

Y-LW0880

Reference Number:

## **DECLARATION OF FDA STANDARD CONFORMITY**

1) PPE Product

Product Name: MASK

Model Number: AOP-KF MASK

Type: Non-sterile protective mask

2) Name and address of the manufacturer and authorized representative:

Manufacturer

Name: ZHONGSHAN XINKE MEDICAL DEVICE LIMITED

(former name: Zhong Shan Civil Tech Electronic Limited)

Address: NO.6, INDUSTRIAL ZONE, NANLANG TOWN,

ZHONGSHAN, GUANGDONG, CHINA

3) This declaration of conformity is issued under the sole responsibility of the manufacturer (or installer):

Manufacturer Name: ZHONGSHAN XINKE MEDICAL DEVICE LIMITED

4) Object of the declaration:

(identification of product allowing traceability. It may include a colour image of sufficient clarity to enable the identification of the product, where appropriate.)

5) The object of the declaration described in Section 4 had been tested and verified by the FDA to be conforming under the standards and requirements set forth in Classification:

Face Mask (Except N95 Respiratior) For General Public/Healthcare Personnel Per IJE Guidance.

6) For verification and relevant information, please visit the official FDA website at:

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/c-fRL/rl.cfm?lid=667355&lpcd=QKR

7) Additional information:

None

Signed for and on behalf of:

Yang Lin Wei Director

Zhongshan Xinke Medical Device Limited 20 April 2020