



# DECLARATION OF CONFORMITY

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

**Manufacturer:**

Company name: SILVERFOX CORPORATION LIMITED  
Address: No.18, 1st TongLe Road, TangXia Town, Pengjiang District ,JiangMen City, GuangDong Province, China  
Tel: 86-20-87514019

**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	UMDNS Code	Model	Basic UDI-DI
Disposable medical mask	Masks	I, Rule1 (Annex VIII of MDR)	12447	Y100B、Y100C、Y300B、Y300W、Y301B、Y301W	/

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.

Signed:

Name of authorized signatory: Bill zhang

Date: 2020-7-8

Position held in the company: General Manager

Place: Guangdong, China

SILVERFOX CORPORATION LIMITED

