

Certificate of Compliance



No. 0H2003295.ZLE0W20

Technical Construction File no. XM70202001251LY/PPE

Certificate's
Holder:

Zhongshan Lulutong Electronic Co.,
Ltd
Floor 2 and 5, Left Side, Building 1, No. 27, Jinyi
South Road, Dongfeng Town, Zhongshan City,
Guangdong Province

Certification ECM
Mark:



Product:

Disposable earloop face mask

Model(s):

Ear Hanging Type

Trade Mark:

Heng Shu Kang

Verification to:

Standard:
EN 149:2001+A1:2009

related to CE Directive(s):
R 2016/425 (Personal Protective Equipment)

Remark: This document has been issued on a voluntary basis and upon request of the manufacturer. It is our opinion that the technical documentation received from the manufacturer is satisfactory for the requirements of the ECM Certification Mark. The conformity mark above can be affixed on the products according to the ECM regulation about its release and its use.

Additional information and clarification about the Marking:



The manufacturer is responsible for the CE Marking process, and if necessary, must refer to a notified body. This document has been issued on the basis of the regulation on ECM Voluntary Mark for the certification of products. RG01-ECM rev.3 available at: www.entecerna.it

Issuance date: 29 March 2020

Expiry date: 28 March 2025

Reviewer
Technical expert
Amanda Payne



Approver
ECM Service Director
Luca Bertoni



Ente Certificazione Macchine Srl

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Fiscal Year 2020 CERTIFICATION OF REGISTRATION

This certifies that:

Zhongshan LULUTONG Electronic Co., Ltd

Floor 2 and 5, left side, building 1, No. 27, Jinyi South Road, Dongfeng Town,

Zhongshan City, Guangdong Province

has completed the FDA Establishment Registration and Device Listing with the US Food & Drug Administration, through

Shenzhen CHW Testing Technology Co., Ltd.

Owner/Operator Number:10064650

Device Listing#:



Listing No	Code	Device Name	Proprietary Name
D379592	LYU	MASK	Disposable medical mask 418 Four layer protective mask Earloop 175mm×95mm

This CHW will confirm that such registration remains effective upon request and presentation of this certificate until the end of the calendar year stated above, unless said registration is terminated after issuance of this certificate. CHW makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. CHW assumes no liability to any person or entity in connection with the foregoing.

Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding." The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration, CHW is not affiliated with the U.S. Food and Drug Administration.



Issued: March 26, 2020

Expiration Date: December 31, 2020