DECLARATION OF CONFORMITY

Regarding Medical Device Regulation (EU) 2017/745

Manufacturer: Zhejiang Lanhine Medical Products Ltd.

Address: 1989 Cidong Road, Cidongbinhai District, 315300 Cixi City, Zhejiang Province, People's Republic of China

EC Representative: SUNGO Europe B.V.

Address: Olympisch Stadion 24, 1076DE Amsterdam, Netherlands

Product Name: Procedure Face Mask

Model: 15603F

SRN: _____/_____ **Basic UDI-DI:** _____/_____

Classification: Class I

Rule: Rule 1, Annex VIII, Regulation (EU) 2017/745

Conformity Assessment Procedure: Annex II+III of Regulation (EU) 2017/745

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 1041:2008+A1:2013

EN ISO 10993-5: 2009

EN 14683:2019+AC:2019

EN ISO 15223-1: 2016

ISO 10993-1: 2018

EN ISO 10993-10: 2013

Signature: Jun Cao

Name / Position: Jun Cao / General Manager

Date: 10/26/2020

Place: Ningbo, Zhejiang / China

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

Sungo global service

Authorized Signature (S)