

Test Report **SL52035285082201TX**

Date: August 25, 2020

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GUANGXI BIKANG MEDICAL DEVICE CO., LTD.

BUILD 3, ANYING INDUSTRIAL PARK, WEST JIANGNAN AVENUE, GANGNAN DISTRICT, GUIANG CITY, GUANGXI, CHINA

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

Sample Description : (A)Medical face mask

Composition : (A)Non-woven fabric, Melt-blown fabric

Sample Color : (A)Blue-white

Style No. : Earloops

Lot No./Batch Code : 2020072202

Manufacturer : GUANGXI BIKANG MEDICAL DEVICE CO., LTD.

Country of Destination : EUR

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

Sample Receiving Date : Aug 05, 2020

Testing Period : Aug 05, 2020 - Aug 25, 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<sup>2</sup>  
 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 : ~172mm x 155mm  
 Positive Control Average : 2049 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%.

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3<sup>rd</sup> Building, No. 889, Yishan Road, Xuhui District Shanghai, China 200233 t (86-21) 61402666 f (86-21) 64958763 www.sgsgroup.com.cn  
 中国·上海·徐汇区宜山路889号3号楼 邮编: 200233 t (86-21) 61402666 f (86-21) 64958763 e [sgs.china@sgs.com](mailto:sgs.china@sgs.com)



**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<sup>2</sup>

Flow Rate : 8 l/min

Specimen No.	Test Area No.	Different Pressure for each tested area (Pa/cm <sup>2</sup> )	The average value for each test specimen (Pa/cm <sup>2</sup> )
1	1-1	33.4	34
	1-2	34.8	
	1-3	32.5	
	1-4	34.6	
	1-5	35.6	
2	2-1	37.8	35
	2-2	37.2	
	2-3	34.8	
	2-4	34.9	
	2-5	32.2	
3	3-1	36.2	36
	3-2	35.2	
	3-3	36.8	
	3-4	32.8	
	3-5	37.2	
4	4-1	32.0	34
	4-2	34.1	
	4-3	33.6	
	4-4	33.6	
	4-5	34.4	
5	5-1	37.9	35
	5-2	30.4	
	5-3	33.6	
	5-4	34.5	
	5-5	37.9	

**Remark:**

- 1) Performance Requirement: Type I<40 Pa/cm<sup>2</sup>, Type II<40 Pa/cm<sup>2</sup>, Type IIR<60 Pa/cm<sup>2</sup>
- 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#	3.29	<3	<0.91
2#	3.29	3	0.91
3#	3.25	<3	<0.92
4#	3.26	3	0.92
5#	3.24	3	0.93

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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SGS-CSI Technical Services (Shanghai) Co., Ltd.  
Testing Center

3<sup>rd</sup> Building, No. 889, Yishan Road, Xuhui District Shanghai, China 200233  
中国·上海·徐汇区宜山路889号3号楼 邮编: 200233

t (86-21) 61402666 f (86-21) 64958763  
t (86-21) 61402666 f (86-21) 64958763

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