



DECLARATION OF CONFORMITY

Regarding Medical Device Regulation (EU) 2017/745



Manufacturer: Changzhou Huankang Medical Device Co., Ltd
Address: 22 Changhe Road, Changzhou, Jiangsu, China

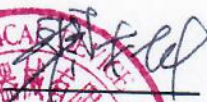
EC Representative: SUNGO Europe B.V.
Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product Name: Disposable Medical Face Masks
Model: HK-Z01, HK-Z01-01, HK-Z01-02, HK-Z01-03
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: Zhai Cailong / GM
Date: 2020.7.14
Place: Jiangsu / China



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




Authorized Signature (S)