Test Report

No.T32120320793SN Date: Dec 16, 2021

SPRO MEDICAL PRODUCTS (XIAMEN) CO., LTD

139 FACTORY BLDG, TONGAN GARDEN, TONGAN INDUSTRIAL AREA, TONGAN, XIAMEN, FUJIAN PROVINCE, 361100 P.R.CHINA

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

ZERO MASK

Case No.	:	CA321203242029
Lot No. / Batch Code	:	211101
Color	:	WHITE
Style / Item No.	:	ZERO
Sample Description	:	WHITE MASK
Quantity Submitted	:	150 PCS
Manufacturer	:	SPRO MEDICAL PRODUCTS (XIAMEN) CO., LTD
Country of Origin	:	CHINA
Country of Destination	:	EUROPE AND UNITED KINGDOM
Sample Receiving Date	:	NOV 30, 2021
Testing Period	:	NOV 30, 2021 TO DEC 16, 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

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

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: 17.2 cm Width: 9.4 cm (Folded); 15.8 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	Excluded
5.2.7	Summary of performance requirements	See Table 1
6	**Marking, labelling and packaging**	Excluded

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	:	White Colour without earloop (Inside)
Pre-Conditioning	:	Minimum of 4 hours at 21±5°C and 85±5% R.H.
Dimensions of test specimen	:	169 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	:	2.1 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	:	White 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	52.0	56.9	41.2	54.0	61.8
Centre	47.1	57.9	60.8	57.9	61.8
Bottom Centre	49.1	54.9	58.9	58.9	52.0
Centre Left	51.0	46.1	47.1	56.9	59.8
Centre Right	54.9	54.9	64.7	57.9	55.9
Average	50.8	54.2	54.5	57.1	58.3

Result 3 Splash resistance (ISO 22609:2004)

Test Side	:	White side 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	:	31

Test Specimen #	Synthetic Blood Penetration
1-14, 16-32	None Seen
15	Yes

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.

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.:HKHC211100003527-101

Article Number	Mask Weight	Total Bioburden, cfu/mask	Total Bioburden, cfu/g
1	3.79g	< 3	< 0.79
2	3.73g	21	5.63
3	3.75g	18	4.80
4	3.75g	12	3.20
5	3.82g	33	8.645
	Mean:		

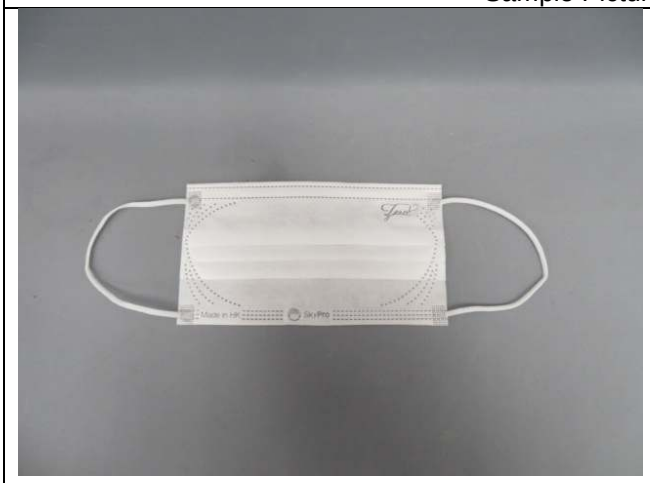
Recovery Efficiency	Correction Factor
55.1%	1.8

Microbial Cleanliness (Bioburden): < 8.4 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)	
	

SGS authenticate the photo on original report only

*** End of Report ***