

# CE DECLARATION OF CONFORMITY CE

According to Art. 19 of Regulation (EU) 2017/745 on Medical Devices

**Manufacturer:** Wuhan Youfu International Trade Co., Ltd.  
Room 3, 18F, unit B, Building S-1, Kaile Guiyuan,  
No.108, Zhuodaoquan Road, Hongshan District,  
Wuhan City, Hubei Province, China

**Trademark:**

**SRN:** NL-AR-00000121

**European Representative:** Lotus NL B.V  
Koningin Julianaplein 10, 1e Verd, 2595AA,  
The Hague, Netherlands.  
Medicines and Healthcare Products Regulatory Agency  
Competent Authority NL (CIBG)

**SRN:** Not available yet

**Trade name:** Disposable medical face mask (non-sterile)

**Product Name:** Disposable medical face mask (non-sterile)

**Product code / Catalogue number:** YF-3PM

**Basic UDI:** Not available yet

**Classification acc. to MDR Ax. VIII:** Class I, rule I

**Applied Standard & Common Specification:** EN 14683:2019 EN ISO 14971:2012 EN 1041:2013  
EN ISO 15223-1:2016 EN ISO 10993-10:2013  
EN ISO 10993-1:2009/AC:2010 EN ISO 10993-5:2009

**Conformity assessment procedure:** Annex II + Annex III of MDR

**CE certificate No.:** N.A.

**Name and ID of the Notified Body:** N.A.

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU) 2017/745 on Medical Devices (MDR), and the provision of the Regulation (EU) 2016/425 on personal protective equipment. All supporting documentations are retained under the premises of the manufacturer.

Signature: 

General Manager

Wuhan, 22 11 2020

