

POSI

CERTIFICATE

质量管理体系认证证书

兹证明

仙桃富源医疗保健品有限公司

统一社会信用代码： 91429004615404554A

注册地址： 仙桃市彭场镇富源路2号

经营地址： 湖北省仙桃市彭场镇富源路2号

的质量管理体系适用于：

医用一次性无纺布制品（衣服，帽子，袖套，床单，床罩，鞋套，口罩，枕套，胡须套）的生产及出口贸易；一次性塑料制品（鞋套、袖套、围裙、探视服）的出口贸易

已经通过上海波西认证有限公司根据标准：

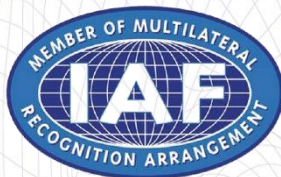
ISO13485:2016

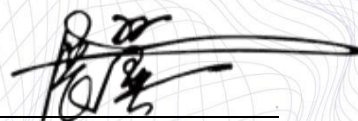
审核和注册

本注册要求组织必须按照上述标准保持其质量管理体系，并由POSI进行监督。

查询网站： www.posicert.com

该证书信息可在国家认证认可监督管理委员会官方网站<http://cx.cnca.cn>查询。





总经理

证书编号： 381210061R0S

首次发证日期： 2021.05.08

本次发证日期： 2021.05.08

有效期： 2024.05.07



上海波西认证有限公司

上海市浦东新区世纪大道1500号1301-C-7室 Email: info@posicert.com

POSI

CERTIFICATE

This is to certify that the Quality Management System of
Xiantao Fortune Medical Supplies Co., Ltd.

Business License Number: 91429004615404554A

Registered Address: No. 2, Fuyuan Road, Pengchang Town, Xiantao City, Hubei, China

Audit Address: No. 2, Fuyuan Road, Pengchang Town, Xiantao City, Hubei, China

applicable to

Production and Export of Medical Disposable Non-woven Products
(clothing, caps, sleeves cover, bed sheet, bedcover, shoe covers, face mask
pillowcase, beard cover); Export Trade of Disposable Plastic Products
(shoe covers, sleeves cover, aprons, visiting clothes)

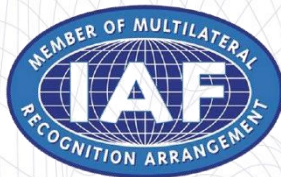
has been assessed and registered by POSI against the provisions of

ISO13485:2016

This registration is subject to the company maintaining a quality management system,
to the above standard, which will be monitored by POSI.

Please consult the website: www.posicert.com

The certificate information is also available on the CNCA official website: <http://cx.cnca.cn>.



Joe Zhou

General Manager

Certificate Registration No: 381210061R0S

Initial issue date: 2021.05.08

Issue date: 2021.05.08

Valid until: 2024.05.07



Shanghai POSI Certification Co., Ltd.

Room 1301-C-7, No.1500, Century Avenue, Pudong New Area, Shanghai ,China.Email:info@posicert.com

Test Report SL52025269709001TX
XIANTAO FORTUNE MEDICAL SUPPLIES CO., LTD.
NO.182 NEW STREET, HECHANG, HUBEI, CHINA

Date: June 29, 2020

Page 1 of 4

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

Sample Description : (A) Disposable face mask

Composition : (A) Non-woven fabric

Sample Color : (A) Blue

Manufacturer : XIANTAO FORTUNE MEDICAL SUPPLIES CO., LTD.

Lot No./Batch No. : Not provided

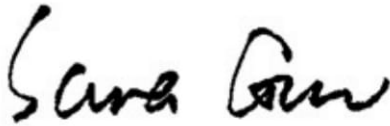
Test Performed : Selected test(s) as requested by applicant

Sample Receiving Date : Jun 03, 2020

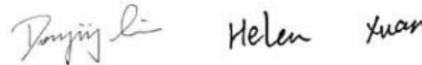
Testing Period : Jun 05, 2020 - Jun 29, 2020

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)



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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 : 174 mm x 151 mm
 Test Area : ~60 cm²
 Test Side : Inside
 Flow Rate : 28.3 l/min
 Positive Control Average : 2713 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)	36	36	38	37	37

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)

Sample: A

Penetration on inside surface							
1#	2#	3#	4#	5#	6#	7#	8#
Pass	Pass	Pass	Pass	Pass	Fail	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	Fail	Pass	Pass	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: ≥ 16.0 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)

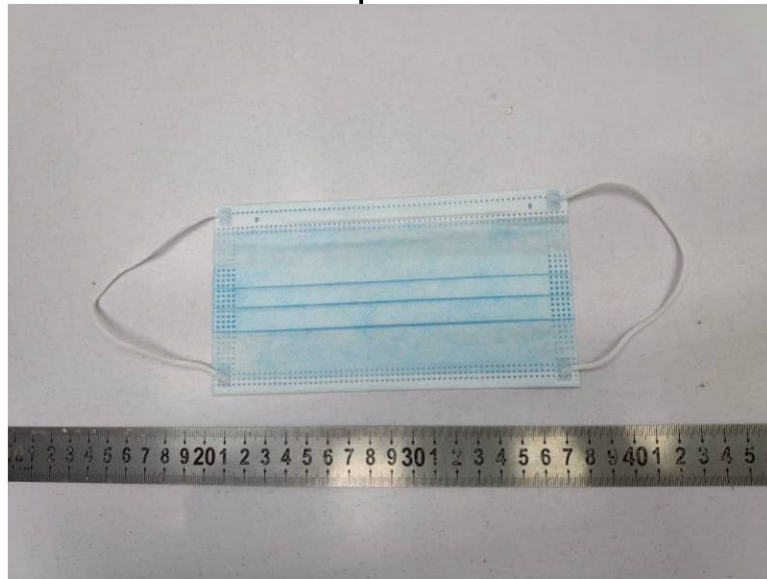
Sample: A

Sample Number	Mask Weight(g)	Total Bioburden, (cfu/mask)	Total Bioburden, (cfu/g)
1#	2.58	3	1.16
2#	2.66	3	1.13
3#	2.62	<3	<1.15
4#	2.64	6	2.27
5#	2.63	6	2.28

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



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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FY1601
Round Nurse Cap

Material: non-woven PP
Weight: 10g/m², 12g/m², 14g/m², 16g/m², etc
Size: 18", 21", etc
Color: white, blue, green, etc



FY1602
Clip Cap

Material: non-woven PP
Weight: 10g/m², 12g/m², 14g/m², etc
Size: 20", 21", 22", etc
Type: single elastic/double elastic
Color: white, blue, green, etc



FY1605
Non-woven Face Mask

Material: non-woven PP or non-woven PP and filter paper
Specification: ear-loop/tie and 2ply (18g/m²+25g/m²)
/3ply (18g/m²+20g/m²+25g/m²) /4ply (22g/m²+25g/m²+23g/m²+25g/m²)
Size: 17.5×9.5cm
Color: white, blue, green, etc



FY1603
Doctor Cap

Material: non-woven PP
Weight: 20g/m², 25g/m², 30g/m², etc
Size: 61×14cm, 64×23cm, etc
Type: tie/elastic back
Color: white, blue, green, etc



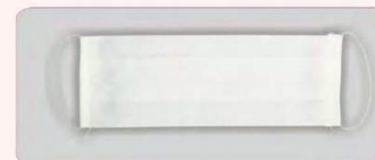
FY1604
Net Cap

Made from high quality nylon net fabric material
Weight: 2.7g/m², etc
Size: 19", etc
Color: white, blue, green, etc



FY1632
Non-woven Face Mask with Charcoal

Description:
Conforms to American NEL SON N95 test standards.
Adjustable nose seal, easy to fold and carry. Mini-fiber high electrostatic filter, filtration efficiency of dust & powder is over 95%.
Repel continually contamination of dangerous blood and saliva continually.
Specification: Ear-loop type: 4 ply
Detailed weight: 4 ply: 25g/m²+20g/m²+40g/m²+25g/m²
Size: 18×9cm
Color: white, green, blue etc.
Packing: 50pcs/box, 40boxes/carton, Dia.: 520×380×300cm



FY1606
Paper Face Mask

Material: high quality wet-strength paper
Specification: ear-loop and 1ply/2ply
Size: 20 × 7cm
Color: white



FY1609
Surgical Hood

Material: non-woven PP
Weight: 16g/m², 20g/m², 25g/m², 30g/m², etc
Size: 30×124cm, etc
Type: tie
Color: white, blue, green, etc



FY1608
Face Mask With Shield

Composition : non-woven face mask and PET shield (prevent mist)
Specification : ear-loop and 3ply/4ply
Size : 17.5×9.5cm
Color : white, blue, green, etc



FY1629
Face Guard

Material : PET
Type : elastic
double-sided anti-fog
Pack : 1pc/pe bag



FY3101
Protective Spectacle

Impact resistant PC lens, Lens thickness: 2mm
Integrated side legs
High strength structure
Integrated wide side shields