NIOSH Conformity Assessment Letter to Manufacturers

NIOSH CA 2022-1045
June 2022

Subject: Updated Information for NIOSH-Approval Holders having Public Health Emergency (PHE) Approvals issued during the COVID-19 Response, and the NIOSH action to obsolete (phase out) these PHE approvals

Supersedes NIOSH CA 2021-1036

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

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1) SUMMARY

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 supply shortages during that time.

In July 2021, NIOSH reminded PHE approval holders that these approvals are limited and temporary and will be revoked when the COVID-19 public health emergency declaration ends.

Because there are adequate supplies of NIOSH-approved respirators in the United States, NIOSH is immediately obsoleting (phasing out) the remaining PHE approvals. 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approval holder but can continue to be sold, used, and recognized as NIOSH approved until the approval is revoked or rescinded.

Approval holders may rescind a PHE approval by emailing the NIOSH Approval Program to identify the approval number to be rescinded.

Approval holders may submit a new approval application to obtain a conventional NIOSH approval. An application for a new NIOSH approval must be submitted and approved by NIOSH through the respirator approval process described in 42 CFR Part 84, NIOSH Conformity Assessment Notice NIOSH CA 2021-1034R1, and the NIOSH Standard Application Procedures.

The table provided below clearly identifies the obsoleted PHE FFRs and PAPRs and the PHE approval holders. Respirator users should also reference the information provided in NIOSH CA 2022-1044 when making decisions about respirator selection and use.

OBSOLETED 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-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	
TC-21C-PH02	Ford Motor Company
TC-21C-PH03	Allegro Industries
TC-21C-PH04	American PAPR, LLC
TC-21C-PH05	AirBoss Defense Group, LLC
TC-21C-PH06	Hunter Engineering Company

Seven other PHE approvals were 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

2) AUTHORITY

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

3) REFERENCES

Reference Public Health Emergency Declarations 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*.

Letter from RADM Denise M. Hinton, FDA, to Dr. Robert Redfield, CDC, March 11, 2020, to clarify Emergency Use Authorization ("EUA") issued by the Food and Drug Administration ("FDA") on March 2, 2020

Letter from RADM Denise M. Hinton, FDA, to Dr. Robert Redfield, CDC, March 28, 2020, authorizing emergency use of NIOSH-approved air-purifying respirators for use in healthcare settings by HCP to prevent wearer exposure to pathogenic biological airborne particulates during FFR shortages resulting from the Coronavirus Disease 2019 (COVID-19) outbreak, pursuant to Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. § 360bbb-3)

Authorization for Medical Products for Use in Emergencies, 21 U.S.C. § 360bbb-3

NIOSH Conformity Assessment Notice (CA 2021-1034R1), June 2021, Summarized information about NIOSH Respirator Approval Program (i) Basic Application Procedures (ii) Quality Assurance Requirements and (iii) Supplier or Subcontractor Agreements

Standard Application Procedure for the Approval of Air-Purifying Filtering Facepiece Respirators Under 42 CFR Part 84, revised March 12, 2018, Section 3.1 and 3.2

Standard Application Procedure for the Approval of Powered Air-Purifying Respirators and Chemical, Biological, Radiological and Nuclear Powered Air-Purifying Respirators Under 42 CFR Part 84, revised March 12, 2018, Section 3.1 and 3.2