

File No: HF-MDR-08-02



EC Declaration of Conformity
Regarding Medical Device Regulation(2017/745)

Manufacturer

Name: Anhui Jingcheng Non-woven Technology Co;Ltd
Address: North of Hong Tu Avenue Cuo Zhen Circular Economy-Industrial
Park Hefei City, Anhui Province, China

EC Representative

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

Product

Name: Disposable Medical Face Mask
Specification: JCM01

Classification: I
Rule: Rule 1, Annex VIII, EU Medical Device Regulation (2017/745)

We confirm our product meets the requirements of Medical Device Regulation and the following harmonized standards.

EN ISO 14971: 2012	EN ISO 15223-1: 2016
ISO 10993-1: 2018	EN ISO 10993-5: 2009
EN ISO 10993-10: 2010	EN 1041: 2008
EN ISO13982-1: 2011	EN ISO13982-2: 2004
EN ISO13034: 2013	EN ISO 17491-4: 2008
EN 14325: 2018	IEC 62366-1:2015
EN 14683 : 2019	

Signature:  Position:

Date:

2020.4.9

