



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Centers for Disease Control
and Prevention (CDC)
National Institute for Occupational
Safety and Health (NIOSH)
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March 17, 2009

Ms. Julia Huang
Shuenn Bao Shing Corporation
No. 90, Hsin Kung 6 Road
Tien Chung Chen
Chang Hwa Hsien,
TAIWAN

Dear Ms. Huang:

The National Institute for Occupational Safety and Health (NIOSH) has reviewed your request dated January 20, 2009. This request was for an approval of the model AP0708 N95 filtering facepiece air purifying respirator (APR) as described on assembly matrix AP0708AMa.xls. In addition, the updated Quality System Manual, document number T-M-001, revision level 1.5 and dated 02/05/2009, was presented for review.

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. Approval number TC-84A-4990 has been assigned. This respirator is approved for protection at a N95 particulate efficiency level.

NIOSH has also reviewed the quality manual presented and has found that this manual meets or exceeds the minimum technical requirements for quality assurance plans as outlined in Title 42, *Code of Federal Regulations* (CFR), Part 84.41(a) and, on the basis of this review, this quality manual is accepted.

The CD enclosed with this letter contains the final respirator approval label. 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).

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

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.

A copy of the quality manual and associated documents will be retained by NIOSH and incorporated into our files. Any future changes to these accepted quality documents must be submitted to NIOSH for a modification of this accepted quality system.

Sincerely yours,

Heinz W. Ahlers
Chief, Technology Evaluation Branch
National Personal Protective Technology Laboratory

Enclosures