottom Centre	48.1	47.1	47.1	50.0	50.0
Centre Left	60.8	52.0	60.6	61.8	56.9
Centre Right	44.1	46.1	49.1	46.1	49.1
Average	48.7	45.1	47.6	48.7	48.1

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 : 30

Test Specimen #	Synthetic Blood Penetration
1-10, 12-17, 19-32	None Seen
11, 18	Yes

Note: Targeting-plate method was used.

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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.:HKHC210600001805-101

Article Number	Mask Weight	Total Bioburden, cfu/mask	Total Bioburden, cfu/g
1	4.06g	18	4.43
2	4.25g	9	2.12
3	4.25g	6	1.41
4	4.10g	21	5.12
5	4.11g	3	0.73
Mean:		11.4	2.8

Recovery Efficiency	Correction Factor
78.5%	1.3

Microbial Cleanliness (Bioburden): 3.5 cfu/g

Standard requirement#: ≤30 cfu/g

Note:

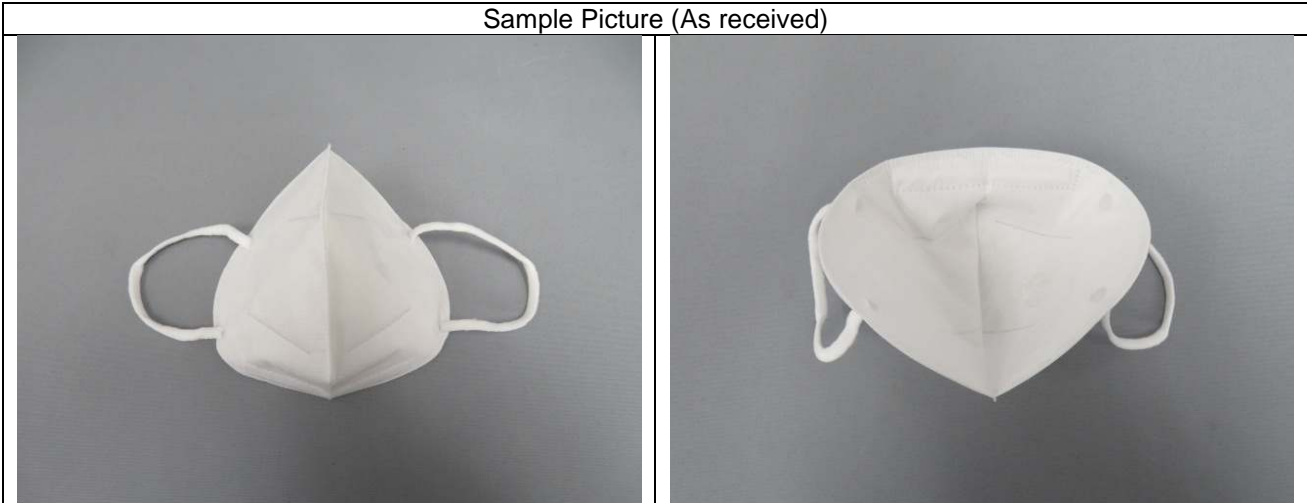
1. Results reported on the submitted sample on an as received basis.
2. < = less than
3. cfu = Colony Forming Units
4. Extraction method: by stomacher at 250rpm for 5 minutes
5. # EN 14683:2019+AC:2019 - Medical face masks - Requirements and test methods – Performance requirements for medical face masks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