

EU Certificate

Quality Management System REGULATION (EU) 2017/745 on Medical Devices Annex IX Chapter I, Section 2 and 3 and Chapter III

Registration No.: HZ 2077355-1

Manufacturer: Xiantao Xingrong Protective Products Co., Ltd.
Pengchang Ave (South of Xianpeng Road),
Xiantao, 433018 Hubei
P.R. China

EUDAMED Single
Registration No.: CN-MF-000020687

Products: Products of class I, sterile:
T020604 - MEDICAL USE FACE MASKS, TYPE II AND IIR
- Disposable medical masks
T020401 - STANDARD SURGICAL GOWNS
- Standard Surgical Gowns
T0207 - CAPS AND HEADWEAR (EXCLUDING PERSONAL
PROTECTIVE EQUIPMENT - PPE)
- Disposable Caps
T0208 - SHOE COVERS (EXCLUDING PERSONAL
PROTECTIVE EQUIPMENT - PPE)
- Disposable Shoe Covers
T0205 - NON-SURGICAL GOWNS (EXCLUDING PERSONAL
PROTECTIVE EQUIPMENT - PPE)
- Coveralls
- Isolation Gowns

The scope of certification is limited to the aspects relating to
establishing, securing and maintaining sterile conditions

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled.

If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.: 244567553-200

Effective date: 2024-09-26

Expiry date: 2029-09-25

Issue date: 2024-09-26



Fuxiu Sheng
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.

© TÜV, TÜEV and TÜV are registered trademarks. Utilisation and application requires prior approval.



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



TÜVRheinland®
Precisely Right.

EU Certificate

**Quality Management System
REGULATION (EU) 2017/745 on Medical Devices
Annex IX Chapter I, Section 2 and 3 and Chapter III**

Registration No.: HZ 2077355-1
Manufacturer: Xiantao Xingrong Protective Products Co., Ltd.
Pengchang Ave (South of Xianpeng Road),
Xiantao,
433018 Hubei
P.R. China
EUDAMED Single Registration No.: CN-MF-000020687
Authorized representative(s): Luxus Lebenswelt GmbH
Kochstr. 1, 47877, Willich, Germany

Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2024-09-26

Report No.: 244567553-200
Effective date: 2024-09-26
Expiry date: 2029-09-25
Issue date: 2024-09-26



Fuxiu Sheng
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.zflg.de
BS-MDR-091

