



# DECLARATION OF CONFORMITY

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

**Manufacturer:**

Name: Zhejiang The Purples Protective Products Co.,Ltd  
Address: 1/F, North Zone, Building B, No.66, Qunying Road, Houzhai, Yiwu, Jinhua, Zhejiang.china  
Telephone: 18305890175  
E-mail: 2187672261@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 products

Product Name	Medical Device	Device Class	Model	UMDN S Code	Basic UDI-DI
Disposable Medical Face Mask(Non sterile)	Masks	I, Rule1 (Annex VIII of MDR)	TP-100	12447	

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  
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 REGULATION (EU) 2017/745. We agree to develop, implement and maintain a documented post-production monitoring process.

Name of authorized signatory: Zeng Yuqing

Signature:

Position held in the company: General Manager Date:

Place: Zhejiang, China

Zhejiang The Purples Protective Products Co.,Ltd

Seal/Stamp:

