

NIOSH Respiratory Protective Device Information

NIOSH CA 2020-1026
April 2020

Information regarding Shanghai Dasheng Health Products Manufacture Co., Ltd. (SDH) filtering facepiece respirators (FFRs) with ear loops and labeled as NIOSH-approved



**Centers for Disease Control
and Prevention**
National Institute for Occupational
Safety and Health

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Based on the COVID-19 response and numerous inquiries regarding potentially noncompliant NIOSH-approved N95 respirators, NIOSH is issuing this notice to alert users about potential counterfeit products. Specifically, NIOSH is concerned about FFRs misrepresented as “Shanghai Dasheng,” “Dasheng,” or “Raxwell” NIOSH-approved N95 respirators. **These models include, but may not be limited to, models DTC3X (marked as TC-84A-4329), DTC3W (marked as TC-84A-4335), DTC3B (marked as TC-84A-4336), and Raxwell RX9501P.** Reports of counterfeit respirators or respirators misrepresented as NIOSH-approved are reviewed and, if confirmed, are posted on the [Counterfeit Respirators/Misrepresentation of NIOSH Approval](#) webpage.

NIOSH approvals issued to Shanghai Dasheng Health Products Manufacture Co., Ltd. (SDH) are for respirators that include two headbands, **not ear loops**, to secure the respirator to the face. NIOSH has received reports stating there is product being obtained directly from the Shanghai Dasheng factory, labeled as NIOSH-approved, with ear loops.

In accordance with the NIOSH regulation, [42 CFR Part 84, Approval of Respiratory Protective Devices](#), any changes a manufacturer wishes to make to NIOSH-approved respirators must first be evaluated and approved by NIOSH. Switching from headbands to ear loops is typical of the type of change requiring prior notice and approval by NIOSH; therefore, the modified respirators are not NIOSH-approved.

NIOSH has been communicating with Shanghai Dasheng Health Products Manufacture Co., Ltd. (SDH) and users concerned about this situation. **NIOSH is also pursuing further actions to mitigate the situation. If you have any questions**, please contact ppeconcerns@cdc.gov.