



July 28, 2020

GUANGZHOU CARROT MALL NETWORK TECHNOLOGIES CO., LTD.  
ROOM 203, BUILDING 5, 3 LIUXIN ROAD, NANSHA DISTRICT  
GUANGZHOU GUANGDONG, CN 510700

EUA201789

Re: FFRs Made in China

Dear Division Two:

This letter is in response to your request that the Food and Drug Administration (FDA) add your respirator model IRYS-01 (Brand Name: IVROU) as an authorized respirator to the Emergency Use Authorization (EUA) for non-NIOSH-approved filtering facepiece respirators manufactured in China<sup>1</sup>, which was revised and reissued under Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. §360bbb-3) on June 6, 2020. We have reviewed your request to be added to Appendix A of this EUA and determined that model included meets the eligibility criteria in the June 6, 2020 EUA for non-NIOSH approved respirators made in China. As such, your respirator(s) is hereby added to Appendix A 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, these respirator models are 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](mailto: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/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/personal-protective-equipment-euas>. 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 authorized respirator's manufacturer, model, intended use, manufacturer's webpage (if applicable), etc.

<sup>1</sup> The EUA Letter of Authorization is available at, <https://www.fda.gov/media/136664/download>.





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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](mailto:COVID19FDAIMPORTINQUIRIES@fda.hhs.gov).

Sincerely,

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