

## **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 Cap**

**UMDNS CODE:** 16081

**Product Code:** FGHC

**BASIC UDI-DI:** 1697386655FGHCS9

**Product Size:** Round cap, 18inch / 19 inch / 21 inch, or customized size

Tie-on cap, 14x62cm, 16x64cm or customized 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)





**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:*

