



DECLARATION OF CONFORMITY

Regarding Medical Device Regulation (EU) 2017/745



Manufacturer: Hubei Kangning Protective Products Co., Ltd
Address: Special No. 1, Xuefu Road, Xiantao, Hubei, China

EC Representative: SUNGO Europe B.V.
Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product Name: Disposable Medical Face Mask (Type I)
Model: 17.5cm×9.5cm, 14.5cm×9.5cm
Classification: Class I
Rule: Rule 1, Annex VIII, Regulation (EU) 2017/745
Conformity Assessment: Annex II+III of Regulation (EU) 2017/745
Procedure:
SRN: _____ **Basic UDI-DI:** _____

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

- EN ISO 14971:2012 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: 
Name / Position: 肖伟 Wei Xiao / GM
Date: 2020-09-30
Place: Hubei / China

On behalf of SUNGO Europe office, I confirmed we are EU REP of the company who issue this document.



Authorized Signature (S)

