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-22871
Mfr. Reference: GER00421

April 30, 2019

Ms. Chelsey Souza
Louis M. Gerson Company, Inc.
16 Commerce Blvd.
Middleboro, MA 02346

Dear Ms. Souza:

The National Institute for Occupational Safety and Health (NIOSH) has reviewed your request accepted January 25, 2019. This request was for extension of approvals to add private label versions of Louis M. Gerson Company's model 9955 full facepiece respirators with various Gerson chemical cartridges, filters, and combination filter cartridges to Libus of Buenos Aires, Argentina. The Libus private label versions will use the same part numbers as Gerson Company. The complete respirator configurations are detailed on the assembly matrix, file name *9900AMau.xls*, revision au, dated 3/11/2019. In addition, Libus user instructions (part number 711616) is added to the assembly matrix.

This request is granted. Extension of 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.

The final respirator approval label is 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 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 assemblies consist 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 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,

Jeffrey Peterson
Chief, Conformity Verification and
Standards Development Branch

Enclosures