## **NIOSH Respiratory Protective Device Information**

## NIOSH CA 2022-1044 June 2022

Immediate information for respirator users regarding NIOSH Public Health Emergency (PHE) Approvals issued during the COVID-19 Response and the action to obsolete (phase out) these PHE approvals



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

### Immediate information for respirator users regarding NIOSH Public Health Emergency (PHE) Approvals issued during the COVID-19 Response and the action to obsolete (phase out) these PHE approvals

#### 1) <u>SUMMARY</u>

Between May and November 2020, NIOSH issued limited, temporary Public Health Emergency (PHE) approvals for N95 filtering facepiece respirators (FFRs) and powered air-purifying respirators (PAPRs) to address respirator supply shortages during that time.

The PHE-approved respirators are easily recognized by the assigned approval number, which includes the designation "PH." PHE-approved FFRs are marked <u>TC-84A-PHXX</u> and PHE-approved PAPRs are marked <u>TC-21C-PHXX</u>, and both are easily identified on the NIOSH <u>Certified Equipment List</u> (CEL). These respirators were approved for immediate use during the early months of the pandemic and were <u>NOT</u> intended for creating or replenishing stockpiles.

Because there are adequate supplies of conventional NIOSH-approved respirators (not PHEapproved) in the United States, effective immediately, the 14 active FFR PHE and 5 active PAPR PHE approvals are obsolete. Obsoleted respirators are no longer permitted to be manufactured by the approval holder but can continue to be sold, used, and recognized as NIOSH-approved.

Users in <u>workplace settings that require the use of NIOSH-approved respirators</u> may continue to use the obsoleted PHE-approved FFRs and PAPRs until the COVID-19 public health emergency ends.

All PHE approvals listed below will remain in the obsoleted status on the CEL until the COVID-19 <u>public</u> <u>health emergency</u> ends, unless there is an action by the approval holder to change that status more quickly. Once the public health emergency ends, the obsoleted approvals will be **revoked by NIOSH**, meaning they are no longer recognized as NIOSH-approved and cannot be used in <u>workplace settings</u> where the use of NIOSH-approved respirators is required.

By obsoleting the PHE-approved FFRs and PAPRs now, users have time to exhaust any remaining supply of PHE-approved respirators and can plan to purchase other (non-PHE) NIOSH-approved respirators.

NIOSH-approved respirators can be identified using the NIOSH <u>CEL</u>. The current status of the PHE approvals for <u>PAPRs</u> and <u>FFRs</u> can also be checked using the CEL.

#### 2) <u>SUPPLEMENTAL INFORMATION</u>

# The table provided below clearly identifies the obsoleted PHE FFRs and PAPRs with the assigned PHE approval holders.

PHE-approved FFRs and PAPRs are easily recognized by the approval number assigned (TC-84A-**PH**XX or TC-21C-**PH**XX) and the NIOSH approval label, which includes the **caution and limitation PH**: *The limited FFR approval will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of personal respiratory protective devices during the COVID-19 outbreak is terminated under Section 564(b)(2) of the Act, or the EUA is revoked under Section 564(g) of the Act, or until such time that the approved configuration can no longer be maintained.* 

OBSOLETED PHE FFR APPROVALS and APPROVAL HOLDERS			
TC-84A-PH01	General Motors Company		
ТС-84А-РН04	General Motors Company		
TC-84A-PH05	Ford Motor Company		
TC-84A-PH06	ViruDefense Inc.		
ТС-84А-РН08	General Motors Company		
TC-84A-PH10	ThermoPore Materials Corporation		
TC-84A-PH11	ThermoPore Materials Corporation		
TC-84A-PH12	ThermoPore Materials Corporation		
TC-84A-PH13	ThermoPore Materials Corporation		
TC-84A-PH14	ThermoPore Materials Corporation		
TC-84A-PH15	Protective Health Gear, Inc.		
TC-84A-PH16	Pandmedic, Inc.		
TC-84A-PH17	AmSafe Inc.		
TC-84A-PH18	Outdoor Research, LLC		
OBSOLETED PHE PAPR APPROVALS and APPROVAL HOLDERS			
ТС-21С-РН02	Ford Motor Company		

ТС-21С-РН03	Allegro Industries	
ТС-21С-РН04	American PAPR, LLC	
TC-21C-PH05	AirBoss Defense Group, LLC	
ТС-21С-РН06	Hunter Engineering Company	

The table provided below identifies seven other PHE approvals previously rescinded by the approval holder or revoked by NIOSH. Revoked or rescinded respirators are <u>not</u> recognized as NIOSH- approved and cannot be used in workplace settings where the use of NIOSH-approved respirators is required.

RESCINDED or REVOKED PHE APPROVALS and APPROVAL HOLDERS			
TC-84A-PH02	Advoque	Revoked 9/10/20	
TC-84A-PH03	Well Span Health	Rescinded 4/29/22	
TC-84A-PH07			
TC-84A-PH09	Outdoor Research, LLC	Rescinded 9/29/20	
TC-84A-PH19	Plasticon Industries, LLC	Revoked 4/18/21	
TC-84A-PH20	United States Mask, LLC	Rescinded 6/22/22	
TC-21C-PH01	Whirlpool Corporation	Rescinded 5/25/21	

#### 3) <u>AUTHORITY</u>

42 C.F.R. Part 84, Approval of Respiratory Protective Devices

#### 4) <u>REFERENCES</u>

Reference <u>Public Health Emergency Declarations</u> for the most current *Renewal of the Determination* that a Public Health Emergency Exists Nationwide as the Result of the Continued Consequences of Coronavirus Disease 2019 (COVID-19) Pandemic.

<u>NIOSH Conformity Assessment Letter to Manufacturers (CA 2021-1036) | NPPTL | NIOSH | CDC</u>, Immediate Information for NIOSH-Approval Holders having Public Health Emergency (PHE) Approvals issued during the COVID-19 Response, and the forthcoming NIOSH revocation of these PHE approvals.

Occupational Safety and Health Administration, Personal Protective Equipment, Respiratory Protection. <u>1910.134 - Respiratory protection.</u> <u>Occupational Safety and Health Administration</u> (osha.gov)