



**VERIDIA**

**Certification Pack**

# Harley Particulate Respirator.

## 80102

Harley Commodity  
 哈雷®  
L-188  
TC-84A-6973  
NIOSH N95

**This pack contains**  
TGA Certificate  
Resistance Test Reports

Date Released

**January 2022**



**HARLEY N95 L188 Particulate Respirator Folded, Head Strap**

**80102**

Features	<ul style="list-style-type: none"> <li>- Provides soft nose pad to reduce constriction</li> <li>- Unique sponge strip prevents upwelling of moisture &amp; fits the nose closely to avoid fog</li> <li>- Inner layer is soft &amp; smooth, comfortable to wear</li> <li>- Fluid Resistance: 160mmHg Bacterial</li> <li>- Filtration Efficiency: PFE ≥ 95%</li> <li>- ASTM: Level 3</li> </ul>
Colour	- White
Unit	- Each
Pack Qty	- 20
Carton Qty	- 20 x 20



Australian Government  
Department of Health  
Therapeutic Goods Administration

# Australian Register of Therapeutic Goods Certificate

Issued to

**GMP Consulting Pty Ltd**

for approval to supply

**GMP Consulting Pty Ltd - Public respirator, single-use**

<b>ARTG Identifier</b>	341498
<b>ARTG Start Date</b>	13/08/2020
<b>Product Category</b>	Medical Device Included Class 1
<b>GMDN</b>	57793
<b>GMDN Term</b>	Public respirator, single-use
<b>Intended Purpose</b>	A single-use NIOSH-Approved N95 Particulate Filtering Facepiece Respirators designed to be placed over the nose and mouth of a member of the general public to permit normal breathing while protecting the wearer from exposure to pathogenic biological airborne particulates during a public health medical emergency.

Manufacturer Details	Address	Certificate number(s)
Guangzhou Harley Commodity Co Ltd	Floor 1 to 4 274 Group 1 Team 17 Sandong Village Huacheng Street Huadu District , Guangzhou , China	

## ARTG Standard Conditions

The above Medical Device Included Class 1 has been entered on the Register subject to the following conditions:

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

## Products Covered by This Entry

### 1. Public respirator, single-use

## Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration  
PO Box 100, Woden ACT 2606 Australia  
Phone: 1800 020 653  
Email: [info@tga.gov.au](mailto:info@tga.gov.au)

ARTG Identifier: 341498  
ARTG Start Date: 13/08/2020



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.

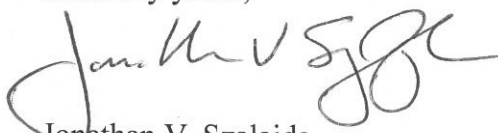
The approved assembly consists of the parts as listed on the approval label and the assembly matrix. Parts are to be marked with the numbers indicated on the approval label in a legible and permanent manner (marking cannot be removed without evidence of its previous presence).

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 black 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



National Institute for Occupational Safety and Health  
National Personal Protective Technology Laboratory  
Technology Evaluation Branch  
Certification, Evaluation and Testing Section  
P.O. Box 18070  
Pittsburgh, PA 15236

**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:** 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 H <sub>2</sub> O)	Actual Resistance (MM of H <sub>2</sub> O)	Result
	Inhalation	Inhalation	
1	35	10.5	PASS
2	35	10.5	PASS
3	35	9.7	PASS

**Overall Result:** PASS

**Signature:**

*Nichole L. Petetta*

**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. Petetta*

**Date:** 11/4/2014

**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 samples 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:**

*Siende L. Petitta*

**Date:** 11/13/2014

**Engineering Technician**

Client: GMP Trading  
 P.O. Box 573  
 Balwyn VIC 3103

Test Report Number: 201172

Testing Requested By: Steven Lai

Client's Order Number: Not Supplied

Date Samples Received: 10/11/2020

Date Testing Completed: 17/11/2020

Sample Description: 2D N95 Particulate Respirator Mask, Model No: L-188, Manufacture Date: 2020-07-19, Expiry Date: 2025-07-18, Lot Number: 20200169. Half facepiece respirator mask, Twin elastic ear loops, External metal nose clip, Internal foam nose padding, Mask stamped Harley Commodity L-188, TC-84A-6973, NIOSH N95, Samples as supplied.

Manufacturer: Guangzhou Harley Commodity Company Limited  
 Floor 1 to 4, #8, Team 17, Sandong Village, Xinhua Street, Huadu District, Guangzhou 510800 China.



Testing Requested:

Resistance to penetration by synthetic blood, minimum pressure in mm Hg, as required by AS 4381:2015 using Test method ISO 22609

Special Instructions: Deviation from standard – Client has only supplied 20 masks for testing.



Legend:  
 NA = Not Applicable  
 NT = Not Tested  
 NS = Not Supplied  
 TBA = To Be Ascertained

Document name: Differential Pressure

Accredited for compliance with ISO/IEC 17025 - Testing

The results of the tests, calibrations and/or measurements in this document are traceable to Australian National Standards. The results are applicable to the sample tested and may not apply to other batches of the same material or similar materials. It is a condition of the provision of these test results that you do not use the name of VicLab in connection with the promotion or sale of your products, unless VicLab has given express written authority to do so. This document shall not be reproduced except in full

**AUTHORISED SIGNATORY:**

*R. A. Vickery*

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Client: GMP Trading  
 Test Report Number: 201172  
 Sample Description: 2D N95 Particulate Respirator Mask, Model No: L-188, Manufacture Date: 2020-07-19, Expiry Date: 2025-07-18, Lot Number: 20200169. Half facepiece respirator mask, Twin elastic ear loops, External metal nose clip, Internal foam nose padding, Mask stamped Harley Commodity L-188, TC-84A-6973, NIOSH N95, Samples as supplied.

### Summary of Testing and Results:

Resistance to penetration by synthetic blood, minimum pressure in mm Hg, as per ISO 22609

Samples conditioned at  $21 \pm 5^\circ\text{C}$  and  $85 \pm 10\%$  relative humidity for a minimum of 4 hours prior to testing.

Test pressure: 21.3 kPa

General location of the areas of the mask specimens target area: Centre of Mask

Was targeting-plate method used: Yes

Specimen Number	Synthetic Blood Penetration	Result mm Hg	Pass/Fail
1	None Seen	160 mmHg	Pass
2	None Seen	160 mmHg	Pass
3	None Seen	160 mmHg	Pass
4	None Seen	160 mmHg	Pass
5	None Seen	160 mmHg	Pass
6	None Seen	160 mmHg	Pass
7	None Seen	160 mmHg	Pass
8	None Seen	160 mmHg	Pass
9	None Seen	160 mmHg	Pass
10	None Seen	160 mmHg	Pass



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TBA = To Be Ascertained

Document name: Differential Pressure



*R.A. Vickery*

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Client: GMP Trading  
 Test Report Number: 201172  
 Sample Description: 2D N95 Particulate Respirator Mask, Model No: L-188, Manufacture Date: 2020-07-19, Expiry Date: 2025-07-18, Lot Number: 20200169. Half facepiece respirator mask, Twin elastic ear loops, External metal nose clip, Internal foam nose padding, Mask stamped Harley Commodity L-188, TC-84A-6973, NIOSH N95, Samples as supplied.

#### Summary of Testing and Results Continued:

Resistance to penetration by synthetic blood, minimum pressure in mm Hg, as per ISO 22609

Specimen Number	Synthetic Blood Penetration	Result mm Hg	Pass/Fail
11	None Seen	160 mmHg	Pass
12	None Seen	160 mmHg	Pass
13	None Seen	160 mmHg	Pass
14	None Seen	160 mmHg	Pass
15	None Seen	160 mmHg	Pass
16	None Seen	160 mmHg	Pass
17	None Seen	160 mmHg	Pass
18	None Seen	160 mmHg	Pass
19	None Seen	160 mmHg	Pass
20	None Seen	160 mmHg	Pass

Samples supplied have achieved Level 3 Barrier Resistance to penetration by synthetic blood requirement.

Resistance to penetration by synthetic blood, minimum pressure in mm Hg requirement as per AS 4381:2015	Level 1 Barrier	Level 2 Barrier	Level 3 Barrier
	80 mm Hg	120 mm Hg	160 mm Hg



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**AUTHORISED SIGNATORY:**



*R.A. Vickery*

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