RIZHAO SANQI MEDICAL & HEALTH ARTICLES CO.,LTD
HESHAN INDUSTRY PARK, DONGGANG DISTRICT, RIZHAO, SHANDONG PROVINCE, CHINA

THIS REPORT CANCELS AND SUPERSEDES THE TEST REPORT NO. SL52035286037801TX
DATE: Sep 04, 2020 ISSUED BY SGS (SHANGHAI)
UPDATED CLIENT INFORMATION

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

Sample Description	:	(A)Medical Face Mask Type I
SGS Internal Ref.No.	:	14S20015722
Sample Color	:	(A)white
Lot No.	:	200801
Manufacturer	:	RIZHAO SANQI MEDICAL & HEALTH ARTICLES CO.,LTD
Other Info.	:	Product code: SQE-1001 (L/M/S)
Test Performed	:	Selected test(s) as requested by applicant
Sample Receiving Date	:	Aug 18, 2020
Testing Period	:	Aug 18, 2020 - Sep 04, 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).

Comment:

EN 14683:2019+AC:2019 Medical Face Masks-Requirements and Test Methods **Clause 5.2 Performance Requirement**	(A)
Clause 5.2.2 Bacterial filtration efficiency (BFE)	M
Clause 5.2.3 Breathability	M
Clause 5.2.4 Splash Resistance	EXCLUDED
Clause 5.2.5 Microbial Cleanliness	M
Clause 5.2.6 Biocompatibility	EXCLUDED

Remark: M=Meet EN 14683:2019+AC:2019 Performance Requirement (Type I)
F=Below EN 14683:2019+AC:2019 Performance Requirement (Type I)

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	:	~170mm x 170mm
Positive Control Average	:	2548.5 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	29.7	33
	1-2	33.0	
	1-3	39.5	
	1-4	30.8	
	1-5	31.4	
2	2-1	36.8	34
	2-2	34.3	
	2-3	34.5	
	2-4	30.6	
	2-5	33.6	
3	3-1	32.6	36
	3-2	39.6	
	3-3	35.9	
	3-4	33.0	
	3-5	38.3	
4	4-1	32.4	31
	4-2	26.1	
	4-3	24.8	
	4-4	33.5	
	4-5	39.6	
5	5-1	31.2	34
	5-2	33.6	
	5-3	26.8	
	5-4	38.7	
	5-5	39.0	

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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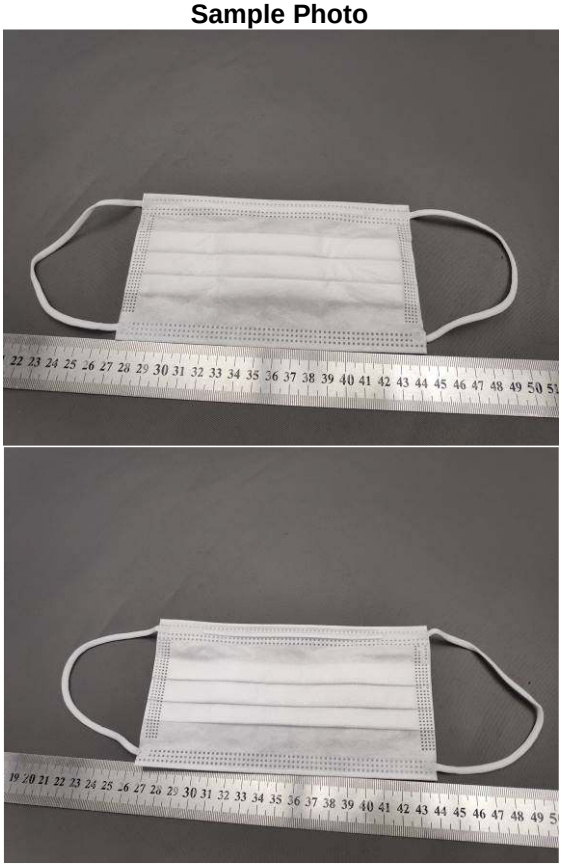
Clause 5.2.5 Microbial Cleanliness
(EN 14683:2019+AC:2019 Annex D and EN ISO 11737-1:2018)

Sample: A

Test Specimen#	Mask Weight(g)	Total Bioburden, (CFU/mask)	Total Bioburden, (CFU/g)
1#	3.34	21	6.29
2#	3.37	48	14.24
3#	3.39	15	4.42
4#	3.34	12	3.59
5#	3.37	30	8.90

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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