Certificate – Сертификат – 證明書 – Certificat – 증명서 – شهادة

Certificate of Compliance

No. 4N200402B.YKM0D49

Certificate's Holder: Yushan Kuster Medical Technology Co., Ltd.
Shifang Line (No. 2 Cross Square Line), High-tech Zone, Yushan County, Shangrao City, Jiangxi Province

Certification ECM Mark: European Conformity – Type Approved

Product: Protective mask
Model(s): JNKZ001 (FFP2)
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 accordingly to the ECM regulation about its release and its use.

Additional information and clarification about the Marking:

CE

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.entecerma.it

Issuance date: 02 April 2020

Expiry date: 01 April 2025

Reviewer
Technical expert
Amanda Payne

Approver
ECM Service Director
Luca Bedonni

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FISCAL YEAR 2020
CERTIFICATION OF REGISTRATION

This certifies that:

YUSHAN COUNTY KUST MEDICAL TECHNOLOGY CO.,LTD
HIGH-TECH ZONE TEN LINE (CROSS LINE 2)
JIANGXI CHUANGFENG PHOTOELECTRIC DEVELOPMENT CO.,LTD.
PLANT 9 YUSHAN, SHANGRAO, JIANGXI 334000 CHINA

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

Listing No. :D386653

Product Codes : QKR

Owner/Operator Number :10067685

Proprietary Name :Face mask (except N95 respirator) for general public/healthcare personnel per IIE guidance

ZBJ 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.ZBJ makes no other representations or warranties,nor does this certificate make any representations or warranties to any person pr 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.ZBJ 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 misleading." 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,ZBJ is not affiliated with the U.S. Food and Drug Administration.

ZBJ NETWORK INC

Chief Engineer

Issued: Apr 01 2020

Expiration Date: December 31.2020

FDA