

File No: CE-TCF-001 A/0



EC Declaration of Conformity



Applicant

Name: Guangzhou Dayun Medical Technology Co.,Ltd.

Address: No.632, Xintang Avenue, Xintang Town, Zengcheng District Guangzhou, Guangdong, China

EC-Representative

Name: SUNGO Europe B.V.

Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product

Name: Disposable medical mask (Non-sterile)

Model: DY-01(17.5cm×9.5cm), DY-02(14.5cm×9.5cm), DY-03(12.0cm×7.0cm)

Classification: Class I (MDD, Annex IX), Rule 1(All non-invasive devices are in class I)
Conformity Assessment Route: Annex VII

We confirm our product can meet the requirement of Medical Device Directive(MDD 93/42/EEC) 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

Signature:
(Name/ Position)

Date:

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

Authorized Signature (S)