



NIOSH Reference: TN-14513
Mfr. Reference: SDHDTC3XAF-2

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
July 20, 2006

Ms. Maggie Zhong
Shanghai Dasheng Health Products Manufacture Co., Ltd.
Room 604, No. 7 Building
No.20 Handan Road
Shanghai, 200437
CHINA

Dear Ms. Zhong:

The National Institute for Occupational Safety and Health (NIOSH) has reviewed your request dated May 15, 2006. This request was for approval of the model DTC3X N95 filtering facepiece air purifying respirator. In addition, the request included the presentation of the Shanghai Dasheng Health Products Manufacture Co. Quality Manual, Edition B, dated May 10, 2003.

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-4329 has been assigned. The respirator is approved for protection at a N95 particulate efficiency level.

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

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).

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.

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 will be retained by NIOSH and incorporated into our files. Any future changes to this approved quality manual must be submitted to NIOSH for a modification of this approval.

Sincerely yours,



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

Enclosures