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 **Clause 5.2 Performance Requirement**	(A)
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 cm^2
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 cm^2
Flow Rate	:	8 l/min

	1#	2#	3#	4#	5#
Differential pressure △P (Pa/cm^2)	36	36	38	36	37

Remark: Performance Requirement: Type I<40 Pa/cm^2, Type II<40 Pa/cm^2, Type IIR<60 Pa/cm^2

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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: ≥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)

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≤30 CFU/g, Type II≤30 CFU/g, Type IIR≤30 CFU/g

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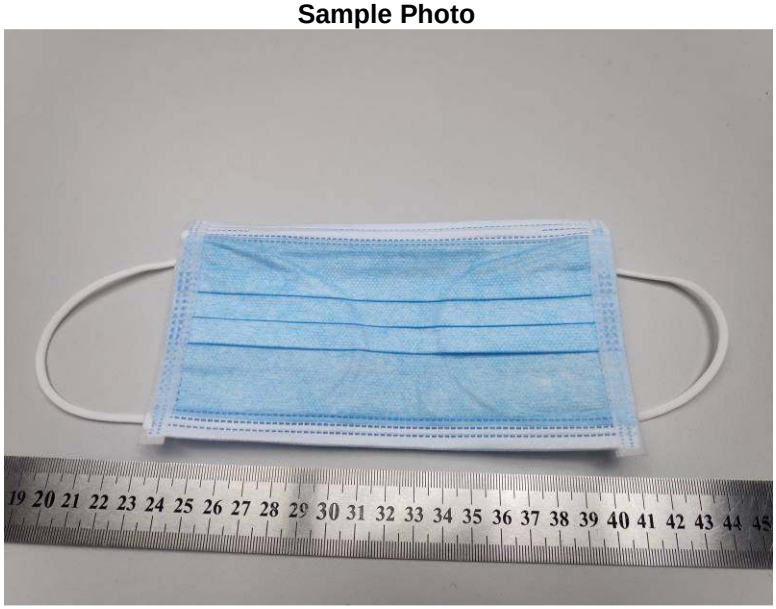
Sample Photo



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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