



Declaration of Conformity



Regarding Medical Device Directive(93/42/EEC)

including Directive 2007/47/EC

Manufacturer

Name: NINGBO JOYSON TECHNOLOGY Co., Ltd.

Address: No.198 Lingyun Rd., High-Tech Park, 315040 Ningbo, Zhejiang, China

European Authorised Representative

Name: SUNGO Europe B.V.

Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product

Name: Face mask(non-sterile)

Model: JS01-00

SRN: -

UDI-DI: -

Classification: Class 1

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

ISO 10993-1: 2018

EN ISO 10993-5: 2009

EN ISO 10993-10: 2013

EN 1041: 2008

EN 62366-1:2015

EN 14683:2019

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



Authorized Signature (S)



Signature:

Position:

CEO

Date:

Mar 21 2020