

TEST REPORT FOR KIDS MASK



中国认可
国际互认
检测
TESTING
CNAS L0599

Test Report

SL52035272538801TX

Date: July 08, 2020

Page 1 of 5

XIAMEN PROBAIN MEDICAL TECHNOLOGY CO.,LTD
4TH FLOOR, NO.1 BUILDING, NO.6 JI'AN ROAD, TONG'AN DISTRICT, XIAMEN, FUJIAN, CHINA

THIS REPORT CANCELS AND SUPERSEDES THE TEST REPORT NO. SL52035260218001TX
DATE: Jul 01, 2020 ISSUED BY SGS (SHANGHAI)
UPDATED SAMPLE INFORMATION

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

Sample Description : (A)3 ply face mask medical - for kids (Claimed Type IIR)

SGS Internal Ref No. : TJHL2006003587MD

Style No. : MP9017 14.5*9.5CM

Sample Color : (A)blue

Manufacturer : XIAMEN PROBAIN MEDICAL TECHNOLOGY CO.,LTD

Lot No./Batch No. : Not provided

Country of Destination : EUR

Country of Origin : China

Item No. : MP9017 14.5*9.5CM

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

Sample Receiving Date : Jun 11, 2020

Testing Period : Jun 11, 2020 - Jul 01, 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).



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

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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 : ~145 mm x 150 mm
 Test Area : ~60 cm²
 Test Side : Inside
 Flow Rate : 28.3 l/min
 Positive Control Average : 2242.5 CFU
 Negative Monitor Count : < 1 CFU

(BFE), %	1#	2#	3#	4#	5#
	99.9	99.8	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

Differential pressure ΔP (Pa/cm ²)	1#	2#	3#	4#	5#
	30	30	30	29	29

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



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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	Pass	Pass	Pass	Fail	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	Pass	Pass
Number of Pass:			30				
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#	2.74	3	1.09
2#	2.76	3	1.09
3#	2.79	<3	<1.08
4#	2.79	3	1.08
5#	2.70	6	2.22

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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