



DECLARATION OF CONFORMITY

Regarding Medical Device Directive(93/42/EEC)
including Directive 2007/47/EC

Manufacturer: Fujian Leephick Pharmaceutical Industry CO., LTD

Address: Economic & Technology Development Zone, Longyan City, Fujian Province, China

EC Representative: SUNGO Europe B.V.

Address: Olympisch Stadion 24, 1076DE Amsterdam,
Netherlands

Product Name: Medical Surgical Mask

Specification: Flat-type, Ear Loop, 17.5*9.5cm

Classification: Class I (MDD, Annex IX)

Conformity Assessment

Procedure: Annex VII of Medical Device Directive(93/42/EEC)

We herewith declare that the above-mentioned products meet the requirements of Medical Device Directive (93/42/EEC) including Directive 2007/47/EC 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

Signature:

Name/ Position: Xu Youchi / GM

Date:

Place: Fujian / China

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



Xu Youchi
Authorized Signature (S)