



DECLARATION OF CONFORMITY

Regarding Medical Device Regulation (EU) 2017/745



Manufacturer: GUANGDONG YADE INDUSTRY CO.,LTD.
Address: (ZHULIN VILLAGE)ZIYUNGAOXIN DISTRICT MEIYUN OFFICE
 RONGCHENG JIEYANG CITY, GUANGDONG PROVINCE, CHINA
EC Representative: SUNGO Europe B.V.
Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands
Product Name: Disposable Medical Mask
Model: KYD01, KYD02, KYD03
Type: EN14683:2019 Type II
Classification: Class I
Rule: Rule 1, Annex VIII, Regulation (EU) 2017/745
Conformity Assessment Procedure: Annex II+III of Regulation (EU) 2017/745
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 14683:2019+AC:2019 | |

The above mentioned declaration of conformity is exclusively under the responsibility of
GUANGDONG YADE INDUSTRY CO., LTD.

Signature: 
 Name / Position: Kaizhao Hong/ GM
 Date: 2020.8.17
 Place: Guangdong / China

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



Authorized Signature (S)