File No: CE-TCF-001 A/0

EC Declaration of Conformity

Applicant

Name:K.Y.Health Medical Equipment Co., Ltd.

Address:777 Wangcongdong Rd, Pidu, Chengdu, Sichuan, China.

EC-Representative

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

Product

Name:Disposable Face Mask

Model:Y6002
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 TYPE I

Signature:

Zhen Wang, Sales Director

Date: May 24th, 2020

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

Sungo good service

Authorized Signature (S)