



DECLARATION OF CONFORMITY

According to COUNCIL DIRECTIVE 93/42/EEC-Article 19 and Annex VII.

Manufacturer: Whose Authorized Representative:

Company name: Zhangzhou Anyue Sanitation
Supplies Co., Ltd.
Address: No.402, Fengle Village, Shiting Town,
Xiangcheng District, Zhangzhou,
Fujian, 363000, P.R.China

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
Non-sterile surgical mask Non-sterile medical face mask	Class I	I, Rule I (Annex IX of COUNCIL DIRECTIVE 93/42/EEC)

meet the provisions of the COUNCIL DIRECTIVE 93/42/EEC which apply to them.

Conformity Assessment Route: Article 19 and Annex VII according to COUNCIL DIRECTIVE 93/42/EEC.

Applicable Standards:

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

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

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

We, the manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the COUNCIL DIRECTIVE 93/42/EEC. We agree to develop, implement and maintain a documented post-production monitoring process.

Signed on:

Name of authorized signatory: Lin Zhao ju

Position held in the company: General Manager

Place: Zhangzhou, China

Seal/Stamp: Zhangzhou Anyue Sanitation Supplies Co., Ltd.

