



为好呼吸而来
For good respiration

Date : 2020-6-16

RE: End User Letter for Non-NIOSH approved FFR Authorized for Use RG19501

Dear Valued Customer,

This letter relates to the use of the following RESGOOD filtering facepiece respirators (FFR) that have been imported in response to the FFR shortage resulting from the COVID-19 outbreak: **RG19501**.

In its Strategies for Optimizing the Supply of N95 Respirators, the US Centers for Disease Control and Prevention (CDC) has recommended that healthcare institutions that no longer have access to NIOSH-approved N95 respirators consider respirators approved under standards used in other countries that are similar to NIOSH approved N95 filtering facepiece respirators for occupational use.

On June 6, 2020, the US Food and Drug Administration (FDA) issued an Emergency Use Authorization (June 6 EUA) that addresses the use of certain imported disposable FFRs that are not NIOSH-approved Respirators manufactured in China. Pursuant to the June 6 EUA, the Resgood respirator model listed above **is intended to be worn by clinical medical staffs in medical environment, to provide protection for medical staffs, filtering the aerosol particles, shield against the spread of droplet, blood, body fluids, secretion and splashes**. It could be used on an emergency basis in accordance with CDC recommendations to help prevent healthcare personnel exposure to pathogenic biological air borne particulates during filtering facepiece respirator (FFR) shortages resulting from the COVID-19 outbreak.

The RESGOOD respirator model listed above is **certified and approved by NMPA** of P.R. China, and meet the requirements of GB 19083-2010 (Technical requirements for Protective Face Mask for Medical Use). More information about the approval and respirator – including User Instructions – is available at:

<http://www.resgood.com/show/?id=401>.

When properly selected and worn, the above listed respirator help reduce exposure to airborne particles, including biological aerosols that may contain viruses or bacteria. OSHA respiratory protection standards mandate that individuals using new respirator models receive training and a fit test prior to the first time they use the respirator. In addition, individuals should read and follow all user instructions, including conducting a user seal check everytime they put on a respirator.

Sincerely,

Resgood Medical Limited

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