## **DEPARTMENT OF HEALTH & HUMAN SERVICES**

NIOSH Reference: TN-19348 Mfr. Reference: GER00359 Centers for Disease Control and Prevention (CDC) National Institute for Occupational Safety and Health (NIOSH) National Personal Protective Technology Laboratory (NPPTL) P.O. Box 18070 Pittsburgh, PA 15236-0070 Phone: 412-386-4000 Fax: 412-386-4051 February 26, 2014

Mr. Geoff White Director of Regulatory Affairs Louis M. Gerson Company, Inc. 16 Commerce Boulevard Middleboro, Massachusetts 02346

Dear Mr. White:

The National Institute for Occupational Safety and Health (NIOSH) has reviewed your request accepted on November 7, 2013. This request was for approval of the Air Purifying Respirators consisting of the model 9900 Full Facepiece or the model 9950 Full Facepiece or the 9000 series half mask with the particulate filter, part number GX70 for protections against particulates at a P100 filter efficiency level, reference the assembly matrices 9900AMag.xls, revision ag, dated 10/28/2013, and Rcr18AMz.xls, revision Az, 10/28/2013.

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 approval numbers have been assigned as shown in the table below:

APPROVAL NUMBER TC- AS SHOWN	DESCRIPTION	CARTRIDGE/ FILTER	PROTECTION <sup>1</sup>
84A-6807	9900 Full Facepiece with Filter	GX70	P100
84A-6808	9950 Full Facepiece with Filter	GX70	P100
84A-6809	9000 Series Half Mask with Filter	GX70	P100

Protection - Codes are defined on the enclosed approval labels.

The CD enclosed with this letter contains the final respirator and filter approval labels. 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).

This certificate of approval is not an endorsement of the respirators by NIOSH, and such endorsement shall not be stated or implied in advertisements or other publicity. However, you may publicize the fact that these respirators have met the requirements of Title 42, *Code of Federal Regulations*, Part 84 (42 CFR 84).

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 to the 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, mh Sfl Johathan Szalajda

Acting Chief, Technology Evaluation Branch National Personal Protective Technology Laboratory

Enclosures