NIOSH Respiratory Protective Device Information

NIOSH CA 2023-1059 May 16, 2023

Subject: Effective Immediately -- Revocation of NIOSH Public Health Emergency (PHE) Approvals issued during the COVID-19 Response

Supersedes NIOSH CA 2022-1044



Document Number	Page 2 of 4
NIOSH CA 2023 – 1059	

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1) <u>SUMMARY</u>

Between May and November 2020, the National Institute for Occupational Safety and Health (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. In July 2021, NIOSH published NIOSH CA 2021-1036 to remind PHE approval holders that these approvals are limited and temporary and will be revoked when the COVID-19 public health emergency declaration ends. In June 2022, NIOSH published NIOSH CA 2022-1044 and NIOSH CA 2022-1045, which obsoleted the remaining PHE approvals and advised users to phase-out the use of these respirators. HHS Secretary Xavier Becerra issued a Statement on the End of the COVID-19 Public Health Emergency on May 11, 2023. May 11, 2023, marked the end of the U.S. federal COVID-19 PHE declaration.

Effectively immediately, NIOSH revokes eight PHE FFR approvals and four PHE PAPR approvals issued to the PHE approval holders listed in the table, below. These respirators are <u>NO LONGER</u> recognized as NIOSH Approved® respirators and therefore cannot be used in <u>workplace settings that require the use of NIOSH Approved respirators</u>. Respirators bearing the NIOSH approval numbers listed below are no longer considered approved and may not be used to fulfill any standard or statute requiring the use of a NIOSH Approved respirator.

NIOSH REVOKED PHE FFR APPROVALS and APPROVAL HOLDERS		
TC-84A-PH01	General Motors Company	
TC-84A-PH04	General Motors Company	
TC-84A-PH05	Ford Motor Company	
TC-84A-PH06	ViruDefense Inc.	
TC-84A-PH08	General Motors Company	
TC-84A-PH15	Protective Health Gear, Inc.	

Document Number	Page 3 of 4
NIOSH CA 2023 – 1059	

TC-84A-PH16	Pandmedic, Inc.		
TC-84A-PH18	Outdoor Research, LLC		
NIOSH REVOKED PHE PAPR APPROVALS and APPROVAL HOLDERS			
TC-21C-PH02	Ford Motor Company		
TC-21C-PH03	Allegro Industries		
TC-21C-PH05	AirBoss Defense Group, LLC		
TC-21C-PH06	Hunter Engineering Company		

Prior to May 11, 2023, 14 other PHE approvals were previously rescinded by the approval holder or revoked by NIOSH, as described in the table, below. 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 PRIOR to May 11, 2023			
TC-84A-PH02	Advoque	Revoked 9/10/20	
TC-84A-PH03	Wall Span Haalth	Rescinded 4/29/22	
TC-84A-PH07	Well Span Health	Rescinded 4/29/22	
TC-84A-PH09	Outdoor Research, LLC	Rescinded 9/29/20	
TC-84A-PH10			
TC-84A-PH11	The war a Dama Make viele Come a veticu		
TC-84A-PH12	ThermoPore Materials Corporation	Rescinded 10/28/22	
TC-84A-PH13			
TC-84A-PH14			
TC-84A-PH17	AmSafe Inc	Rescinded 1/31/23	
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	
TC-21C-PH04	American PAPR, LLC	Rescinded 12/5/22	

Note: PHE-approved FFRs and PAPRs are easily recognized by the approval number assigned (TC-84A-PHXX or TC-21C-PHXX) 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.

The NIOSH certified equipment list identifies all active NIOSH Approved respirators.

Document Number	Page 4 of 4
NIOSH CA 2023 – 1059	

2) <u>AUTHORITY</u>

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

3) REFERENCES

End of the Federal COVID-19 Public Health Emergency (PHE) Declaration | CDC

Fact Sheet: COVID-19 Public Health Emergency Transition Roadmap | HHS.gov

Fact Sheet: End of the COVID-19 Public Health Emergency | HHS.gov

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)

NIOSH Conformity Assessment Letter to Manufacturers (CA 2021-1036) | NPPTL | NIOSH | CDC

NIOSH Respiratory Protective Device Information (CA 2022-1044) | NPPTL | NIOSH | CDC

NIOSH Conformity Assessment Letter to Manufacturers (CA 2022-1045) | NPPTL | NIOSH | CDC

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