





中国认可 国际互认 检测 TESTING **CNAS L0599** 

SL52035260282401TX-1 Page 1 of 3 Test Report Date:July 13,2020

GUANGXI KANGXIANG TECHNOLOGY CO., LTD.

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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)

GZF20-010630.001 SGS Internal Ref No.

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:

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	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

Minimum of 4 hours at 21±5°C and 85±5% R.H. Conditioning Parameters

Dimensions of test specimen ~170 mm x 160 mm

~60 cm<sup>2</sup> Test Area Test Side Inside Flow Rate 28.3 l/min Positive Control Average 2097.5 CFU **Negative Monitor Count** < 1 CFU

> 1# 3# 5# 2# 4# 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

(BFE), %

Test number and location 5 random areas for each specimen (face mask) Minimum of 4 hours at 21±5°C and 85±5% R.H. Conditioning Parameters

4.9 cm<sup>2</sup> Test Area Flow Rate 8 l/min

1# 2# 3# 4# 5# Differential pressure 37 36 39 39  $\triangle P (Pa/cm^2)$ 

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)

1#	on inside sur 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
lumber of P	ass:		31				
Overall result:			Acceptable				



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### Remark:

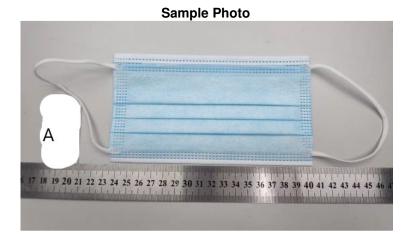
- 1) Performance Requirement Type I: N/A, Type II: N/A, Type IIR: ≥16.0kPa
- 2) Distance of the medical face mask target area surface to the tip of cannula is 300±10mm.
- 3) Condition and Test temperature (21±5)° C, relative humidity (85±10)%
- 4) An acceptable quality limit of 4.0% is met for a single 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)

	Mask Weight(g)	Total Bioburden, (cfu/mask)	Total Bioburden, (cfu/g)
Sample Number		,	, -,
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≤30 CFU/g, Type II≤30 CFU/g, Type IIR≤30 CFU/g



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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