



DECLARATION OF CONFORMITY

Regarding Medical Device Regulation (EU) 2017/745



Manufacturer: Hubei Yazhi Hygiene Products Co., Ltd
Address: South side of Shahu Avenue, Shahu Town, Xiantao City,
 Hubei Province, China

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

Product Name: Disposable Medical Face Mask
Model: 17.5*9.5cm

SRN: _____ / _____ **Basic UDI-DI:** _____ / _____

Classification : Class I
Rule: Rule 1, Annex VIII, 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 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 Type IIR | |

Signature: 周曼玉
Name / Position: Manyu Zhou / GM
Date: 2020年8月11日
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)