U.S. FOOD & DRUG ADMINISTRATION

Acknowledgment Letter

6/5/2020

Yuqiang Li
Qingdao Miuton Medical Co. Ltd.
Two/Three/Four floor No.1 Jinye Road, High Tech
Industrial Development Zone
Qingdao, Shandong
CHINA

Dear Yuqiang Li:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the above letterhead address. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please notify the Program Operations Staff at (301) 796-5640.

Submission Number: EUA201030/A001
Received: 6/5/2020
Applicant: Qingdao Miuton Medical Co. Ltd.
Device: KN95 Protective Mask

We will notify you when the review of this document has been completed or if any additional information is required. If you are submitting new information about a submission for which we have already made a final decision, please note that your submission will not be re-opened. For information about CDRH review regulations and policies, please refer to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm.

Sincerely yours,

Center for Devices and Radiological Health

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

U.S. FOOD & DRUG ADMINISTRATION

June 6, 2020

Qingdao Miuton Medical Co., Ltd
Two/three/four floor, No.1 Jinye Road
High-tech Industrial Development Zone
Qingdao, Shandong, China

EUA201030/A001

Re: FFRs Made in China

Dear Yuqiang Li:

This letter is in response to your request that the Food and Drug Administration (FDA) add your respirator model Stereoscopic Type, Ear Worn KN95 Protective Mask as an authorized respirator to the May 7, 2020 Emergency Use Authorization (EUA)[1], which was issued under Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3). We have reviewed your email and determined that the models included meet the eligibility criteria in the May 7, 2020 EUA for non-NIOSH approved respirators made in China. As such, your respirator(s) is hereby added to Appendix A[2] as an authorized respirator.

Having concluded that the eligibility criteria are met, I am adding your respirators to Appendix A, as described in the Scope of Authorization (Section II). As such, the respirator is authorized for use by healthcare personnel in healthcare settings in accordance with CDC recommendations and subject to the Conditions of Authorization (Section IV) of the attached letter. We remind you that, among other things, you are required to meet the following labeling requirements:

Manufacturers

A. Manufacturers of authorized respirators are required to publish the intended use and other instructions (such as fit testing, etc.) about all authorized models that are imported and authorized under this EUA on their website in English. Additionally, manufacturers must notify FDA by emailing FDA at CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov of the website address (URL) that meets this condition. The subject line of this email should read "URL for FFR Made in China." FDA will make this information available to the public on its EUA website at https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ppe. Manufacturers must notify FDA of any changes to this page.

B. In addition to the above electronic labeling condition, manufacturers of authorized respirators are additionally required to include a letter, in English, that can be distributed to each end user facility (e.g., each hospital, etc.) that receives the authorized respirator model. This letter must include the

[1] The EUA Letter of Authorization is available at, https://www.fda.gov/media/136664/download.
[2] Appendix A is available at, https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations.

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authorized respirator's manufacturer, model, intended use, manufacturer's webpage (if applicable), etc.

Additionally, please be advised that if your firm does not have the appropriate fluid resistance testing, the respirator should not be labeled as "surgical."

Import information can be found on the Information for Filing Personal Protective Equipment and Medical Devices During COVID-19 page. If you need to resolve entry issues for shipments, please contact 301-796-0356 or COVID19FDAIMPORTINQUIRIES@fda.hhs.gov.

Sincerely,

Suzanne B. Schwartz -S

Digitally signed by Suzanne B. Schwartz -S
Date: 2020.06.06 18:24:29 -04'00'

Suzanne Schwartz, MD, MBA
Deputy Director (& Acting Office Director)
Office of Strategic Partnerships & Technology Innovation
Center for Devices and Radiological Health

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