DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
National Institute for Occupational
Safety and Health - ALOSH
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NIOSH Reference: TN-08402
Mfr. Reference: NDI00001

May 21, 1996

Mr. Robert Sell
Senior Mechanical Designer
National Draeger, Incorporated
101 Technology Drive
P.O. Box 120
Pittsburgh, Pennsylvania 15230

Dear Mr. Sell:

The National Institute for Occupational Safety and Health (NIOSH) and the Mine Safety and Health Administration (MSHA) have reviewed your request dated February 21, 1996. This request was for approval of the Drager Limited, thirty-minute, high-pressure, open-circuit, pressure-demand, combination, self-contained breathing apparatus (SCBA) for escape and Type-C, pressure-demand, supplied-air respirator (SAR) or thirty-minute, high-pressure, open-circuit, pressure-demand, SCBA listed in your standard application form.

Approval TC-13F-378 is granted to cover the Drager Limited, thirty-minute, high-pressure, open-circuit, pressure-demand, combination, SCBA for escape and Type-C, pressure-demand, SAR or thirty-minute, high-pressure, open-circuit, pressure-demand, SCBA. The respirator models affected by this approval are listed in your standard application form. A copy of the NIOSH test report is enclosed. The cautions and limitations listed on your approval label and in your instruction manual, copies of each enclosed, apply to this approval.

In making renewals or repairs, parts identical with those furnished by the manufacturer under the pertinent approval shall be maintained.

The approved assembly consists of the Drager Limited, parts indicated by the approval label draft plus the assembly matrix. These parts are to be marked with the indicated numbers in a legible and permanent manner (marking cannot be removed without evidence of its previous presence).

The use of this approved device in combination with <u>any</u> other additional respirator components not covered under this approval, renders this certification invalid.

The enclosed approval label draft designs are to be used in preparing the approval labels. Label TC-13F-378 shall be prepared for use in the manual and on the harness assembly. Final copies of your labels and user's instructions must be submitted to NIOSH for concurrence before production.

Only those assemblies where approval numbers are assigned apply to this approval action. Production approval labels cannot include information on unapproved configurations.

Your quality control plans for this respirator were reviewed by NIOSH. On the basis of that review, your quality control plans are accepted as a part of this approval.

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 the product has met the requirements of Title 42, Code of Federal Regulations (CFR), Part 84.

Any changes you wish to make to this respirator and accompanying documentation shall be submitted, and a modification of this approval shall be granted (including changes in materials, product design, manufacturing processes, labels, instruction manuals and quality control programs) before any changes are made. (Reference: Title 42, CFR, Part 84.35.)

Please submit samples of respirator packaging, bearing all required labels, instructions, and markings, for our approval, before adopting them. Please send us one production sample to be made a part of the record of this approval. We shall retain several other items as additional record material. All other material will be discarded unless we are otherwise advised by you within 7 days.

Sincerely yours,

William a Hoffman jr

Richard W. Metzler, Chief
Certification and Quality
Assurance Branch
Division of Safety Research

Enclosures