DECLARATION OF CONFORMITY

Regarding Medical Device Regulation (EU) 2017/745

Manufacturer:	Xiantao Fortune Medical Supplies Co.,Ltd
Address:	No.2 Fuyuan Road,Pengchang Town, Xiantao City, Hubei Province, China
EC Representative:	SUNGO Europe B.V.
Address:	Olympisch Stadion 24, 1076 Amsterdam, Netherlands
Product Name:	Face mask(Medical)
Model:	175*95mm or Customized
Classification:	Class I
Rule:	Rule 1, Annex VIII, Regulation (EU) 2017/745
Conformity Assessment Procedure:	Annex II+III of Regulation (EU) 2017/745
SRN:_____	**Basic UDI-DI:**_____

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 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 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.

Signature: _____

Name / Position: Du Dan / GM

Date: 2020/05/29

Place: Hubei / China

XIANTAO FORTUNE MEDICAL SUPPLIES CO., LTD 仙桃富源医疗保健品有限公司

Sungo global service

Authorized Signature (S)

Digitally signed by Azarov Tatiana
Date: 2021.04.22 12:52:08 EEST
Reason: MoldSign Signature
Location: Moldova

REPUBLICA MOLDOVA IDNO 1003600060828 «BECOR» SRL

EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60133273 0001

Report No.: 15085900 005

Manufacturer:

Xiantao Xingrong Protective
Products Co., Ltd.
No. 46, East of Pengchang Road,
433018 Xiantao, Hubei
China

Products:

Aspects of manufacture concerned with securing and maintaining sterile conditions of Face Masks, Surgical Gowns, Non-woven Caps, Non-woven Shoe Covers, Plastic Shoe Covers, Coveralls

Replaces Approval, Registration No.: DD 60104282 0001

Expiry Date: 2023-12-05

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2018-12-06

Date: 2018-12-06

Notified Body

Herbert Zhong

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60133273 0001

Report No.: 15085900 005

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Sungo global service

Authorized Signature (S)