



# 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)

<b>Product Name</b>	Disposable Medical Mask	<b>Model</b>	MSYCY-01
<b>BASIC UDI-DI</b>	/	<b>UMDNS Code</b>	12447
<b>Intended Use</b>	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.		
<b>Classification</b>	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:**

<i>ISO 13485:2016</i>	<i>ISO 14971:2019</i>	<i>ISO 10993-1: 2018</i>
<i>ENISO 10993-5: 2009</i>	<i>ENISO 10993-10: 2013</i>	<i>EN 14683:2019+AC:2019</i>
<i>EN 1041:2008</i>	<i>ENISO 15223-1:2016</i>	

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:** 2020-11-02

**Place:** Zhe jiang, China

**Seal/Stamp:**

Zhejiang Mashang Technology Co.,Ltd.

