

NIOSH Respiratory Protective Device Information

**NIOSH CA 2024-1089
December 2024**

Effective Immediately: Revocation of Six Aegle PPE 1 LLC Approvals



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

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The National Institute for Occupational Safety and Health (NIOSH) has **revoked six approval numbers (provided below) issued to Aegle PPE 1 LLC**. Aegle has failed to maintain their quality management system, resulting in a failure to execute their quality control system.

This notice is to announce that **any Aegle PPE 1 LLC respirator with a NIOSH approval label that includes any of the approval numbers below is no longer approved by NIOSH.**

| Approval Number | Product Line or Model |
|-----------------|--|
| 84A-9314 | C100, Filtering Facepiece |
| 84A-9353 | F100, N95 Filtering Facepiece |
| 84A-9368 | F110 PLUS, Filtering Facepiece |
| 84A-9390 | F100 PLUS, N95 Filtering Facepiece |
| 84A-9391 | F200, N95 Filtering Facepiece |
| 84A-9395 | C100S, Surgical N95, Filtering Facepiece |

Revocation also means that respirators bearing any of the NIOSH approval numbers listed above may no longer be used, manufactured, assembled, sold, or distributed. As of **December 31, 2024**, respirators bearing the NIOSH approval numbers listed above are no longer considered approved and may not be used in fulfillment of any standard or statute requiring the use of a NIOSH Approved® respirator.

Aegle PPE 1 LLC failed to control the quality management for the approvals as required by 42 C.F.R. Part 84. Thus, NIOSH has revoked these approvals in accordance with its authority as set forth in 42 C.F.R. § 84.34, which states, *“The Institute reserves the right to revoke, for cause, any certificate of approval issued pursuant to the provisions of this part. Such causes include, but are not limited to, misuse of approval labels and markings, misleading advertising, and failure to maintain or cause to be maintained the quality control requirements of the certificate of approval.”*