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仙桃富实防护用品有限公司
智利 平件

证 明 书

CERTIFICATE

中 国 国 际 贸 易 促 进 委 员 会 暨 中 国 国 际 商 会

China Council for the Promotion of International Trade is China Chamber of International Commerce

中国国际贸易促进委员会

China Council for the Promotion of International Trade
China Chamber of International Commerce

证 明 书
CERTIFICATE

号码 No. 244200B0/H00065

兹证明： 所附文件的影印件与原件相符。

THIS IS TO CERTIFY THAT: the annexed photostated copy of DOCUMENT is in conformity with the original.

China Council for the Promotion of International Trade

签证员：

Authorized Official: Li Li

日期：2024年03月08日
(Date: Mar. 08, 2024)

证明书查询 Website for verifying the certificate: http://www.rzccpit.com/validate.html

EU Certificate

Production Quality Assurance
REGULATION (EU) 2017/745 on Medical Devices
Annex XI Part A

Registration No.:	DZ 2082765-1
Manufacturer:	Xiantao Fushi Protective Products Co., Ltd. Zhongling Industrial Zone, Pengchang Town, Xiantao City, 433018 Hubei, P.R. China
EUDAMED Single Registration No.:	CN-MF-000017275
Products:	Products of class I, sterile: T020604- MEDICAL USE FACE MASKS, TYPE II AND IIR - Sterile Medical Face Masks T020401- STANDARD SURGICAL GOWNS - Surgical Gowns T02010101- INCISION DRAPES, WITHOUT ANTIBACTERIAL AGENT - Surgical Drapes T020199 - SURGICAL DRAPES - OTHER - Surgical Drapes T0205- NON-SURGICAL GOWNS (EXCLUDING PERSONAL PROTECTIVE EQUIPMENT - PPE) - Isolation Gowns - Coveralls T0207- CAPS AND HEADWEAR (EXCLUDING PERSONAL PROTECTIVE EQUIPMENT - PPE) - Sterile Medical Caps

The Notified Body hereby declares that the requirements of Annex XI, Part A of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a production quality assurance, which is subject to periodic surveillance, defined by Annex XI, Part A, Section 7 of the aforementioned regulation.
If class III devices or class IIb devices are covered by this certificate, an EU type-examination certificate in accordance with Annex X of the aforementioned regulation is required before placing them on the market.

Report No.:	244459055-200
Effective date:	2024-02-02
Expiry date:	2029-02-01
Issue date:	2024-02-02

Herbert Zhong
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

This certificate can be validated on https://www.certipedia.com

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-091

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EU Certificate

Production Quality Assurance
REGULATION (EU) 2017/745 on Medical Devices
Annex XI Part A

Registration No.:	DZ 2082765-1
Manufacturer:	Xiantao Fushi Protective Products Co., Ltd. Zhongling Industrial Zone, Pengchang Town, Xiantao City, 433018 Hubei, P.R. China
EUDAMED Single Registration No.:	CN-MF-000017275
	T0208- SHOE COVERS (EXCLUDING PERSONAL PROTECTIVE EQUIPMENT - PPE) - Sterile Medical Shoe Covers
	The scope of certification is limited to the aspects relating to establishing, securing and maintaining sterile conditions
Authorized representative(s):	SUNGO Europe B.V Fascinatio Boulevard 522, Unit 1.7, 2909VA Capelle aan den IJssel, The Netherlands

Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2024-02-02

Report No.:	244459055-200
Effective date:	2024-02-02
Expiry date:	2029-02-01
Issue date:	2024-02-02

Herbert Zhong
TÜV Rheinland LGA Products GmbH
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附加证明书
APOSTILLE

（1961年10月5日海牙公约）
（Convention de La Haye du 5 octobre 1961）

1. 文书出具国：
Country: 中华人民共和国
People's Republic of China

本公文书 This public document

2. 签署人
has been signed by: 李莉
Li Li

3. 签署人身份
acting in the capacity of: 签证员
Authorized Official

4. 印鉴名称
bears the seal/stamp of: 中国国际贸易促进委员会(17)
China Council for the Promotion of International Trade(17)

证明 Certified

5. 签发地 at: 武汉
Wuhan

6. 签发日期 the: 2024年03月12日
March 12,2024

7. 签发人 by: 范胜军 / Fan Shengjun
湖北省外事办公室
Foreign Affairs Office of Hubei Province

8. 附加证明书编号 No: 认字第244200002448号

9. 签发机关印鉴：
Seal/Stamp:

10. 签名：
Signature: 范胜军