



DECLARATION OF CONFORMITY

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

Manufacturer:

Company name:SHANDONG HAICHUN
BIO-TECHNOLOGY CO.,LTD
Address:No. 1789, Fuzhou Road Heze 274000 Shandong
China
Tel:0530-7155386
E-mail: sdhaichun789@163.com
SRN: /

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 device covered by the present EU declaration is in conformity with the (EU) MDR 2017/745.

Product Name	Medical Surgical Face Mask(Non-sterile)		
Model	FM2M		
Intend use	Medical Surgical Face Mask(Non-sterile) 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. The product is disposable and non-sterile..		
CND code	T020601	Basic UDI-DI	/
Classification and rule	I, rule I	Conformity Assessment Route	Article 19, Annex II and Annex III

Applicable Standards and CS:

ISO 13485:2016
ENISO 10993-5:2009
EN 1041:2008

ISO 14971:2019
ENISO 10993-10:2013
EN 14683:2019 (TYPE IIR)

ISO 10993-1:2018
EN 15223-1:2016

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

Signed:

Date: February 24, 2021

Place:Shandong, China

Name of authorized signatory:tangzhong

Position held in the company: General Manager

SHANDONG HAICHUN BIO-TECHNOLOGY CO.,LTD

