

NIOSH Respiratory Protective Device Information

NIOSH CA 2021-1035
May 2021

Revocation of Public Health Emergency Approval TC-84A-PH19



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

Revocation of Public Health Emergency Approval TC-84A-PH19

The National Institute for Occupational Safety and Health (NIOSH) has **revoked the following public health emergency certificate of approval issued to Plastikon Industries, Inc.:**

TC-84A-PH19

As of April 8, 2021, **Plastikon Industries, Inc. respirator model PLASMA N95-01** N95 filtering facepiece respirator is no longer NIOSH-approved.

Revocation also means that **respirators bearing NIOSH approval numbers TC-84A-PH19** may no longer be manufactured, assembled, sold, or distributed.

NIOSH conducted a product audit of the Plastikon Industries, Inc. model PLASMA N95-01 N95 respirator and found the results to be non-conforming to the approval which had been issued under TC-84A-PH19. Respirator samples tested failed to meet the filter efficiency requirements identified in 42 C.F.R. § 84.174. Thus, NIOSH has revoked these approvals in accordance with the authority granted 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.”*