CE

DECLARATION OF CONFORMITY

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

Manufacturer:

Name:Henan Siyuan Medical Equipment Co., Ltd
Address: Industrial cluster ,Huanglou Road, Shaolin Avenue , Dengfeng City
Telephone:0371-56588158
Email：15036011675@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

We, the manufacturer, herewith declare that the products

Product Name	Medical Device	Device Class	Model	UMDNS Code	Basic UDI-DI
Single-use medical face mask （non-sterile）	Masks	I, Rule1 (Annex VIII of MDR)	Flat Type(red)、Flat Type(blue)、Folded Type	12447	

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
EN 15223-1:2016
ISO 14971:2019
ENISO 10993-10：2013
EN 29073-1:1992
ISO 10993-1：2018
EN 14683:2019+AC
EN ISO 9073-15-2008

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: Xu Guangwen **Signature:** 徐广文

Position held in the company: General Manager **Date:** 2020.4.15

Place: HeNan, China

Henan Siyuan Medical Equipment Co., Ltd

Seal/Stamp: