

Test Report

SL52035297603701TX

Date: September 07, 2020

Page 1 of 4

JIANGSU EYOUNG MEDICAL DEVICES CO., LTD
213115 NO.1 DONGTANG ROAD,ZHENGLU TOWN, TIANNING COUNTY, CHANGZHOU CITY, JIANGSU PROVINCE,CHINA

THIS REPORT CANCELS AND SUPERSEDES THE TEST REPORT NO. SL52035261082601TX
DATE: Jul 10, 2020 ISSUED BY SGS (SHANGHAI)
UPDATED SAMPLE INFORMATION

Sample Description : (A)Disposable Medical Face Mask (Type IIR)

SGS Internal Ref No. : 14S20011359&14S20011359-01

Batch no : 20200503

Manufacture date : 20200503

Sample Color : (A)Blue

Expiration date : 20230502

Manufacturer : JIANGSU EYOUNG MEDICAL DEVICES CO., LTD

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

Sample Receiving Date : Jun 19, 2020

Testing Period : Jun 19, 2020 - Jul 10, 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)
F=Below 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 : ~177 mm x 155 mm
 Test Area : ~60 cm²
 Test Side : Inside
 Flow Rate : 28.3 l/min
 Positive Control Average : 2373.5 CFU
 Negative Monitor Count : < 1 CFU

	1#	2#	3#	4#	5#
(BFE), %	99.7	99.8	99.8	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)	36	36	38	36	37

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



Clause 5.2.4 Splash Resistance

(ISO 22609 :2004, Pressure 16.0 kPa)

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	Fail	Pass	Pass	Pass	Pass
17#	18#	19#	20#	21#	22#	23#	24#
Pass	Pass	Pass	Pass	Pass	Fail	Pass	Pass
25#	26#	27#	28#	29#	30#	31#	32#
Pass	Pass	Pass	Pass	Pass	Pass	Fail	Pass
Number of Pass:			29				
Overall result:			Acceptable				

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#	3.30	6	1.82
2#	3.30	3	0.91
3#	3.31	42	12.69
4#	3.32	33	9.94
5#	3.30	15	4.55

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



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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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