

EU Declaration of Conformity

Manufacturer Name: Xianning Full Guard Medical Products Co., Ltd.

Manufacturer Address: Yongan East Road Wenquan Economic Development Zone, Xianning City, Hubei Province, China

Tel. / Fax: +86 0715-8210013

SRN: CN-MF-000013685

Authorized Representative Name: ZOUSTECH S.L.

Authorized Representative Address: Pso. Castellana, 141 – Planta 19. 28046 Madrid – Spain

SRN: ES-AR-000002008

Basic UDI-DI:

697386655FGSGSGXU, 697386655FGSGRGXR.

Product / Trademark Name:

Disposable Standard Surgical Gown, Disposable Reinforced Surgical Gown.

Product References:

Standard Surgical Gown: FGS-SG-SM50-M, Size M, FGS-SG-SM50-L, Size L, FGS-SG-SM50-XL, Size XL, FGS-SG-SM50-XXL, Size XXL.

Reinforced Surgical Gown: FGS-RF-SM50-M, Size M, FGS-RF-SM50-L, Size L, FGS-RF-SM50-XL, Size XL, FGS-RF-SM50-XXL, Size XXL.

Intended purpose: Surgical Gown is specially designed for doctors and nurses who do operation in surgical room during surgical procedures, intended to prevent the transmission of infective agents between clinical staff and patients.

EMDN Product code: T020401/T020402

Classification: Class Is according to Rule 1 Annex VIII of MDR 2017/745

Conformity assessment procedure: According to Annex II and Annex III of MDR 2017/745:

Notified Body name and address: TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, München, Germany.

Notified Body Identification number: 0123

EU Certificate number: No. G21 003747 0003 Rev.00

Starting date: 2024-06-21

Expire date: 2029-06-20

Relevant Harmonized Standard:

EN 13795-1:2019	EN ISO 11607-1:2020	EN ISO 11607-2:2020	EN 868-5:2018
EN ISO 11135:2014	EN ISO 11135:2014/A1:2019	EN ISO 11737-2:2020	EN ISO 10993-1:2020
EN ISO 10993-5:2009	EN ISO 10993-10:2013	EN ISO 14971:2019	EN ISO 20417:2021
EN ISO 15223-1:2021	EN 22248:1992		

This declaration of conformity is issued under the sole responsibility of Xianning Full Guard Medical Products Co., Ltd. We hereby declare that the medical device specified in the attachment are in conformity with the relevant Union harmonized standards and meet the provision of the Regulation (EU) MDR 2017/745 for medical devices.

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





Xianning Full Guard Medical Products Co.,Ltd.

Address: Yongan East Road Wenquan Economic Development Zone, Xianning City, Hubei Province, China

Tel: 86-715-8210013 Website: www.fullguardmedical.com

Signature and Stamp:

Place and date of issue: Xianning, Hubei 2024-06-21

Name: David Lei

Position: General Manager *

