



DECLARATION OF CONFORMITY

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

Manufacturer:

Company name: Crown Name Disposable Hygiene Products Fty., Ltd.
Address: Chengbei Industrial Zone, Zhucheng Avenue, Xinzhou District., Wuhan, Hubei China
Tel: +86-27-82761385extention 1802

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 medical face mask(non-sterile) with earloops	Masks	I, Rule1 (Annex VIII of MDR)	CN102	

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*
- ISO 14971:2019*
- ISO 10993-1: 2018*
- ENISO 10993-5: 2009*
- ENISO 10993-10: 2013*
- EN 14683:2019+AC*
- EN 1041:2008*
- EN 29073-1:1992*
- EN ISO 9073-15-2008*
- 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:

Place: Hubei, China

Name of authorized signatory:

Position held in the company: General Manager

Seal/Stamp:

Crown Name Disposable Hygiene Products Fty., Ltd.

