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)
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NIOSH Reference: TN-22286
Mfr. Reference: NIT149510

November 7, 2018

Ms. Maria Vargas
NITTA Corp. S.A.
AU Medellin (Calle 80) km 1 Via Siberia
Centro Empresarial Los Robles, Bodega 3
Bogotá, Cota Cundinamarca
Colombia

Dear Ms. Vargas:

The National Institute for Occupational Safety and Health (NIOSH) has reviewed your request accepted March 27, 2018. This request was for approval of the model 9510, air-purifying filtering-facepiece respirator for protections against particulates at N95 filter efficiency level in four color variants designated by part numbers 9510-1 (white), 9510-2 (black), 9510-3 (blue), and 9510-4 (green). The complete respirator configuration is detailed on assembly matrix, file name *149510AM9.xlsx*, revision 9, dated: 03-20-18.

Non-conformance issues observed during the site qualification conducted at your facility in Bogota, Colombia on September 12, 2018, are deemed to have been resolved. Your response to the Corrective Action Request (CAR), specifically CAR 22286-01, has been accepted.

This request is granted. Approval is 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-8118 has been assigned. This respirator is approved for protection against particulates at N95 filter efficiency level.

NIOSH has also reviewed the quality manual file name, *149510QMr.pdf*, version 18, dated Mar-20-18, 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.

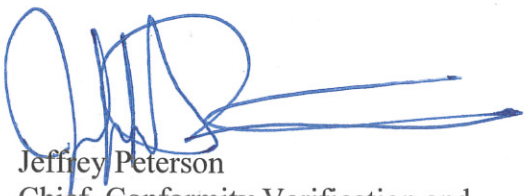
The final respirator approval label is included as an attachment to this letter. The abbreviated labels have been accepted as submitted. The cautions and limitations which apply to this approval are on the approval label. Only those assemblies affected by this request, or where new approval numbers are 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