CHANGZHOU SHUANGMA MEDICAL DEVICES CO., LTD
220 SANHE ROAD, ZHENGLU TOWN, TIANNING DISTRICT, CHANGZHOU CITY, JIANGSU PROVINCE

THIS REPORT CANCELS AND SUPERSEDES THE TEST REPORT NO. SL52035299168801TX DATE: October 16,2020 ISSUED BY SGS (SHANGHAI)
UPDATED SAMPLE INFORMATION

The following sample(s) was/were submitted and identified on behalf of the client as:

Sample Description	:	(A)Medical face mask
SGS Internal Ref.No.	:	15288625
Composition	:	(A)70%spunbond fabric, 30%meltblown fabric
Sample Color	:	(A)inner: white, outer: print
Style No.	:	3 Layrs earloop.14.5*9.5,
Lot No.	:	20200920
Manufacturer	:	CHANGZHOU SHUANGMA MEDICAL DEVICES CO., LTD
Supplier	:	CHANGZHOU SHUANGMA MEDICAL DEVICES CO., LTD
Test Performed	:	Selected test(s) as requested by applicant
Sample Receiving Date	:	Sep 25, 2020
Testing Period	:	Sep 25, 2020 - Oct 16, 2020
Test Result(s)	:	Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s).

Signed for and on behalf of
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd Testing Center

Sara Guo (Account Executive)

Dongjing Liu / Hailian Xuan (Authorized Signatory)

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Test Result

EN 14683:2019+AC:2019 Medical Face Masks-Requirements and Test Methods

Clause 5.2 Performance Requirement

Clause 5.2.2 Bacterial Filtration Efficiency (BFE)
(EN 14683:2019+AC:2019 Annex B)

Sample: A

Test Side	:	Inside
Test Area	:	Approximately 60 cm^2
Flow Rate	:	28.3 L/min
Pre-Conditioning	:	Minimum of 4 hours at 21±5°C and 85±5% R.H.
Dimensions of test specimen	:	~143mm x 142mm
Positive Control Average	:	2108 CFU
Negative Monitor Count	:	< 1 CFU
Mean Particle Size	:	3.0 ±0.3μm
Test bacteria	:	Staphylococcus aureus ATCC 6538

Test Item	Specimen No.	Result
Bacterial Filtration Efficiency (BFE), %	1	99.9
	2	99.9
	3	99.9
	4	99.9
	5	99.9

Remark:
1) Performance Requirement: Type I≥95%, Type II≥98%, Type IIR ≥98%
2) The number of specimens that shall be tested is minimum 5, but can be greater and shall be increased if necessary to allow for an AQL(Acceptable Quality Level) of 4%.

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Clause 5.2.3 Breathability

(EN 14683 :2019+AC:2019 Annex C)

Sample: A

Test Side : Randomly test in different location (1 around and 4 away from the centric point) on each of the 5 masks

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

Specimen No.	Test Area No.	Different Pressure for each tested area (Pa/cm^2)	The average value for each test specimen (Pa/cm^2)
1	1-1	36.2	38
	1-2	38.2	
	1-3	39.5	
	1-4	37.6	
	1-5	38.7	
2	2-1	39.8	38
	2-2	37.5	
	2-3	36.4	
	2-4	38.2	
	2-5	39.7	
3	3-1	38.4	37
	3-2	35.5	
	3-3	34.9	
	3-4	39.6	
	3-5	38.6	
4	4-1	39.5	38
	4-2	38.9	
	4-3	36.7	
	4-4	38.3	
	4-5	34.5	
5	5-1	39.3	39
	5-2	38.6	
	5-3	39.5	
	5-4	39.8	
	5-5	36.6	

Remark:

1) Performance Requirement: Type I<40 Pa/cm^2, Type II<40 Pa/cm^2, Type IIR<60 Pa/cm^2
2) The number of specimens that shall be tested is minimum 5, but can be greater and shall be increased if necessary to allow for an AQL(Acceptable Quality Level) of 4%.

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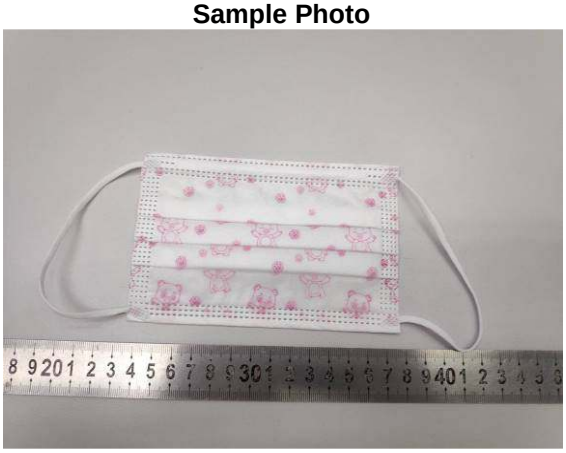
Clause 5.2.5 Microbial Cleanliness

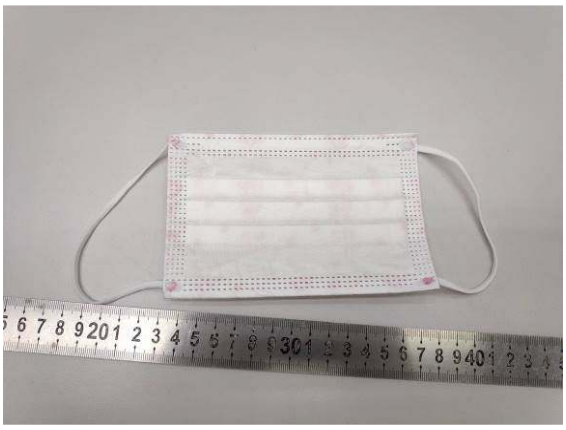
(EN 14683:2019+AC:2019 Annex D and EN ISO 11737-1:2018)

Sample Number	Mask Weight(g)	Total Bioburden, (cfu/mask)	Total Bioburden, (cfu/g)
1#	2.69	<3	<1.12
2#	2.68	<3	<1.12
3#	2.69	9	3.35
4#	2.70	<3	<1.11
5#	2.69	<3	<1.12

Remark: Performance Requirement: Type I≤30 CFU/g, Type II≤30 CFU/g, Type IIR≤30 CFU/g

Sample Photo





The statement of conformity in this test report is only based on measured values by the laboratory and does not take their uncertainties into consideration.

End of Report

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