



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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and Prevention (CDC)  
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The National Institute for Occupational Safety and Health (NIOSH) has reviewed your request accepted December 16, 2011. This request was for approval of the models MS6115 filtering facepiece air purifying respirators (APR), part numbers SC-MS6115 and SC-MS6115L, for protection against particulates at a N95 filter efficiency level, reference assembly matrix MS6115AMB.xls. In addition, the Suzhou Sanical Protective Product Manufacturing Company Quality Manual, document number SC-QM-2011, revision A/0 and effective date 2011-03-11 was presented for review.

This request is granted. Approval is 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-5530 has been assigned. These respirators are approved for protection against particulates at a N95 filter efficiency level.

NIOSH has also reviewed the quality manual presented and finds 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.

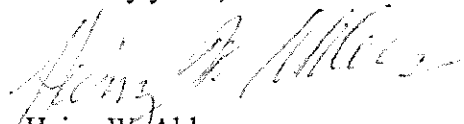
The CD enclosed with this letter contains the final respirators approval label. The abbreviated labels have been accepted as submitted. The cautions and limitations which apply to this approval are on the approval label. Only those assemblies affected by this request, or where new approval numbers are assigned, apply to this approval action. Production approval labels cannot include information on unapproved configurations.

The approved 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 labels 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).

No changes may be made to any respirator 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,



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

Enclosures