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 PLUS P401

Case No.	:	CA321203025599
Lot No. / Batch Code	:	G1C
Sample Description	:	WHITE MASK
Style / Item No.	:	FM3D-M-LOT-P401
Manufacturer	:	10A LIMITED
Country of Origin	:	HONG KONG
Sample Receiving Date	:	SEP 20, 2021
Testing Period	:	SEP 20, 2021 – NOV 16, 2021

Test Requested	Conclusion
Accelerated Ageing of Sterile Barrier Systems for Medical Devices (ASTM F1980-16)(As Client's Specification)	PASS
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

Test Results:

Accelerated Ageing of Sterile Barrier Systems for Medical Devices (ASTM F1980-16)(As Client's Specification)

Nos. of Specimen	:	100 pcs. for testing, remain as control.
Ambient Temperature	:	23°C
Test Temperature	:	65°C*
Accelerated Aging Time		39.8 days*
Testing Procedures	:	1. Visually inspect sample and record any cosmetic defects. 2. Place the item in the oven at 65°C until reach equilibrium and maintain for 39.8 days. 3. Remove the item from the oven and cool down to room temperature. 4. Examine the item for any signs of defects.
Test Results	:	PASS. No noticeable appearance change was found.

Note: *Based on the accelerated aging theory, aged at 65 °C for 39.8 days is equivalent to TWO year ambient temperature (23°C) aging.

Test Results:

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 after aged at 65°C for 39.8 days as mentioned in this test report.

Clause	Test Items/requirement	Test Result Summary
5	**Requirements**	
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: 10.9 cm (Folded); 14.5 cm (Expanded) Width: 16.3 cm (Folded); 14.5 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	**Marking, labelling and packaging**	Not Conducted as per client requested

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, $w = \ddot{U}_{95}$) 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	:	197 mm x 158 mm
BFE Test Area	:	49 cm^2
BFE Flow Rate	:	28.3 l/min
Test bacteria	:	Staphylococcus aureus ATCC 6538
Positive Control Average	:	2.1 x 10^3 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 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	31.4	37.3	31.4	36.3	36.3
Centre	52.0	43.2	47.1	46.1	46.1
Bottom Centre	55.9	48.1	45.1	49.1	51.0
Centre Left	51.0	49.1	56.9	56.9	61.8
Centre Right	51.0	45.1	50.0	54.9	47.1
Average	48.3	44.5	46.1	48.7	48.5

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	:	31

Test Specimen #	Synthetic Blood Penetration
1-2, 4-32	None Seen
3	Yes

Note: Targeting-plate method was used.

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.:HKHC211100003218-101

Article Number	Mask Weight	Total Bioburden, cfu/mask	Total Bioburden, cfu/g
1	5.75g	< 3	< 0.52
2	5.74g	< 3	< 0.52
3	5.88g	< 3	< 0.51
4	5.85g	3	0.51
5	5.84g	3	0.51
	Mean:	< 3	＜0.5

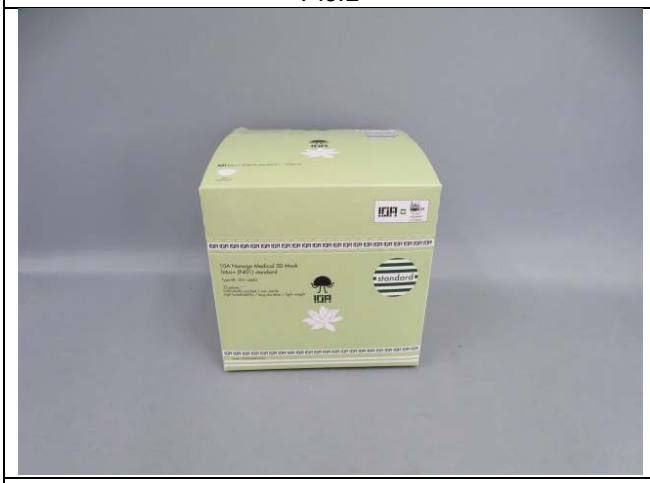
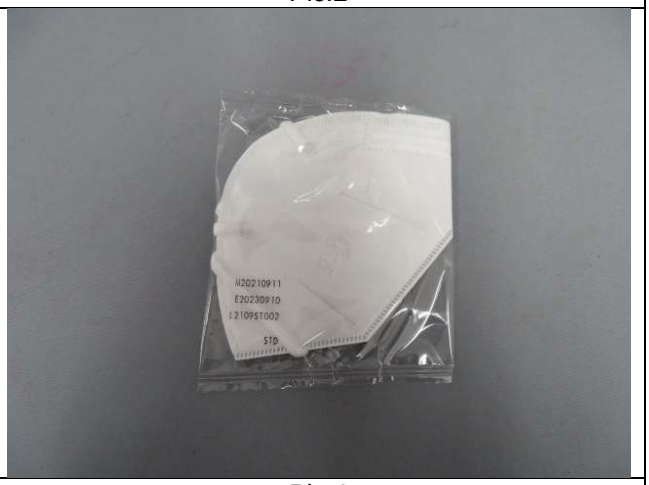
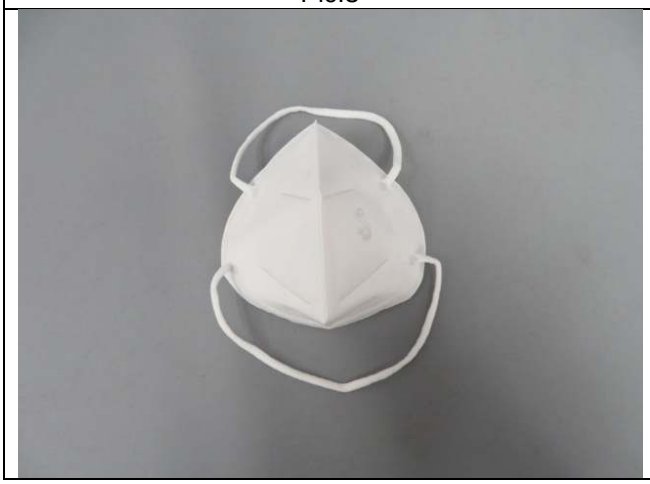
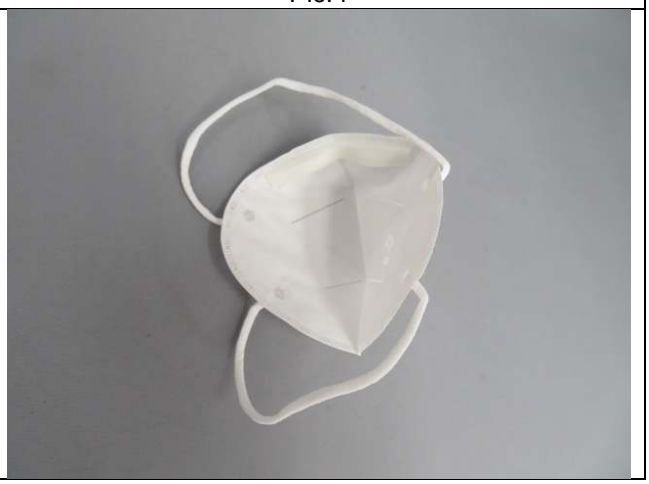
Recovery Efficiency	Correction Factor
36.5%	2.7

Microbial Cleanliness (Bioburden): < 1.4 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

Sample Photo:

Sample Picture (As received)	
Pic.1	Pic.2
	
Pic.3	Pic.4
	

SGS authenticate the photo on original report only

*** End of Report ***