



DECLARATION OF CONFORMITY

Manufacturer:

Name: Quzhou Glory Safety Clothing Co.,Ltd

Address: No.15,10th Road, Huibu Town, Changshan County , Qvzhou,Zhejiang,China

E-mail: ada@glorysafety.com

Whose Authorized Representative:

Name: Lotus NL B.V.

Address: Koningin Julianaplein 10,1e Verd, 2595AA, The Hague, Netherlands.

E-mail: peter@lotusnl.com

We, the manufacturer, herewith declare that the product(s)

Product Name	Single-use medical face mask(non-sterile)	Model	GFM-M001
BASIC UDI-DI	/	UMDNS Code	12447
Intend Use	Single-use medical face mask(non-sterile) is used for patients in order to reduce the risk of the spread of infections, and it is not intended for use by healthcare professionals in an operating room or in other medical settings with similar requirements. The product is disposable and non-sterile.		
Classification	I, (MDR, Annex VIII Rule 1)		

meet(s) the provisions of the REGULATION (EU) 2017/745 which apply to them.

Conformity Assessment Route: Article 19, Annex II and Annex III according to REGULATION (EU) 2017/745.

Applicable Standards:

ISO 13485:2016

ISO 10993-5: 2009

EN 1041:2008

EN ISO 14971:2012

ISO 10993-10:2010

EN 15223-1:2016

ISO 10993-1: 2018

EN 14683:2019

EN 62336-1:2015

We, the manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the REGULATION (EU) 2017/745. We agree to develop, implement and maintain a documented post-production monitoring process.

Name of authorized signatory: Jianliang Chen **Signature:**

Position held in the company: General Manager

Place: Zhejiang, China

Quzhou Glory Safety Clothing Co.,Ltd

Date:

Seal/Stamp:

