



DEPARTMENT OF HEALTH & HUMAN SERVICES

NIOSH Reference: TN-19824
Mfr. Reference: GHCL-188

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
December 15, 2014

Mr. Wanghua Xu
Management Representative
Guangzhou Harley Commodity Company Limited
Floor 1 to 4, #8, Team 17, Sandong Village
Xinhua Street, Huadu District
Guangzhou 510800
CHINA

Dear Mr. Xu:

The National Institute for Occupational Safety and Health (NIOSH) has reviewed your request accepted September 17, 2014. This request was for approval of the model L-188 N95 filtering facepiece air purifying respirator for protections against particulates at a N95 filter efficiency level, reference assembly matrix L-188 Ama.xls. In addition, the Guangzhou Harley Commodity Company QA Manual, version A1, effective date 2014-06-10, was submitted for review.

This request is granted. Approvals are granted for English language only on all documentation. It is the manufacturer's responsibility to correctly translate materials desired in languages other than English. Approval number TC-84A-6973 has been assigned. This respirator is 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 respirator label. The abbreviated label is 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.

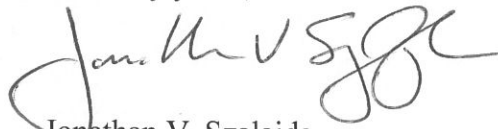
The approved assembly consists of the parts as listed on the approval label and the assembly matrix. Parts are to be marked with the numbers indicated on the approval label in a legible and permanent manner (marking cannot be removed without evidence of its previous presence).

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 (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 will be retained by NIOSH and incorporated into our files. Any future changes to this accepted quality document must be submitted to NIOSH for a modification of this accepted quality system.

Sincerely yours,

A handwritten signature in dark ink, appearing to read 'Jonathan V. Szalajda', with a stylized flourish at the end.

Jonathan V. Szalajda
Acting Chief, Technology Evaluation Branch
National Personal Protective Technology Laboratory

Enclosures



TEST REPORT

Task Number: TN-19824

Manufacturer: Guangzhou Harley Commodity Company Limited

Prepared by: Nichole Petitta

Tests Conducted by: Nichole Petitta

Date: November 13, 2014

Respirator Tested: L-188 N95

Background Information

Respirator tested as per test request.

Tests Assigned

<u>Test Description</u>	<u>STP Number</u>
A. Exhalation Resistance Test	RCT-APR-STP-0003
B. Inhalation Resistance Test	TEB-APR-STP-0007
C. Sodium Chloride (NACL) N95 Test	TEB-APR-STP-0059

Overall Results

The respirator system tested met the requirements of all the procedures listed above.

National Institute for Occupational Safety and Health
Respirator Branch
Test Data Sheet



Task Number: TN-19824

Reference No.: CFR 84.180

Test: Exhalation Resistance Test

STP No.: 3

Manufacturer: Guangzhou Harley Commodity Company Limited

Filter Type: Filter Only

Item Tested: L-188 N95

Sample	Maximum Allowable Resistance (MM of H2O)	Actual Resistance (MM of H2O)	Result
	Exhalation	Exhalation	
1	25	9.6	PASS
2	25	8.9	PASS
3	25	8.5	PASS

Overall Result: PASS

Comments:

Samples were tested on Brooks meter 0000283.

Was all equipment verified to be in calibration throughout all testing?

☒ Yes ☐ No

Signature:

Nicholas L. Petetta

Date: 11/4/2014

Engineering Technician

National Institute for Occupational Safety and Health
Respirator Branch
Test Data Sheet



Task Number: TN-19824

Reference No.: CFR 84.180

Test: Inhalation Resistance Test

STP No.: 7

Manufacturer: Guangzhou Harley Commodity Company Limited

Item Tested: L-188 N95

Filter Type: Filter Only

Sample	Maximum Allowable Resistance (MM of H2O)	Actual Resistance (MM of H2O)	Result
	Inhalation	Inhalation	
1	35	10.5	PASS
2	35	10.5	PASS
3	35	9.7	PASS

Overall Result: PASS

Signature:

Nichole L. Petitta

Date: 11/4/2014

Engineering Technician

Task Number: TN-19824

Reference No.: CFR 84.180

Test: Inhalation Resistance Test

STP No.: 7

Manufacturer: Guangzhou Harley Commodity Company Limited

Item Tested: L-188 N95

Comments:

Samples were tested on Brooks meter 000036.

Was all equipment verified to be in calibration throughout all testing?

☒ Yes ☐ No

Signature:

Nichole L. Petitta

Date: 11/4/2014

Engineering Technician

National Institute for Occupational Safety and Health
Respirator Branch
Test Data Sheet



Task Number: TN-19824

Reference No.: CFR 84.181

Test: Sodium Chloride (NaCl) - N95

STP No.: 59

Manufacturer: Guangzhou Harley Commodity Company Limited

Item Tested: L-188 N95

Filter	Flow Rate	Initial Filter Resistance	Maximum Allowable Percent Leakage	Initial Percent Leakage	Maximum Percent Leakage	Result
1	85	9.6	5.00	0.517	0.517	PASS
2	85	10.6	5.00	0.694	0.694	PASS
3	85	9.8	5.00	0.718	0.718	PASS
4	85	10.3	5.00	0.651	0.654	PASS
5	85	9.3	5.00	0.682	0.682	PASS
6	85	9.7	5.00	0.755	0.755	PASS
7	85	10.7	5.00	0.621	0.621	PASS
8	85	9.9	5.00	0.744	0.744	PASS
9	85	9.8	5.00	0.535	0.535	PASS
10	85	10.8	5.00	1.500	1.580	PASS
11	85	10.5	5.00	0.688	0.688	PASS
12	85	9.7	5.00	0.692	0.692	PASS
13	85	10.6	5.00	0.757	0.757	PASS
14	85	10.8	5.00	0.671	0.671	PASS
15	85	10.8	5.00	0.981	0.981	PASS
16	85	10.3	5.00	0.678	0.678	PASS
17	85	9.8	5.00	0.661	0.661	PASS
18	85	10.3	5.00	0.680	0.680	PASS
19	85	9.6	5.00	1.660	1.660	PASS
20	85	9.8	5.00	0.769	0.769	PASS

Overall Result: PASS

Signature:

Nichole L. Petetta

Date: 11/13/2014

Engineering Technician

Task Number: TN-19824

Reference No.: CFR 84.181

Test: Sodium Chloride (NaCl) - N95

STP No.: 59

Manufacturer: Guangzhou Harley Commodity Company Limited

Item Tested: L-188 N95

Comments:

All samoles were tested on TSI 8130 machine 000192 with samples 1-3 using timer 000214.

Was all equipment verified to be in calibration throughout all testing?

☒ Yes ☐ No

Signature:

Nichole L. Petitta

Date: 11/13/2014

Engineering Technician