DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Disease Control and Prevention (CDC)

National Institute for Occupational Safety and Health (NIOSH)
National Personal Protective Technology Laboratory (NPPTL)
626 Cochrans Mill Road
Pittsburgh, PA 15236-0070
Phone: 412-386-4000
Fax: 412-386-4051

NIOSH Reference: TN-24530
Mfr. Reference: ALG01_SURG

January 29, 2021

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 January 12, 2021. This request was for Surgical N95 approval of the model PT-N95F-01S air-purifying filtering facepiece respirator for protections against particulates at N95 filter efficiency level. The complete respirator configuration is detailed on assembly matrix, file name *ALG01_SURG_AMd.xls*, revision D, dated: January 22, 2021.

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-9288** has been assigned. This respirator is approved and cleared for use in healthcare settings under the FDA/NIOSH MOU 225-18-006. This Surgical N95 provides protection against particulates at the N95 filter efficiency level and conforms to recognized standards for flammability, fluid resistance and biocompatibility.

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). You may market the device, subject to the general controls

provisions of the Federal Food, Drug and Cosmetic Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

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 A. Peterson -S

Digitally signed by Jeffrey A. Peterson -S
Date: 2021.01.29 13:10:39 -05'00'

Jeffrey Peterson
Chief, Conformity Verification and
Standards Development Branch

Enclosures