

EU Declaration of Conformity

Manufacturer:

Name: Xianning Full Guard Medical Products Co., Ltd

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

Tel/Fax: +86-715-8200113

SRN: CN-MF-000013685

Whose single Authorized Representative:

Name: Humiss Beratung GmbH

Address: Gneisenaustraße 8. 40477, Düsseldorf, Deutschland

Tel/Fax: +49-211-90760042

SRN: DE-AR-000023447

Non-Sterile Disposable Surgical Gown

UMDNS CODE: 11901

Product Code:

FGNS-SG-SM40-M, FGNS-SG-SM40-L, FGNS-SG-SM40-XL, FGNS-SG-SM40-XXL

Product Size: M/L/XL/XXL

BASIC UDI-DI: 697386655FGNSSGSM40M4V, 697386655FGNSSGSM40L4T

697386655FGNSSGSM40XL7D, 697386655FGNSSGSM40XXLFM

Intended purpose: The products are mainly used for general isolation in outpatient clinics, wards, inspection rooms, cleaning room, laboratory ect. It is intended to be used by healthcare professionals in hospitals and clinics to maintain a good level of hygiene and contribute to infection control.

Classification According To MDR, Annex VIII: Class I – Rule 1

Conformity Assessment Route: Annex II and Annex III



Applied Common Specification/Standard:

EN ISO 14971:2019 Medical devices - Application of risk management to medical devices (ISO 14971:2019).

EN ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009).

EN ISO 10993-10:2021 Biological evaluation of medical devices - Part 10: Tests for skin sensitization.

EN ISO 15223-1:2021 Medical devices—Symbols to be used with information to be supplied by the manufacturer-Part 1:General requirements.

We, the manufacturer, herewith declare under our sole responsibility that the above mentioned product, meets the provision of Regulation (EU) 2017/745 on Medical Devices (MDR). All supporting documentations are retained under the premises of the manufacturer.

REGULATION

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices.



Place of Issue: Xianning, Hubei

Date of Issue: 2023.10.11

Signature:

Name: Rosen Jiang

Position: Managing Director

Stamp:

