CERTIFICATION OF REGISTRATION

This certifies that:
SHANDONG INF MEDICAL

is registered and has listed the following medical device with the U.S. Food and Drug Administration :

Owner/Operator Number : 10064811

Listing Number: D380103

Product Code : MSH

Product : Respiratory-KN95 mask

Model(s) : KN95A

Date Of Registration Status: 2020

Registrar Corp will confirm that such registration remains effective upon request and presentation of this certificate until the end of the year stated above, unless said registration is terminated after issuance of this certificate. Registrar Corp 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-holderd's device or establishment by the U.S. Food and Drug Administration. Registrar Corp 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. Registrar Corp is not affiliated with the U.S. Food and Drug Administration

Chief Engineer / Zacchao Lee

Issued: Mar. 27, 2020
Validity Period:2020-12-31

Web rep/www.fda.gov Tel 1-888-INF0-FDA(1-888-0332) E-mal vcrp@fda.gov

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

Form QAT_10-M04, version 00, effective since March 6th, 2020

Certificate of Compliance

No. 3Q200329B.SIM0026

Certificate's Holder: Shandong INF medical

Certification ECM Mark: Type Approved

Product: Respiratory- KN95 mask
Model(s): KN95A, KN95B, KN95C, KN95D, KN95E
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: 29 March 2020

Expiry date: 28 March 2025

Reviewer
Technical expert
Amanda Payne

Approver
ECM Service Director
Luca Bedonni

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