

**Test Report** SL52035260282401TX-1 **Date: July 13, 2020** **Page 1 of 3**  
 GUANGXI KANGXIANG TECHNOLOGY CO., LTD.  
 BUILDING 6, STANDARD WORKSHOP, CHENGDONG ROAD, WUXUAN TOWN, WUXUAN COUNTY

**THIS REPORT CANCELS AND SUPERSEDES THE TEST REPORT NO. SL52035260282401TX**  
**DATE: July 13, 2020 ISSUED BY SGS (SHANGHAI)**  
**UPDATED CLIENT INFORMATION**

Sample Description : (A)Medical surgical mask(non-sterile)002 (Claimed Type IIR)  
 SGS Internal Ref No. : GZF20-010630.001  
 Sample Color : (A)Blue  
 Lot No./Batch No. : Not provided  
 Test Performed : Selected test(s) as requested by applicant  
 Sample Receiving Date : Jun 11, 2020  
 Testing Period : Jun 11, 2020 - Jul 13, 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:**

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

Remark: M=Meet EN 14683:2019+AC:2019 Performance Requirement (Type IIR)

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

Conditioning Parameters : Minimum of 4 hours at 21±5°C and 85±5% R.H.  
 Dimensions of test specimen : ~170 mm x 160 mm  
 Test Area : ~60 cm<sup>2</sup>  
 Test Side : Inside  
 Flow Rate : 28.3 l/min  
 Positive Control Average : 2097.5 CFU  
 Negative Monitor Count : < 1 CFU

	1#	2#	3#	4#	5#
(BFE), %	99.9	99.9	99.9	99.9	99.9

Remark: Performance Requirement: Type I≥95%, Type II≥98%, Type IIR ≥98%

**Clause 5.2.3 Breathability**

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

Sample: A

Test number and location : 5 random areas for each specimen (face mask)  
 Conditioning Parameters : 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

	1#	2#	3#	4#	5#
Differential pressure ΔP (Pa/cm <sup>2</sup> )	37	36	39	39	38

Remark: 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>

**Clause 5.2.4 Splash Resistance**

(ISO 22609 :2004, Pressure 16.0 kPa)

<b>Penetration on inside surface</b>							
1#	2#	3#	4#	5#	6#	7#	8#
Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
9#	10#	11#	12#	13#	14#	15#	16#
Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
17#	18#	19#	20#	21#	22#	23#	24#
Pass	Pass	Pass	Pass	Fail	Pass	Pass	Pass
25#	26#	27#	28#	29#	30#	31#	32#
Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Number of Pass:			31				
Overall result:			Acceptable				



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Remark:

- 1) Performance Requirement Type I: N/A, Type II: N/A, Type IIR:  $\geq 16.0\text{kPa}$
- 2) Distance of the medical face mask target area surface to the tip of cannula is  $300\pm 10\text{mm}$ .
- 3) Condition and Test temperature  $(21\pm 5)^\circ\text{C}$ , relative humidity  $(85\pm 10)\%$
- 4) An acceptable quality limit of 4.0% is met for a single sampling plan when 29 or more of the 32 tested specimens show pass results

**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#	3.25	27	8.31
2#	3.24	18	5.56
3#	3.27	24	7.34
4#	3.26	15	4.60
5#	3.27	36	11.01

Remark: Performance Requirement: Type I  $\leq 30\text{ CFU/g}$ , Type II  $\leq 30\text{ CFU/g}$ , Type IIR  $\leq 30\text{ CFU/g}$

**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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