CE

DECLARATION OF CONFORMITY

According to Medical Device Regulation (MDR) 2017/745 Annex II and Annex III.

Manufacturer:

Name:Qingdao Huaren Medical Product Co.,Ltd.
Address: No. 187 Zhuzhou Road, Laoshan District, Qingdao CN 266101
E-mail:hryl@qdhuaren.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)	HRKYY-C	12458	

meet the provisions of the Medical Device Regulation (MDR) 2017/745 which apply to them.

Conformity Assessment Route: Annex II and Annex III according to MDR 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 Medical Device Regulation (MDR) 2017/745.We agree to develop, implement and maintain a documented post-production monitoring process.

Signed:

Name of authorized signatory:
Position held in the company: General Manager

Place: Shandong, China

Seal/Stamp:

Qingdao Huaren Medical Product Co.,Ltd.