EC Declaration of Conformity

Manufacturer: Xianning Full Guard Medical Products Co., Ltd

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

Province, China Tel: 0715-8200113 SRN: CN-MF-000013685

European Representative: ZOUSTECH S.L.

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

Tel/Fax:+34694426446 SRN:ES-AR-000002008

Product Name: Disposable Surgical Gown

Type: M,L,XL,XXL

Product Code: FGS-SG-SM50-M,FGS-SG-SM50-L,FGS-SG-SM50-XL,FGS-SG-SM50-XXL,

FGS-RF-SM50-M,FGS-RF-SM50-L,FGS-RF-SM50-XXL

UMDNS Code: 11897

Classification (MDD, Annex VII): Class Is, Rule 1

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and All applicable harmonised Standards. All supporting documentations are retained under the premises of the manufacturer.

Xianning Full Guard Medical Products Co., Ltd is exclusively responsible for the declaration of conformity .

DIRECTIVES

Medical Device Directive:

COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC), Amended by DIRECTIVE 2007/47/EC of 5 September 2007.

CE NO.:G2S 003747 002 Rev.00

Report No.:SH18131701

Notified Body: TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339, MÜnchen, Germany

NB Identification number:

(EC) Certificate(s): Yes

Expire date of the Certificate: 2023-11-04

Start of CE Marking: Yes

Place of Issue:Xianning,Hubei

Date of Issue: 2018-11-05

Signature/date: 2018-11-05

Signature: 2 ch

Name:Rosen Jiang

Position: Managing Director