

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: 697386655FGNSGU7

Intended purpose: The products are mainly used for general isolation in out patient 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

The manufacturer declares that the device complies with the Medical Device Regulation (EU) 2017/745, Standard(s) used for showing compliance with the essential requirements in the specified directive(s):



EN ISO 13485:2016, EN ISO 14971:2019, EN ISO 20417:2021, EN ISO 15223-1:2021, EN 62366-1:2015, ISO 10993-1:2020, ISO 10993-5:2009, ISO 10993-10:2021, ISO 10993-23:2021, EN 13795-1:2019.

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.

The referred report(s) show that the device complies with standard(s) recognized as giving presumption of compliance with the essential requirements in the specified EU Directive(s). The manufacturer has marked the device with the CE mark.



Place of Issue: Xianning, Hubei

Date of Issue: 2023.10.11

Signature:

Name: David Lei

Position: Managing Director

Stamp:

