

EC Declaration of Conformity

Manufacturer:

Name: Xianning Full Guard Medical Products Co., Ltd

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

Tel/Fax: 0715-8200113

SRN: Not available yet

Whose single Authorized Representative:

Name: ZOUSTECH S.L

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SRN: Not available yet

Disposable Isolation Gown

UMDNS CODE: 15037

Product Code: FGIS-PP25-M, FGIS-PP25-L.

Product Size: M, L, XL, XXL

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 湖北咸宁

Date of Issue: 2021.4.21

Signature:

Name: Rosen Jiang

Position: Managing Director

Stamp:



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Approved By: Rosen Jiang

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