

## EC Declaration of Conformity

Manufacturer: Xianning Full Guard Medical Products Co., Ltd  
Address: Yongan East Road Wenquan 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-XL, 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:  0123

(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: 

Name: Rosen Jiang

Position: Managing Director

