

File No: CE-TCF-001



EC Declaration of Conformity



Regarding Medical Device Directive(93/42/EEC)

including Directive 2007/47/EC

Applicant

Name: Jiangyin Hongmeng Rubber Plastic Product Co., Ltd

Address: NO.166 HETUN ROAD, LINGANG STREET, JIANGYIN, JIANGSU, CHINA

EU Authorized Representative

Name: SUNGO Europe B.V.

Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product

Name: Surgical Face Mask,Single-use

Item Code: HM3L

Type: 17.5*9.5cm

Classification: Class I

Rule: According to Rule 1

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

EN ISO 10993-1:2009/AC:2010

EN ISO 10993-5:2009

EN ISO 10993-10:2013

EN 14683-2019+AC-2019

Name: Cuijun

Position: Quality director

Signature:

Date: 2020/05/13

