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)
626 Cochrans Mill Road
Pittsburgh, PA 15236-0070
Phone: 412-386-4000
Fax: 412-386-4051

NIOSH Reference: TN-23906
Mfr. Reference: GSFN1900f

May 27, 2020

Mr. John Schwind
Global Safety First
545 Washington Blvd. Suite 2
Sea Girt, NJ 08750

Dear Mr. Schwind:

The National Institute for Occupational Safety and Health (NIOSH) has reviewed your request accepted on May 14, 2020. This request was for the extension of approval TC-84A-8133, ReadiMask family of N95 air-purifying filtering facepiece respirators. The application adds a new manufacturing subcontract partner, Avery Dennison Medical, located at 7100 Lindsay Dr., Mentor, Ohio, and included the subcontractor's Quality Manual and the subcontracting agreement. Typically, this information is submitted and reviewed as a Quality Assurance application, with a subsequent extension for application to update the NIOSH documentation. NIOSH processed this application as submitted due to the COVID-19 response.

This application also includes updates to the quality control manual (*GBL-MAN-000002-B Quality Manual (ver 5).pdf*), and Process Quality Control Plan (*N1900PQPg1.docx*) to facilitate the manufacturing at this new site location. The complete respirator configurations are detailed on assembly matrix file name *N1900AMe (2).xlsx*, revision e, dated: 5/19/20.

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.

Since this request does not affect the full approval labels, final labels are not enclosed.

The approved assemblies consist of the parts as listed on the approval labels and the assembly matrix. Parts are to be marked with the numbers indicated on the approval labels in a legible and permanent manner (marking cannot be removed without evidence of its previous presence).

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 A. Peterson -S
Digitally signed by Jeffrey A. Peterson -S
Date: 2020.05.27 15:18:22 -04'00'

Jeffrey Peterson
Chief, Conformity Verification and
Standards Development Branch

Enclosures