File No: CE/MDR-MSSL-02-02

EC Declaration of Conformity

Regarding Medical Device Regulation (EU)2017/745

Manufacturer:

Name: Xiantao Maosheng Plastic Products Co., Ltd.
Address: NO.3 of Xinmin Road III, Zhanggou Town, Xiantao City, Hubei , China.
SRN: CN-MF-000009821

European Authorized Representative:

Name: SUNGO Europe B.V.
Add:Fascinatio Boulevard 522, Unit 1.7, 2909VA Capelle aan den IJssel,The Netherlands
SRN: NL-AR-000000247

Product:

Name: Face mask

Model: : 02/02/340 type IIR face mask

UDI Code: 06973635611016

Classification: Class I

Rule: According to Rule 1, Annex VIII, Chapter III of Medical Device Regulation (EU) 2017/745

Conformity assessment procedure: Annex II+III of Regulation (EU) 2017/745

We herewith declare that the above-mentioned products meet the requirement of Medical Device Regulation (EU) 2017/745 and the following harmonized standards:

EN ISO 14971: 2019 EN ISO 15223-1:2016
EN 1041: 2008+A1:2013 ISO 10993-1:2018
EN ISO 10993-5: 2009 EN ISO 10993-10: 2013
EN 14683:2019+AC:2019

Signature: Date：Mar,8th, 2022

Position: General Manager