TAIZHOU RICH MEDICAL PRODUCTS CO.,LTD
INDUSTRIAL AREA, SUCHEN TOWN TAIZHOU, 225300, JINAGSU, CHINA.

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

Sample Description	:	(A-L) Medical Surgical face mask
Sample Color	:	(A)Black;(B)Malaga;(C)Pink Yarrow;(D)Fairy Tale;(E)Misty Rose;(F)Primrose Pink;(G)Persimmon Orange;(H)Yellow Iris;(I)Jasmine Green;(J)Nile Blue;(K)White;(L)Light Blue
Claimed Type	:	Type IIR
Lot No.	:	Not provided
Other Info.	:	A-K: adult; L: children
Test Performed	:	Selected test(s) as requested by applicant
Sample Receiving Date	:	Oct 09, 2021
Testing Period	:	Oct 20, 2021 - Nov 11, 2021
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).

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Comment:

Conclusion	B	C	D	E	F	G	H
pH Value	See result	See result	See result	See result	See result	See result	See result
Conclusion	I	J	K	L			
pH Value	See result	See result	See result	See result			

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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COMPONENT LIST / List of Materials

Sample No.	Component No.	Description	Color	Remark
B	1	outer layer	malaga	
C	2	outer layer	pink yarrow	
D	3	outer layer	fairy tale	
E	4	outer layer	misty rose	
F	5	outer layer	primrose pink	
G	6	outer layer	persimmon orange	
H	7	outer layer	yellow iris	
I	8	outer layer	jasmine green	
J	9	outer layer	nile blue	
K	10	inner layer	white	
L	11	outer layer	light blue	

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Test Result

pH Value

(ISO 3071:2020; 0.1mol/L KCL extraction)

-	Unit	1	2	3	Requirement
pH Value	-	6.4	6.4	6.4	-
Conclusion		**See Results**	**See Results**	**See Results**	
-	Unit	**4**	**5**	**6**	Requirement
pH Value	-	7.5	6.7	6.6	-
Conclusion		**See Results**	**See Results**	**See Results**	
-	Unit	**7**	**8**	**9**	Requirement
pH Value	-	6.5	6.5	6.4	-
Conclusion		**See Results**	**See Results**	**See Results**	
-	Unit	**10**	**11**	Requirement	
pH Value	-	6.2	6.5	-	
Conclusion		**See Results**	**See Results**		

Note:
1) pH value of extraction medium: 5.63
2) Temperature of the extraction solution: 22.3ºC

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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

Test Side	:	Inside
Test Area	:	Approximately 60 cm^2
Flow Rate	:	28.3 L/min
Pre-Conditioning	:	Minimum of 4 hours at 21±5°C and 85±5% R.H.
Dimensions of test specimen	:	~175mm x 157mm
Positive Control Average	:	2825 CFU
Negative Monitor Count	:	< 1 CFU
Mean Particle Size	:	3.0 ±0.3μm
Test bacteria	:	Staphylococcus aureus ATCC 6538

Test Item	Specimen No.	Result
Bacterial Filtration Efficiency (BFE)	1	99.9%
	2	99.9%
	3	99.9%
	4	99.9%
	5	99.9%

Remark:
1) Performance Requirement: Type I≥95%, Type II≥98%, Type IIR ≥98%
2) The number of specimens that shall be tested is minimum 5, but can be greater and shall be increased if necessary to allow for an AQL(Acceptable Quality Level) of 4%.

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Clause 5.2.3 Breathability

(EN 14683:2019+AC:2019, Annex C;Test number and location: Test in different location on each of the 5 masks; Pre-Conditioning: Minimum of 4 hours at 21±5oC(70±10oF) and 85±5% R.H.; Test Area: 4.9 cm2; Flow Rate: 8 l/min.)

A

As Received	No. 1	No. 2	No. 3	No. 4	No. 5
Differential Pressure					
Top Centre(Pa/cm²)	35.6	38.4	33.4	36.7	36.2
Centre Left(Pa/cm²)	37.7	37.2	35.6	38.5	37.5
Centre(Pa/cm²)	36.3	38.4	39.7	36.9	39.8
Centre Right(Pa/cm²)	34.4	34.7	34.6	38.5	36.4
Bottom Centre(Pa/cm²)	35.9	36.5	32.9	36.2	35.7
Average Differential Pressure(Pa/cm²)	36	37	35	37	37

Remark:

1) Performance Requirement for EN 14683 :2019+AC:2019 Annex C: Type I<40 Pa/cm2, Type II<40 Pa/cm2, Type IIR<60 Pa/cm2

2) The number of specimens that shall be tested is minimum 5, but can be greater and shall be increased if necessary to allow for an AQL(Acceptable Quality Level) of 4%.

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Clause 5.2.4 Splash Resistance

(ISO 22609:2004;)

A

Type IIR- 16.0kPa	No. 1	No. 2	No. 3	No. 4	No. 5	No. 6	No. 7
Resistance to Penetration by Synthetic Blood(No Unit)	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Type IIR- 16.0kPa	No. 8	No. 9	No. 10	No. 11	No. 12	No. 13	No. 14
Resistance to Penetration by Synthetic Blood(No Unit)	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Type IIR- 16.0kPa	No. 15	No. 16	No. 17	No. 18	No. 19	No. 20	No. 21
Resistance to Penetration by Synthetic Blood(No Unit)	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Type IIR- 16.0kPa	No. 22	No. 23	No. 24	No. 25	No. 26	No. 27	No. 28
Resistance to Penetration by Synthetic Blood(No Unit)	Pass	Pass	Pass	Pass	Pass	Pass	Pass
Type IIR- 16.0kPa	No. 29	No. 30	No. 31	No. 32			
Resistance to Penetration by Synthetic Blood(No Unit)	Pass	Pass	Pass	Pass			

Number of Test Specimen Passed:32
Conclusion: Pass

Remark:
1. Pre-Conditioning: Minimum of 4 hours at 21±5oC and 85±5% R.H.
2. Distance of the mask to the tip of cannula: 300±10mm.
3. Test was conducted within 60s after removal from conditioning chamber.
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.
5. Pass: No Penetration on inside surface
   Fail: Penetration on inside surface

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Clause 5.2.5 Microbial Cleanliness
(EN 14683:2019+AC:2019 Annex D and EN ISO 11737-1:2018)

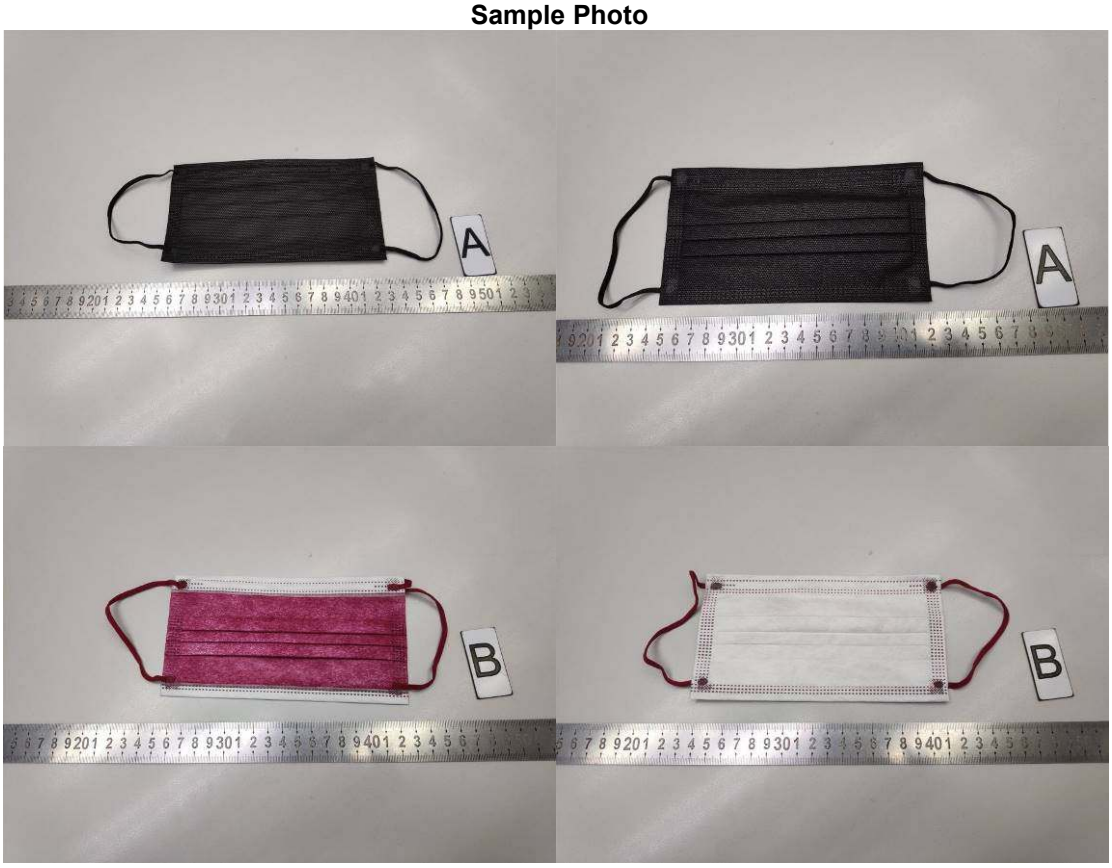
Sample: A

Test Specimen#	Mask Weight(g)	Total Bioburden, (CFU/mask)	Total Bioburden, (CFU/g)
1	3.04	21.96	7.22
2	3.05	10.98	3.60
3	3.01	18.30	6.08
4	3.07	<3	<0.98
5	3.05	18.30	6.00

Recovery Efficiency : 82.0%
Correction Factor : 1.2

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

Sample Photo



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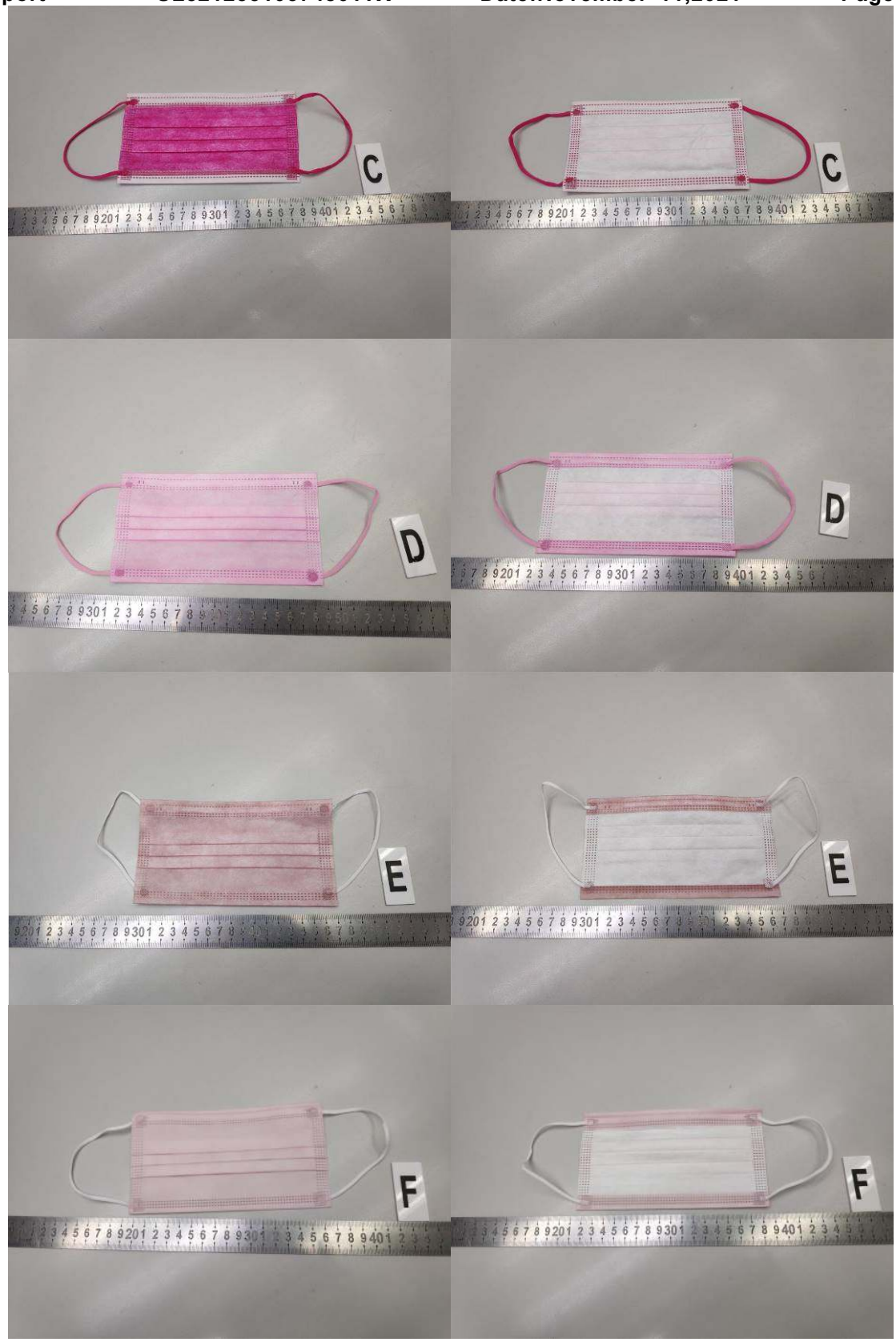

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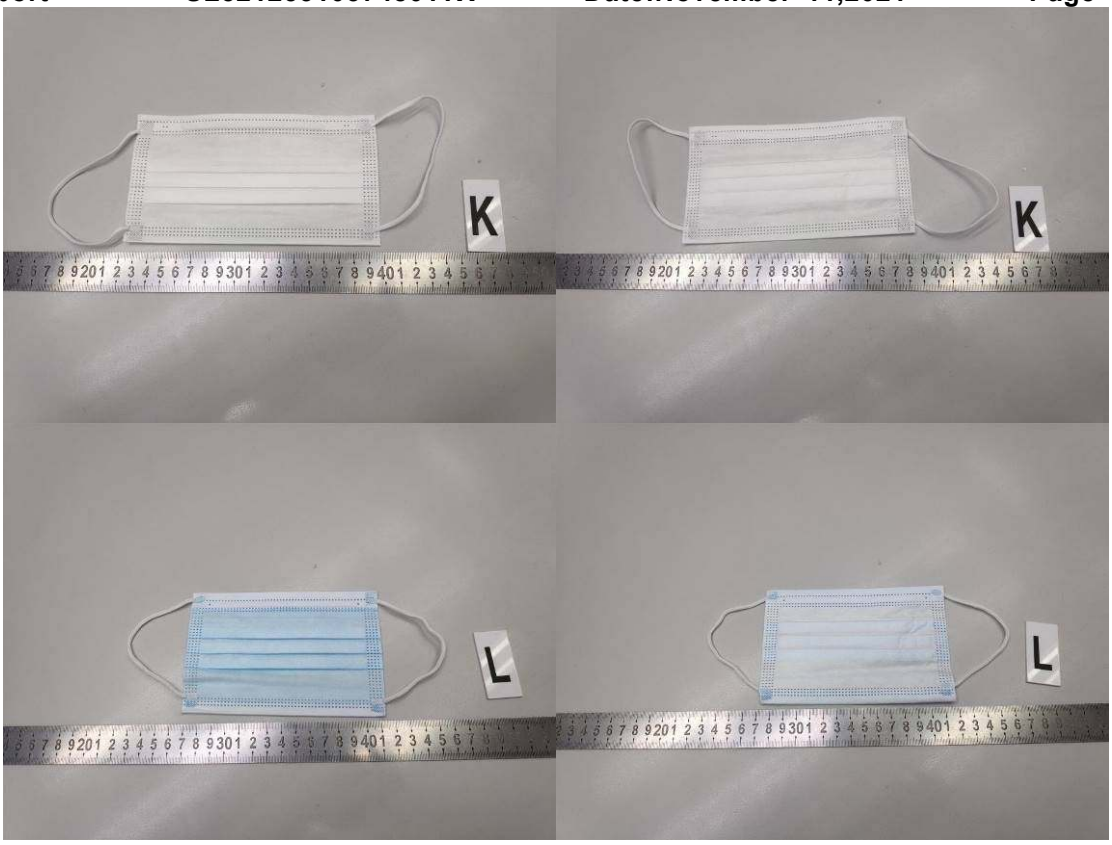

The statement of conformity in this test report is only based on measured values by the laboratory and does not take their uncertainties into consideration.

End of Report

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