

Test Report

SL52035299246501TX

Date: September 28, 2020

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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. SL52035285990701TX
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 II

SGS Internal Ref.No. : 14S20015723
Sample Color : (A) white
Lot No. : 200801
Manufacturer : RIZHAO SANQI MEDICAL & HEALTH ARTICLES CO.,LTD
Other Info. : Product code: SQE-2002 (L/M/S)

Test Performed : Selected test(s) as requested by applicant

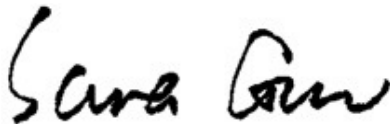
Sample Receiving Date : Aug 17, 2020
Testing Period : Aug 17, 2020 - Sep 04, 2020
Test Result(s) : Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s).

Comment:

EN 14683:2019+AC:2019 Medical Face Masks-Requirements and Test Methods	(A)
Clause 5.2 Performance Requirement	
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 II)
F=Below EN 14683:2019+AC:2019 Performance Requirement (Type II)

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 cm²
 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 160mm
 Positive Control Average : 2475.5 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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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 cm²

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	29.0	31
	1-2	38.1	
	1-3	31.4	
	1-4	29.3	
	1-5	29.6	
2	2-1	38.4	36
	2-2	37.3	
	2-3	35.5	
	2-4	32.2	
	2-5	34.9	
3	3-1	39.7	35
	3-2	35.8	
	3-3	34.1	
	3-4	38.8	
	3-5	26.1	
4	4-1	31.3	34
	4-2	29.4	
	4-3	35.5	
	4-4	35.2	
	4-5	38.7	
5	5-1	39.1	35
	5-2	29.8	
	5-3	33.2	
	5-4	35.6	
	5-5	37.9	

Remark:

- 1) Performance Requirement: Type I<40 Pa/cm², Type II<40 Pa/cm², Type IIR<60 Pa/cm²
- 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%.

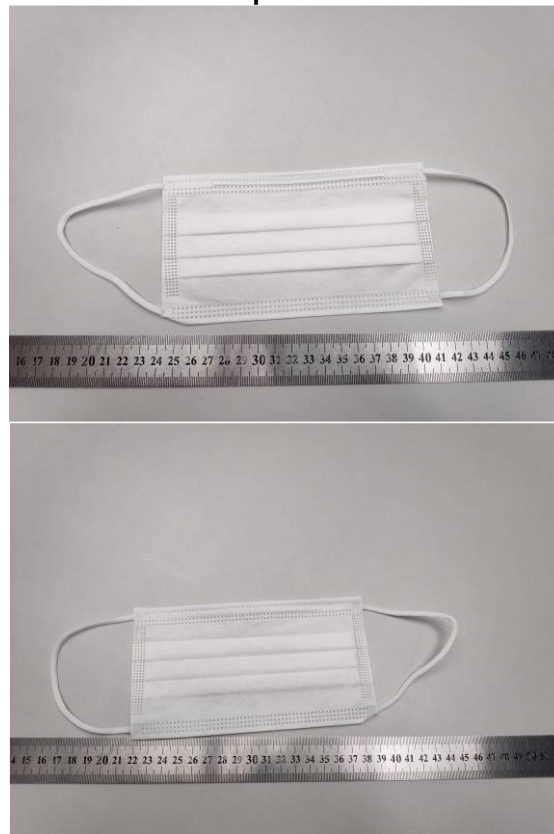
Clause 5.2.5 Microbial Cleanliness

(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	15	4.49
2#	3.43	<3	<0.87
3#	3.38	<3	<0.89
4#	3.32	3	0.90
5#	3.41	12	3.52

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