

GUANGZHOU OKSAFE MEDICAL EQUIPMENT CO.,LTD
ROOM 401, BUILDING 2, NO.12 TUANJI ROAD, HUADU DISTRICT (AIRPORT HUADU), GUANGZHOU,
GUANGDONG PROVINCE, 510000, P.R.CHINA.

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

Sample Description : Non-Sterile Disposable Medical Face Mask

Style No. : 9903/17.5*9.5cm

Sample Color : blue

Manufacturer : GUANGZHOU OKSAFE MEDICAL EQUIPMENT CO.,LTD

Roll/ Lot No. : 20200616

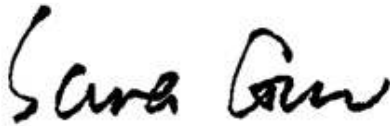
Sample Receiving Date : Jul 10, 2020

Testing Period : Jul 10, 2020 - Jul 30, 2020

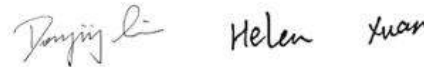
Test Result(s) : Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s).

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

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 150mm
 Positive Control Average : 2189 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	99.8%
	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%.



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 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	28.8	23
	1-2	24.3	
	1-3	22.5	
	1-4	20.4	
	1-5	19.5	
2	2-1	20.0	25
	2-2	22.0	
	2-3	34.8	
	2-4	19.9	
	2-5	27.6	
3	3-1	26.0	28
	3-2	23.3	
	3-3	32.0	
	3-4	38.2	
	3-5	22.8	
4	4-1	23.8	26
	4-2	21.7	
	4-3	26.5	
	4-4	28.9	
	4-5	29.3	
5	5-1	30.5	30
	5-2	28.4	
	5-3	31.2	
	5-4	29.5	
	5-5	28.7	

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

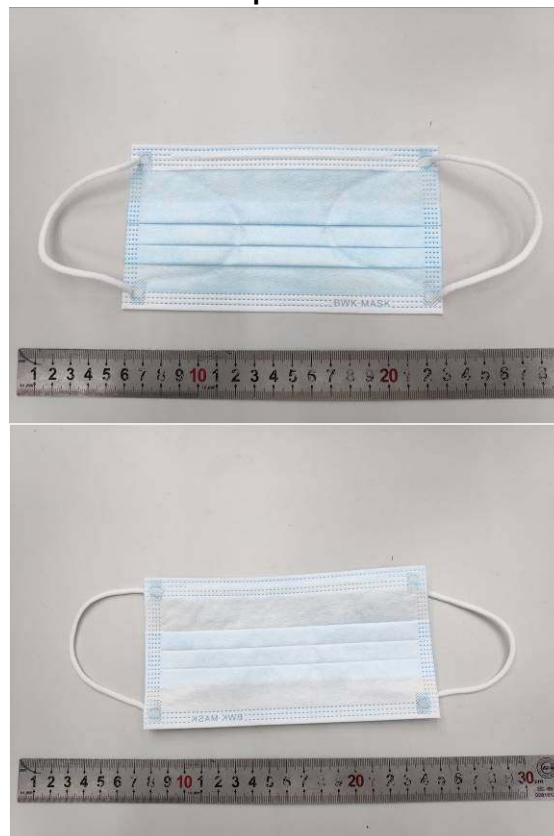
(EN 14683:2019+AC:2019 Annex D and EN ISO 11737-1:2018)

Sample: A

Test Specimen#	Mask Weight(g)	Total Bioburden, (CFU/mask)	Total Bioburden, (CFU/g)
1#	2.91	12	4.12
2#	2.87	30	10.45
3#	2.94	6	2.04
4#	2.94	<3	<1.02
5#	2.88	<3	<1.04

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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