



DECLARATION OF CONFORMITY

Manufacturer:

Name: Zhejiang Mashang Technology Co.,Ltd.
Address: No. 366 Shanhai Avenue, Lingxi
Town ,Cangnan County,Wenzhou City,Zhejiang
Province ,China 325800.
E-mail: 306508132@qq.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 product(s)

Product Name	Disposable Medical Mask	Model	MSYCY-02
BASIC UDI-DI	/	UMDNS Code	12447
Intended Use	Disposable Medical Mask is used for disposable hygiene care in ordinary environment. Not suitable for special protection during surgery. The product is disposable and non-sterile.		
Classification	I, (MDR, Annex VIII Rule 1)		

meet(s) 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:2019*
EN 1041:2008 *ENISO 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.

Name of authorized signatory: Wei Qian

Signature:

Position held in the company: General Manager

Date: 2020-11-03

Place: Zhe jiang, China

Seal/Stamp:

Zhejiang Mashang Technology Co.,Ltd.

