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-20835
Mfr. Reference: MAK-1608

June 3, 2016

Mr. Alexander Freedman
Makrite Industries, Inc.
105 Palmer River Road
Swansea, MA 02777

Dear Mr. Freedman:

The National Institute for Occupational Safety and Health (NIOSH) has reviewed your request accepted April 27, 2016. This request was for an extension of approval to TC-84A-5409 and TC-84A-4652 to add private label versions of Models MKN95-910V and N95V-510W N95 air purifying filtering facepiece respirators with exhalation valve to Masprot S.C. el. LTDA. of Santiago, Chile.

The Makrite model numbers, assembly matrices and private label model numbers are identified in the following table:

Approval Number Makrite Model	Assembly Matrix	Masprot S.C. el. LTDA. Model
TC-84A-5409 Model: MKN95-910V	MKN95-910VAMaR9.xls Dated: 04/20/2016	M300V
TC-84A-4652 Model: N95V-510W	N95V-510WAMaR6.xls Dated: 04/21/2016	M350

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 in languages other than English.

The final respirator approval labels are included as attachments to this letter. The abbreviated labels have been accepted as submitted. The cautions and limitations which apply to these approvals are on the approval labels. 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 assemblies consist of the parts as listed on the approval labels and the assembly matrices. 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). The manufacturer is responsible for properly packaging, labeling, and controlling the respirators produced under these private label approvals. At a minimum, the items that must be controlled are the approved user instructions, all approval labeling, all approved packaging, use claims, marketing materials, and the respirator design and construction details. Any change to these NIOSH-approved respirators or approval documentation without prior notification and approval is a violation of this approval and renders this certification as invalid.

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 yours,

David Chirdon
Chief, Conformity Verification and
Standards Development Branch
National Personal Protective Technology Laboratory

Enclosures