

EC Declaration of Conformity

Regarding Medical Device Directive(93/42/EEC)

including Directive 2007/47/EC

Applicant

Name: HUBEI YUHENG PROTECTIVE PRODUCTS CO.,LTD

Address: NO.1,THE INDUSTRIAL PARK,GUOHE TOWN,XIANTAO CITY,HUBEI,CHINA

EC Representative

Name: SUNGO Europe B.V.

Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product

Name: Face Mask

Type: 17.5cm*9.5cm、 14.5cm*9.5cm or customized tolerance $\pm 5\%$

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(93/42/EEC) and the following harmonized standards.

EN ISO 14971:2012

EN ISO 15223-1:2016

EN 1041:2013

EN ISO 10993-1:2009/AC:2010

EN ISO 10993-5:2009

EN ISO 10993-10:2013

Signature: 付

Date: 2020

