



DECLARATION OF CONFORMITY

Manufacturer:

Name: Xiantao Hongwei Non-woven Fabric Products Co., Ltd

Address: Taizihu Industrial Park, Xiantao City, Hubei, China

Whose Authorized Representative:

Name: Lotus NL B.V.

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

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

Product Name	Disposable Medical Face Mask	Model	Elastic Face Mask
BASIC UDI-DI	/	UMDNS Code	12447
Intend Use	Disposable Medical Face Mask is intended for all personnel in need of protection to wear and use in non-invasive operation conditions. The Disposable Medical Face Mask has the function of covering the user's mouth, nose and jaw, providing a certain physical barrier to prevent the direct passage of pathogens, microorganisms and particles. Disposable Medical Face Mask is used for patients in order to reduce the risk of the spread of infections, and it is intended for use by healthcare professionals in an operating room or in other medical settings with similar requirements. This product is 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

EN ISO 14971:2012

ISO 10993-1: 2018

ISO 10993-5: 2009

ISO 10993-10:2010

EN 14683:2019

EN 1041:2008

EN 15223-1:2016

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: Qingwei Xu

Signature: 

Position held in the company: General Manager

Date:

Place: Hubei, China

Seal/Stamp: 

Xiantao Hongwei Non-woven Fabric Products Co., Ltd