



DECLARATION OF CONFORMITY

Regarding Medical Device Regulation (EU) 2017/745



Manufacturer: Xiantao Fortune Medical Supplies Co.,Ltd

Address: No.2 Fuyuan Road, Pengchang Town, Xiantao City,
Hubei Province, China

EC Representative: SUNGO Europe B.V.

Address: Olympisch Stadion 24, 1076 Amsterdam, Netherlands

Product Name: Face mask(Medical)

Model: 175*95mm or Customized

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.

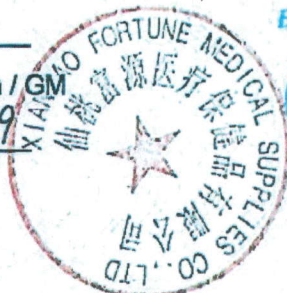
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|----------------------|----------------------|
| EN ISO 14971:2012 | EN ISO 15223-1:2016 |
| EN 1041:2008+A1:2013 | ISO 10993-1:2018 |
| EN ISO 10993-5:2009 | EN ISO 10993-10:2013 |
| EN 62366-1:2015 | EN 14683:2019 |

Signature: *[Handwritten Signature]*

Name / Position: Du Dan / GM

Date: 2020/05/29

Place: Hubei / China



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



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Authorized Signature (S)