

Test Report –TYPE IIR standard



中国认可
国际互认
检测
TESTING
CNAS L0599

Test Report **SL52025269352301TX** **Date: June 24, 2020** **Page 1 of 4**
JIANGXI HEYING PHARMACEUTICAL CO., LTD.
HUANGJINBU TOWN, YUGAN COUNTY, SHANGRAO CITY, JIANGXI PROVINCE, CHINA

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

Sample Description : (A) Disposable medical mask
Sample Color : (A) Blue
Manufacturer : JIANGXI HEYING PHARMACEUTICAL CO., LTD.
Lot No./Batch No. : 20200501

Test Performed : Selected test(s) as requested by applicant
Sample Receiving Date : Jun 02, 2020
Testing Period : Jun 02, 2020 - Jun 24, 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)



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

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Test Result

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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 : 165 mm x 145 mm
Test Area : ~60 cm²
Test Side : Inside
Flow Rate : 28.3 l/min
Positive Control Average : 2729 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 cm²
Flow Rate : 8 l/min

	1#	2#	3#	4#	5#
Differential pressure ΔP (Pa/cm ²)	57	58	58	50	53

Remark: Performance Requirement: Type I < 40 Pa/cm², Type II < 40 Pa/cm², Type IIR < 60 Pa/cm²



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Testing Center for Inspection & Testing Services

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Clause 5.2.4 Splash Resistance

(ISO 22609 :2004, Pressure 16.0 kPa)

Sample: A

Penetration on inside surface

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	Pass	Pass	Pass	Pass
25#	26#	27#	28#	29#	30#	31#	32#
Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Number of Pass:			32				
Overall result:			Acceptable				

Remark:

- 1) Performance Requirement Type I: N/A, Type II: N/A, Type IIR: ≥ 16.0 kPa
- 2) Distance of the medical face mask target area surface to the tip of cannula is 300 ± 10 mm.
- 3) Condition and Test temperature $(21 \pm 5)^{\circ}$ 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: A

	1#	2#	3#	4#	5#
CFU/g	5	2	3	<1	<1

Remark: Performance Requirement: Type I ≤ 30 CFU/g, Type II ≤ 30 CFU/g, Type IIR ≤ 30 CFU/g

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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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