

fullguard

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Xianning Full Guard Medical Products Co., Ltd

ADD: Yong'an East Avenue, Xian'an District, Xianning City, P.R.C

TEL: +86-715-8210013

WEB: www.fullguard-medical.com

EC Declaration of Conformity

Manufacturer:

Name: Xianning Full Guard Medical Products Co., Ltd

Address: Yong'an East Avenue, Xian'an Economic Development Zone, Xianning City, Hubei Province, China

Tel/Fax: 0715-8200113

SRN: Not available yet

Whose single Authorized Representative:

Name: ZOUSTECH S.L

Address: Pso.Castellana, 141- planta 19, 28046-Madrid, Spain

Tel/Fax: +34694426446

SRN: ES-AR-000002008

We, the manufacturer, herewith declare that the products

Disposable Isolation Gown

UMDNS CODE: 15037

Product Code: FGIG

BASIC UDI-DI: 1697386655FGISTC

Product Size: XS, S, M, L, XL, XXL, XXXL or customer size

Classification acc. To MDR Ax. VIII: Class I – Rule 1

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)





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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

EN 1041: 2008 Information supplied by the manufacturer of medical devices

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned product, meet 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: 2021.5.26

Signature:

Name: 姜迪 Rosen Jiang

Position: Managing Director

Stamp:

Issued By: Molly Zheng

Approved By: Rosen Jiang

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