fullguard
福达医疗

Xianning Full Guard Medical Products Co.,Ltd
ADD: Yong'an East Avenue, Xian'an Distrct, 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

Disposable Medium Drapes

UMDNS CODE: 12368

Product Code: FGSD

Product Size: (30~300) x (30~400) cm

Classification According To MDD, Annex VII: Class I Sterile, Rule 1

Digitally signed by Morozov Maria
Date: 2023.09.16 11:40:48 EEST
Reason: MoldSign Signature
Location: Moldova

Applied Common Specification/Standard:

EN 13795-1:2019 Surgical clothing and drapes-Requirements and test methods part1:Surgical drapes and gown

EN ISO 11607-1:2020 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems

EN ISO 11607-2:2020 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes

EN ISO 11135:2014 Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices

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)

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

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 the following EC Council Directives and All applicable harmonized Standards. All supporting documentations are retained under the premises of the manufacturer.

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 0123

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

NB Identification number: 0123

Certificate No.: G2S 003747 0002 Rev.00

(EC) Certificate(s): YES

Expire date of the Certificate: Nov 04, 2023

Start of CE Marking: Nov 05, 2018

Place of Issue: *Xianning, Hubei 湖北咸宁*

Date of Issue: *2021. 5.26*

Signature:

Name: *姜迪 Rosen Jiang*

Position: *Managing Director*

Stamp: