



DECLARATION OF CONFORMITY

Manufacturer:

Name: HUBEI WANFUL PROTECTIVE PRODUCTS CO LTD

Address: NO.113 MIAN YANG DA DAO XIANTAO CITY HUBEI PROVINCE, CHINA

E-mail: wanful.sky@163.com

Whose Authorized Representative:

Name: Lotus NL B.V.

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

E-mail: peter@lotusnl.com

Test report No. : 20R000157MT

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

Product Name	DISPOSABLE MEDICAL MASK(NON-STERILE)	Model	DDM-3-01, DDM-3-02, DDM-3-03
BASIC UDI-DI	/	UMDNS Code	12447
Intended Use	It 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.		
Classification	I, Rule12 (Annex IX of MDD)		

meet(s) the provisions of the Medical Devices Directive 93/42/EEC which apply to them.

Conformity Assessment Route: Annex VII of the Medical Devices Directive 93/42/EEC.

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 62366-1:2015

We, the manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Medical Devices Directive 93/42/EEC. We agree to develop, implement and maintain a documented post-production monitoring process.

Name of authorized signatory: 李春林

Signature: 

Position held in the company: General Manager

Date: 2020-10-20

Place: XianTao, China

Seal/Stamp:

HUBEI WANFUL PROTECTIVE PRODUCTS CO LTD

