

## EU Declaration of Conformity

**Manufacturer:**

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

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**SRN:** CN-MF-000013685

**Whose single Authorized Representative:**

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**SRN:** ES-AR-000002008

## 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)



ISO 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

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

EN ISO 10993-10:2013 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization (ISO 10993-10:2010)

EN ISO 15223-1:2016 Medical devices—Symbols to be used with medical device labels, labeling and information to be supplied.

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: 2021.4.21

Signature: 姜迪

Name: Rosen Jiang

Position: Managing Director

Stamp:

