fullguard 福达医疗

Xianning Full Guard Medical Products Co.,Ltd.

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

Tel: +86-715-8210013 Website: www.fullguardmedical.com

EU 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: +86-715-8200113

SRN: CN-MF-000013685

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 Cap

UMDNS CODE: 16081

Product Code:FGDCE-SM35,FGDCT-SM35

Product Size:62*14.5cm

Basic -UDI -DI:697386655FGDCE-SM35AT,697386655FGDCT-SM35GW

Intended purpose:The products are mainly used for general isolation in outpatient clinices,wards,inspection rooms,cleaning room,laboratory ect.It is intended to be used by healthcare professionals in hospitals and clinics to maintain a good level of hygiene and contribute to infection control.

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

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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.

CE

Place of Issue:Xianning,Hubei

Date of Issue:2021.5.26

Signature:

Name:Rosen Jiang

Position:Managing Director

Stamp: