



# DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

## EU Representative

SUNGO Europe B.V.  
Fascinatio Boulevard 522, Unit 1.7,  
2909VA Capelle aan den IJssel, The  
Netherlands  
SRN: NL-AR-000000247

## Conformity Assessment

**Conformity Assessment Procedure**  
Annex II+III of Regulation (EU) 2017/745

**Applicable Standards**  
EN ISO 14971: 2019  
EN ISO 15223-1: 2016  
EN 1041:2008+A1:2013  
ISO 10993-1: 2018  
EN ISO 10993-5: 2009  
EN ISO 10993-10: 2013  
EN 14683:2019+AC:2019 Type IIR

### Remark

*The declaration of conformity is valid in connection with the release technical document CE/MDR-FM-03.*

*All the supporting documentation is retained at the premises of the manufacturer.*

*The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.*

## Manufacturer

Name: HUBEI FEITENG PROTECTIVE PRODUCTS CO.,LTD.  
Address:NO.72 SHAHU AVENUE SHAHU TOWN XIANTAO CITY HUBEI PROVINCE CHINA

## Product Information

Name: Medical Face Mask

Model: TYPE IIR (blue)-FTIII  
TYPE IIR(white)-R827917L1  
TYPE IIR(pink)-FT2RPL  
TYPE IIR(black)-FT3HB

GMDN: 35177

Basic UDI-DI: /

Classification: Class I, According to Rule 1, Annex VIII, Regulation (EU) 2017/745

## Declaration

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standards above.

Signature: Hu Feng Date: 2023/2/2

Position: GM

Place: Hubei/China



POSI

CERTIFICATE  
质量管理体系认证证书

兹证明

湖北飞腾防护用品有限公司

统一社会信用代码： 91429004MA498CB25P

注册地址： 仙桃市沙湖镇沙湖大道72号

经营地址： 湖北省仙桃市沙湖镇沙湖大道72号

的质量管理体系适用于：

一次性无纺布制品（口罩、衣服）的生产和销售（仅限出口）；  
一次性无纺布制品（袖套、帽子、鞋套、靴套、胡须套、  
床单、枕头套、围裙）的销售（仅限出口）

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。

获证组织必须定期接受监督审核并经审核合格此证书方继续有效。

查询网站： [www.posicert.com](http://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： 381240005R0S

首次发证日期： 2024.01.05

本次发证日期： 2024.01.05

有效期： 2027.01.04



上海波西认证有限公司

中国（上海）自由贸易试验区世纪大道1500号1402A室 Email: [info@posicert.com](mailto:info@posicert.com)

# POSI

## CERTIFICATE

This is to certify that the Quality Management System of

### Hubei Feiteng Protective Products Co., Ltd.

Business License Number: 91429004MA498CB25P  
Registered Address: No.72, Shahu Avenue, Shahu Town,  
Xiantao City, Hubei Province, China  
Audit Address: No.72, Shahu Avenue, Shahu Town,  
Xiantao City, Hubei Province, China

applicable to

Production and sales of disposable non-woven products (face masks, clothes) (export only); sales of disposable non-woven products (sleeves, caps, shoe covers, boot covers, beard covers, bed sheets, pillow cases and aprons) (export only)

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.

Certified organization shall accept regular surveillance audit, the validity of certificates shall be maintained for the positive result of audit.

Please consult the website: [www.posicert.com](http://www.posicert.com)

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



A handwritten signature in black ink, appearing to read 'Jie Chen', written over a horizontal line.

General Manager

Certificate Registration No: 381240005R0S

Initial issue date: 2024.01.05

Issue date: 2024.01.05

Valid until: 2027.01.04



Shanghai POSI Certification Co., Ltd.

Room 1402A, No.1500, Century Avenue, China (Shanghai) Pilot Free Trade Zone. Email: [info@posicert.com](mailto:info@posicert.com)



中国认可  
国际互认  
检测  
TESTING  
CNAS L1842



佛山中纺联检验技术服务有限公司  
CNTAC Testing Service Co.,Ltd.(Foshan)

<b>Testing Report</b>	Security website: <a href="http://www.fcl-sz.org.cn">www.fcl-sz.org.cn</a> Security code: 2578503514
Report No: ZFLJ2703935A	Page 1 of 5



### Applicant Information

Applicant Name : HUBEI FEITENG PROTECTIVE PRODUCTS CO.,LTD.  
Applicant Address : NO. 72 SHAHU AVENUE SHAHU TOWN XIANTAO CITY HUBEI PROVINCE  
CHINA

### Sample Information

Sample Description : Disposable medical mask (black)  
Sample Quantity : 50 pieces  
Colour : Black  
Product number : FT3HB  
Size specification : 17.5\*9.5cm  
Material Components : 65% non-woven 35% melt-blown cloth

- Sample Receiving/Testing date : 2021-07-21  
- Report Date : 2021-07-30  
- The original sample is stucked on the last paper.

### Test Performed

Judgement according to:  
EN 14683:2019+AC:2019 Medical face masks – Requirements and test methods Type II R  
- Selected test(s) as requested by applicants. For details, refer to attached page(s).

### Pronounce

The results shown in this report refer only to sample(s) tested unless otherwise stated.  
All the items are performed in the standard conditions, except the noted cases.  
Except for the requirement of the client, the test results and the conformity judgement of this report do not take the uncertainty of the test results into account.

Signed for and on behalf of  
CNTAC Testing Service Co.,Ltd.(Foshan)

Approved by

( Except for microbiological project )

( Microbiological project )





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**CONCLUSION**

Test Item	Judgement
Resistance to Penetration by Synthetic Blood	Pass
Differential Pressure	Pass
Microbial Cleanliness Test	Pass
Bacterial Filtration Efficiency	Pass





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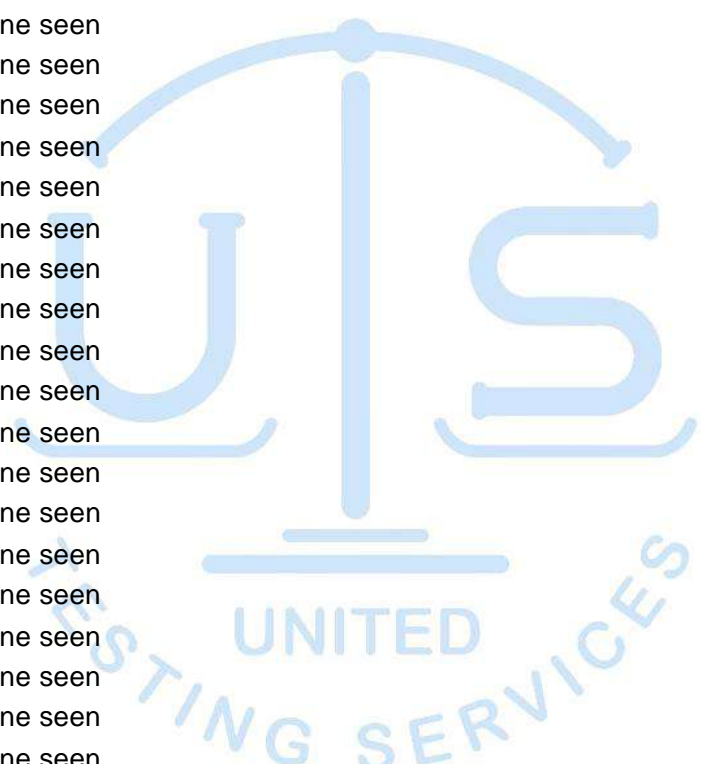
佛山中纺联检验技术服务有限公司  
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--- Test Result ---

Test Result	Requirements	Judgement
<b>1. Resistance to Penetration by Synthetic Blood</b> <u>ISO 22609:2004</u>		
Synthetic blood surface tension: 0.042N/m, Distance between blow head front end and target area: 300mm, Synthetic blood volumes: 2mL, Test pressure: 16.0kPa, Injection velocity: 550cm/s, Use a fixed target board. Test conditions: temperature 21.1℃, relative humidity 85.1%.		
sample 1#	None seen	Pass Pressure at 16.0kPa
sample 2#	None seen	
sample 3#	None seen	
sample 4#	None seen	
sample 5#	None seen	
sample 6#	None seen	
sample 7#	None seen	
sample 8#	None seen	
sample 9#	None seen	
sample 10#	None seen	
sample 11#	None seen	
sample 12#	None seen	
sample 13#	None seen	
sample 14#	None seen	
sample 15#	None seen	
sample 16#	None seen	
sample 17#	None seen	
sample 18#	None seen	
sample 19#	None seen	
sample 20#	None seen	
sample 21#	None seen	
sample 22#	None seen	
sample 23#	None seen	
sample 24#	None seen	
sample 25#	None seen	
sample 26#	None seen	
sample 27#	None seen	
sample 28#	None seen	
sample 29#	None seen	
sample 30#	None seen	
sample 31#	None seen	
sample 32#	None seen	



若对检测报告有异议, 应于收到报告之日起 15 日内向检测单位提出, 逾期不予受理。



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Test Result	Requirements	Judgement
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**2. Differential Pressure** EN 14683:2019+AC:2019 Appendix C

Air flow: 8L/min, Test area diameter 25mm, Test area: 4.9cm<sup>2</sup>

Unit: <Pa/cm<sup>2</sup>>

sample 1#	36.2	< 60	Pass
sample 2#	37.2		
sample 3#	37.8		
sample 4#	37.5		
sample 5#	36.6		
Average	37.1		

**3. Microbial Cleanliness Test** EN 14683:2019+AC:2019 Appendix D

Unit: <CFU/g>

sample 1#	<1	≤ 30	Pass
sample 2#	<1		
sample 3#	<1		
sample 4#	<1		
sample 5#	<1		

**4. Bacterial Filtration Efficiency** EN 14683:2019+AC: 2019 Appendix B

Flow rate: 28.3L/min, Test area: 77cm<sup>2</sup>, Test bacteria culture: Staphylococcus aureus ATCC 6538, Particle Diameter: 3.0μm, Inside of the test mask was facing towards the challenge aerosol, The average plate count results of the positive controls: 1.9×10<sup>3</sup>CFU, The average plate count results of the negative controls: <1CFU

Unit: <%>

sample 1#	99.9	≥ 98	Pass
sample 2#	99.8		
sample 3#	99.8		
sample 4#	99.9		
sample 5#	99.9		
Minimum	99.8		





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**Original Sample**



===== End of Report =====

