



DECLARATION OF CONFORMITY

According to REGULATION (EU) 2017/745 -Article 19, Annex II and Annex III.

Manufacturer:

Company name: Danyang City Huangtang Quintong
Labor Supplies Factory
Address: Jishan Village, Huangtang Town, Danyang
City, Jiangsu Province, China.

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 products

Product Name	Medical Device	Device Class	Model	Basic UDI-DI
Disposable face mask (non-sterile)	Masks	I, Rule I (Annex VIII of MDR)	Ear-loop	/

meet 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
ENISO 10993-5:2009
EN 1041:2008

ISO 14971:2012
ENISO 10993-10:2013
EN 15223-1:2016

ISO 10993-1:2018
EN 14683:2019+AC

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: Huamei Xu

Signature:

Position held in the company: General Manager

Date:

Danyang City Huangtang Quintong Labor Supplies
Factory

Place: Danyang, China

Seal/Stamp:

