



File No: CE-TCF-001 A/0

CE EC Declaration of Conformity CE

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

