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-20969
Mfr. Reference: MAK-1621

October 24, 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 August 10, 2016. This request was for an extension of approval to TC-84A-5408 to add a private label version of the model MK910-N95 air purifying filtering facepiece respirator to Masprot S.C. e l. LTDA of Santiago, Chile. The respirator is rebranded as the model M300 reference assembly matrix MK910-N95AMaR6.xls dated 08/10/2016.

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 label is included as an attachment to this letter. The abbreviated label has 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)

The manufacturer is responsible for properly packaging, labeling, and controlling the respirators produced under this private label approval. 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 this NIOSH-approved respirator 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

Enclosure