

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

Disposable Isolation Gown

UMDNS CODE: 15037

Product Code:FGIS-PP25-M,FGIS-PP25-L,FGIS-PP25-XL, FGIS-PP25-XXL

Product Size: M,L,XL,XXL

Basic -UDI -DI: 697386655FGIS-PP25-MAC,697386655FGIS-PP25-LAA
697386655FGIS-PP25-XL76, 697386655FGIS-PP25-XXL8Y

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 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization (ISO 10993-10:2010)

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:

