



NIOSH Reference: TN-24263
Mfr. Reference: ALG02

National Institute for Occupational
Safety and Health (NIOSH)
National Personal Protective
Technology Laboratory (NPPTL)
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October 30, 2020

Mr. Adam Harmon
President
ALG Health
2106 Baltimore Street
Defiance, OH 43512

Dear Mr. Harmon:

The National Institute for Occupational Safety and Health (NIOSH) has reviewed your request accepted September 23, 2020. This request was for approval of the model PT-N95C-02 air-purifying filtering facepiece respirator for protections against particulates at a N95 filter efficiency level. The complete respirator configuration is detailed on the assembly matrix, file name *ALG02AMa.xls*, revision A, dated: September 22, 2020.

The site qualification conducted on October 13 and October 14, 2020 at your facility in City of Defiance, Ohio and your responses to the Corrective Action Requests (CARs), specifically CARs 24263-01 through 24263-05 have been accepted and all the nonconformance issues related to the site qualification have been resolved.

This request is granted. Approvals are granted only for documentation written in the English language. It is the manufacturer's responsibility to correctly translate materials desired to be produced in languages other than English. Approval number TC-84A-9259 has been assigned. This respirator is approved for protection against particulates at N95 filter efficiency level.

NIOSH has also reviewed the Quality Procedure System presented and finds that this manual meets or exceeds the minimum technical requirements for quality assurance plans as outlined in Title 42, Code of Federal Regulations (CFR), Part 84.41(a) and, on the basis of this review, this quality manual is accepted.

The approval label is included as an attachment to this letter. The abbreviated label has been accepted as submitted. The cautions and limitations are listed on the approval label. Only those assemblies affected by this request, or where new approval numbers are assigned, apply to this approval action. Production approval labels cannot include information on unapproved configurations.

The approved assembly consists of the parts as listed on the approval label and the assembly matrix. Parts are to be marked with the numbers indicated on the approval label in a legible and permanent manner (marking cannot be removed without evidence of its previous presence).

This certificate of approval is not an endorsement of the respirator by NIOSH, and such endorsement shall not be stated or implied in advertisements or other publicity. However, you may publicize the fact that this respirator has met the requirements of Title 42, *Code of Federal Regulations*, Part 84 (42 CFR 84).

No changes may be made to any respirators and accompanying documentation without prior written approval of NIOSH. Requests for changes must be submitted to NIOSH and a modification of this approval must be granted before changes are made.

Sincerely,

Jeffrey Peterson
Chief, Conformity Verification and
Standards Development Branch

Enclosures