# NIOSH Conformity Assessment Letter to Manufacturers

## NIOSH CA 2023-1058 MAY 16, 2023

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

Supersedes NIOSH CA 2022-1045



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

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#### Supersedes NIOSH CA 2022-1045

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

Between May and November 2020, NIOSH issued limited, temporary Public Health Emergency (PHE) approvals for N95<sup>®</sup> filtering facepiece respirators (FFRs) and powered air-purifying respirators (PAPRs) to address supply shortages during that time. In July 2021, NIOSH published <u>NIOSH CA 2021-1036</u> 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 <u>NIOSH CA 2022-1044</u> and <u>NIOSH CA 2022-1045</u>, which obsoleted the remaining PHE approvals and advised users to phase-out the use of these respirators. HHS Secretary Xavier Becerra issued a <u>Statement on the End of the COVID-19 Public Health Emergency</u> 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<sup>®</sup> respirators and therefore cannot be used, manufactured, sold, or distributed. Respirators bearing the NIOSH approval numbers listed below 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.

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	
ТС-84А-РН06	ViruDefense Inc.	
TC-84A-PH08	General Motors Company	
TC-84A-PH15	Protective Health Gear, Inc.	
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		
ТС-21С-РН03	Allegro Industries		
TC-21C-PH05	AirBoss Defense Group, LLC		
ТС-21С-РН06	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Prior to May 11, 2023, 14 other PHE approvals were previously rescinded by the approval holder or revoked by NIOSH, as described in the table, below.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	Well Span Health	Rescinded 4/29/22	
TC-84A-PH07			
TC-84A-PH09	Outdoor Research, LLC	Rescinded 9/29/20	
TC-84A-PH10	ThermoPore Materials Corporation	Rescinded 10/28/22	
TC-84A-PH11			
TC-84A-PH12			
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	
ТС-21С-РН04	American PAPR, LLC	Rescinded 12/5/22	

The <u>NIOSH certified equipment list</u> identifies all active NIOSH Approved respirators.

#### 2) <u>AUTHORITY</u>

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

#### 3) <u>REFERENCES</u>

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

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

N95<sup>°</sup> and NIOSH Approved<sup>®</sup> are registered certification marks of the U.S. Department of Health and Human Services (HHS)