NIOSH Reference: TN-16916
Mfr. Reference: GER000289

Centers for Disease Control
and Prevention (CDC)
National Institute for Occupati
Safety and Health (NIOSH)
National Personal Protective
Technology Laboratory (NP
P.O. Box 18070
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May 4, 2010

CORRECTED LETTER
ISSUED: May 27, 2010
(Changes from original in bold.)
(Corrected Project Report Enclosure Included.)

Mr. Robert Brunell
Quality Control Manager
Louis M. Gerson Company, Inc.
16 Commerce Boulevard
Middleboro, Massachusetts 02346

Dear Mr. Brunell:

The National Institute for Occupational Safety and Health (NIOSH) has reviewed your request dated March 22, 2010. This request was for extensions of approvals to TC-84A-0160, TC-84A-4123, and **TC-84A-4233** to add private label versions of the models 1730, 2130, and 2140 (with exhalation valve) N95 filtering facepiece air purifying respirators for Libus of Buenos Aires, Argentina, under the same model numbers 1730, 2130, and 2140, as referenced on assembly matrix prbb51B23AM23.xls.

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.

The CD enclosed with this letter contains the final respirator approval labels. The abbreviated labels have been accepted as submitted. The cautions and limitations which apply to this approval are on the approval labels. 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 labels 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).

The manufacturer is responsible for properly packaging, labeling, and controlling the respirators produced under this private label approval. At a minimum, the items that must be controlled are the approved user instructions, all approval labeling, all approved packaging, use claims, marketing materials, and the respirator design and construction details. Any change to these NIOSH-approved respirators or approval documentation without prior notification and approval is a violation of this approval and renders this certification as invalid.

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

National Institute for Occupational Safety and Health
Certification and Quality Branch
Air Purifying Respirator Section

TEST REPORT

Task Number: TN-08043

Prepared by: Jeff Peterson

Date: November 21, 1995

Manufacturer: Gerson

Item(s) Tested: Model 1730 N95 respirator without valves -- Models 1731, 2734, 2735, 2737 have the same media and construction.

Background Information:

On September 11,1995, Gerson requested a new approval for the models 1730, 1731, 2734, 2735 and 2737 N95 disposable respirators without exhalation valves. All models are of the same media and dimension. They differ in headstrap attachment, open or close cell foam nosepiece, or triangular or rectangular shaped nosepiece. The model 1730 was tested as representative of all of the models listed.

Tests Assigned:

1. N95 Filter Efficiency Test
2. Initial Inhalation Resistance
3. Initial Exhalation Resistance

Overall Results:

The items tested passed laboratory testing.

Individual Test Results:

See accompanying test sheets.

National Institute for Occupational Safety and Health
Certification and Quality Assurance Branch
Air-Purifying Respirator Section
Test Data Sheet

Task Number: TN-8043 **Reference No.:** CFR 84.181
Test: Sodium Chloride (NaCl) - N95 **STP No.:** 59
Manufacturer: Louis M. Gerson Company, Inc.
Item Tested: Gerson 1730 N95 no valves

Filter	Flow Rate	Initial Filter Resistance	Maximum Allowable Percent Leakage	Maximum Percent Leakage	Result
1	85	11.2	5.00	3.050	PASS
2	85	13.1	5.00	2.030	PASS
3	85	11.2	5.00	2.300	PASS
4	85	11.5	5.00	2.240	PASS
5	85	12.2	5.00	1.470	PASS
6	85	12.2	5.00	2.280	PASS
7	85	13.0	5.00	1.370	PASS
8	85	12.5	5.00	1.810	PASS
9	85	12.6	5.00	1.610	PASS
10	85	13.4	5.00	1.670	PASS
11	85	12.2	5.00	1.790	PASS
12	85	12.2	5.00	1.330	PASS
13	85	10.7	5.00	3.120	PASS
14	85	12.0	5.00	2.610	PASS
15	85	11.8	5.00	2.590	PASS
16	85	11.6	5.00	2.280	PASS
17	85	12.2	5.00	1.860	PASS
18	85	11.3	5.00	2.220	PASS
19	85	12.8	5.00	1.450	PASS
20	85	12.1	5.00	1.760	PASS

Overall Result: PASS

Signature: Robert E Thewlis P **Date:** 9/26/95

Engineering Technician

National Institute for Occupational Safety and Health
Certification and Quality Assurance Branch
Air-Purifying Respirator Section
Test Data Sheet

Task Number: TN-8043 **Reference No.:** CFR 84.180
Test: Inhalation Resistance Test **STP No.:** 7
Manufacturer: Louis M. Gerson Company, Inc.
Item Tested: Gerson 1730 N95 no valves

Filter Type: Filter Only

	Maximum Allowable Resistance (MM of H2O) Inhalation		Actual Resistance (MM of H2O) Inhalation		
Sample	**Initial**	**Final**	**Initial**	**Final**	**Result**
1	35		11.2		PASS
2	35		13.0		PASS
3	35		11.4		PASS

Overall Result: PASS

Signature: Robert E Thewlis

Date: 9/28/95

Engineering Technician

National Institute for Occupational Safety and Health
Certification and Quality Assurance Branch
Air-Purifying Respirator Section
Test Data Sheet

Task Number: TN-8043 **Reference No.:** CFR 84.180
Test: Exhalation Resistance Test **STP No.:** 3
Manufacturer: Louis M. Gerson Company, Inc.
Item Tested: Gerson 1730 N95 no valves

Filter Type: Filter Only

	Maximum Allowable Resistance (MM of H2O) Exhalation		Actual Resistance (MM of H2O) Exhalation		
Sample	**Initial**	**Final**	**Initial**	**Final**	**Result**
	0	0	0.0	0.0	PASS
1	25		11.2		PASS
2	25		13.0		PASS
3	25		11.4		PASS

Overall Result: PASS

Signature: Robert E Thewlis

Date: 9/26/95

Engineering Technician