

 **prepared.**



NIOSH N95 Face Masks

Harley L-188

Guangzhou Harley Commodity Co., Ltd.

Product Details

Specifications

Model:	Harley L-188
Type:	Foldable
Certifications:	NIOSH N95
NIOSH Reference:	TN-19824

Shipping Info (L-188)

Masks/Box:	20 Masks/Box
Boxes/Case:	20 Boxes/Case
Masks/Case:	400 Masks/Case
Case GW / NW:	4.9 KG, 3.9 KG
Case Dimensions:	41.5 x 41.5 x 31.0 cm
Cases/Pallet:	25 Cases/Pallet
Masks/Pallet:	10,000 Masks/Pallet
Pallet Weight:	313 lbs
Pallet Dimensions:	52 x 40 x 59 in



CONTACT & ENQUIRIES

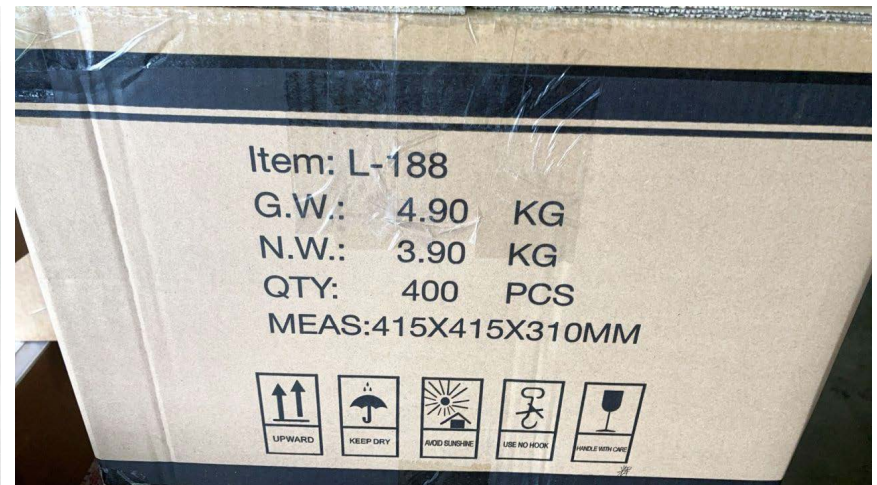
✉ Chris@preparedUS.com
☎ +1 (929) 509 - 0203

ADDRESS

905 Westminster Ave, Unit A
Alhambra, CA 91803

NIOSH N95 Masks (Harley L-188)

Product Photos



CONTACT & ENQUIRIES

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NIOSH N95 Masks (Harley L-188): NIOSH Certification



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).

Page 2- Mr. Wanghua Xu - TN-19824

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,

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

Enclosures

TN-19824 NIOSH Approval

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NIOSH N95 Masks (Harley L-188): NIOSH Test Report

NIOSH 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

Test Description	STP Number
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.

TEB-1020 Rev. 6
Page 1 of 4
PPH

NIOSH 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)		Result
	Exhalation	Actual Resistance (MM of H2O)	
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 000283.
Was all equipment verified to be in calibration throughout all testing? Yes No

Signature: *Nichole L. Petitta* Date: 11/4/2014
Engineering Technician

NIOSH 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)		Result
	Inhalation	Actual Resistance (MM of H2O)	
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

TN-19824 NIOSH Test Report

Task Number: TN-19824 Reference No.: CFR 84.181
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

NIOSH 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. Petitta* 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 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: *Nichole L. Petitta* Date: 11/13/2014
Engineering Technician

CONTACT & ENQUIRIES

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ADDRESS

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M S D S

MATERIAL SAFETY DATA SHEET

Prepared for: Guangzhou Harley Commodity Company Limited
(PLANT A01) YUANZHOU GANG VILLAGE, TAIPING TOWN, CONGHUA DISTRICT, GUANGZHOU

Prepared by: Shenzhen CTB Testing Technology Co., Ltd.
Floor 1&2, Building A, No. 26 of Xinhe Road, Xinqiao Community, Xinqiao Street, Baoan District, Shenzhen, Guangdong, China.

Issue date: March 27, 2020
Report number: CTB200327020CX

Written by: *Wenqian* Approved by: 

Shenzhen CTB Testing Technology Co., Ltd.
Floor 1&2, Building A, No. 26 of Xinhe Road, Xinqiao Community, Xinqiao Street, Baoan District, Shenzhen, Guangdong, China
Tel: 4008-258-120 Email: ctb@ctb-lab.com Web: http://www.ctb-lab.com Page 1 of 7



Report No.: CTB200327020CX

Material Safety Data Sheet

Section 1- Identification of the substance/mixture and of the company/undertaking

Product details:

- **Product name:** Folded Mask
- **Product Model:** L-188
- **Trademarks:** N/A

SUMMARY:
MSDS conforms to the requirements of regulation, evaluation, authorization and restriction of chemicals (REACH) (Regulation (EC) No. 453/2010) and classification, Labeling and packaging of substances and mixtures (Regulation (EC) No 1272/2008)

Manufacturer/Supplier:
Guangzhou Harley Commodity Company Limited
(PLANT A01) YUANZHOU GANG VILLAGE, TAIPING TOWN, CONGHUA DISTRICT, GUANGZHOU

Further information obtainable from:
Guangzhou Harley Commodity Company Limited
(PLANT A01) YUANZHOU GANG VILLAGE, TAIPING TOWN, CONGHUA DISTRICT, GUANGZHOU

Information in case of emergency:
Guangzhou Harley Commodity Company Limited
(PLANT A01) YUANZHOU GANG VILLAGE, TAIPING TOWN, CONGHUA DISTRICT, GUANGZHOU

Contact Person: Mr. Yang **Mobile:** 18620225020


Section 2- Hazards Identification

Hazard Classification: Not a hazardous substance or mixture, as defined by the Globally Harmonized System of Classification and Labelling of Chemicals (GHS).

Harm description: No

Environmental hazards: No

Shenzhen CTB Testing Technology Co., Ltd.
Floor 1&2, Building A, No. 26 of Xinhe Road, Xinqiao Community, Xinqiao Street, Baoan District, Shenzhen, Guangdong, China
Tel: 4008-258-120 Email: ctb@ctb-lab.com Web: http://www.ctb-lab.com Page 2 of 7



Report No.: CTB200327020CX

Material Safety Data Sheet

Section 3- Composition/Information on Ingredient

Chemical Name	CAS No.	In % By Weight
Non-woven fabric	-	48.7%
N95 filtering materials	-	20.3%
Sponge article	-	3.7%
Iron core nose clip	-	10.7%
Elastic	-	16.6%

Section 4- First Aid Measures

Skin exposure: No such exposure hazard is expected in normal use.

Eyes touch: No such exposure hazard is expected in normal use.

Inhalation: No such exposure hazard is expected in normal use.

Ingestion: Swallow small objects, seek medical attention immediately.

Section 5- Fire Fighting Measures

Hazardous properties: Smoke may be produced when burning or heated.

Fire extinguishing method and extinguishing agent: Use foam, dry powder and carbon dioxide.

Fire extinguishing precautions: Fires in confined Spaces should be handled by trained personnel wearing oxygen masks and acid resistant fire resistant protective clothing.

Section 6- Accidental Release Measures

Emergency treatment: Use personal protective equipment. Prevent inhalation of steam, mist, or gas. Ensure adequate ventilation. Remove all sources of fire. Evacuate personnel to a safe area.

Environmental protection measures: Prevent the product to scatter into the surrounding environment, the product has no risk of damage to the environment.

Shenzhen CTB Testing Technology Co., Ltd.
Floor 1&2, Building A, No. 26 of Xinhe Road, Xinqiao Community, Xinqiao Street, Baoan District, Shenzhen, Guangdong, China
Tel: 4008-258-120 Email: ctb@ctb-lab.com Web: http://www.ctb-lab.com Page 3 of 7

Harley L-188 Material Safety Data Sheet

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NIOSH N95 Masks (Harley L-188): Certifications



环境管理体系认证证书

注册号: 0350319E20131R1S

兹证明
广州市哈雷日用品有限公司
广州市从化区太平镇元洲岗村(厂房A01), 510900
统一社会信用代码: 91440114076502373X

管理体系符合
GB/T 24001-2016 / ISO 14001:2015 标准

该管理体系适用于
口罩的设计和制造***
[涉及场所: 广州市从化区太平镇元洲岗村(厂房A01)]

颁证日期: 2019年6月6日
有效期最长可至: 2022年4月26日

签发人: *王启林*

兴原认证中心有限公司
证书专用章

中国认可
国际互认
管理体系
MANAGEMENT SYSTEM
CNAS C035-M

注: 在证书有效期内, 获证组织应按规定接受年度监督审核, 保持认证资格。通过扫描二维码可获知证书的有效状态。该证书信息可在国家认证认可监督管理委员会官方网站(www.cnca.gov.cn)和兴原认证中心有限公司官方网站(www.xyc.com.cn)上查询。



认证证书

标准: **ISO 9001:2015**
证书登记号码: **01 100 1430200**

证书持有者: **广州市哈雷日用品有限公司**
统一社会信用代码: 91440114076502373X
注册地址: 中国广东省广州市花都区花城街三东村一社十七队自编274号首至四层厂房
邮编: 510800
经营地址: 同上地址

认证范围: **口罩的设计和制造**

证明完成了审核并满足了 ISO 9001:2015 标准的要求。

有效期: 证书有效期从 2017-09-01 至 2020-08-31。
此证书须经过符合要求的监督审核保持有效。
初次发证始于 2014 年

本证书信息可在国家认证认可监督管理委员会官方网站上查询
<http://www.cnca.gov.cn>

2017-08-16

K. Jighe
TÜV Rheinland Cert GmbH
Am Grauen Stein 51105 Köln

www.tuv.com

IAF, DAKKS, TÜVRheinland



Certificate

Standard: **ISO 9001:2015**
Certificate Registr. No.: **01 100 1430200**

Certificate Holder: **Guangzhou Harley Commodity Company Limited**
Unified Social Credit Code: 91440114076502373X
Registration Address: Floor 1 to 4, # 274, Team 17, Group 1, Sandong Village, Huacheng Street, Huadu District, Guangzhou City, Guangdong Province 510800, P. R. China
Operation Address: same as above

Scope: **Design and Manufacturing of Respirator**

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid from 2017-09-01 until 2020-08-31. It remains valid subject to satisfactory surveillance audits. First certification 2014

This certificate information can be searched on CNCA official website <http://www.cnca.gov.cn>

2017-08-16

K. Jighe
TÜV Rheinland Cert GmbH
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IAF, DAKKS, TÜVRheinland

ISO 9001

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NIOSH N95 Masks (Harley L-188): Certifications



ISO 14001

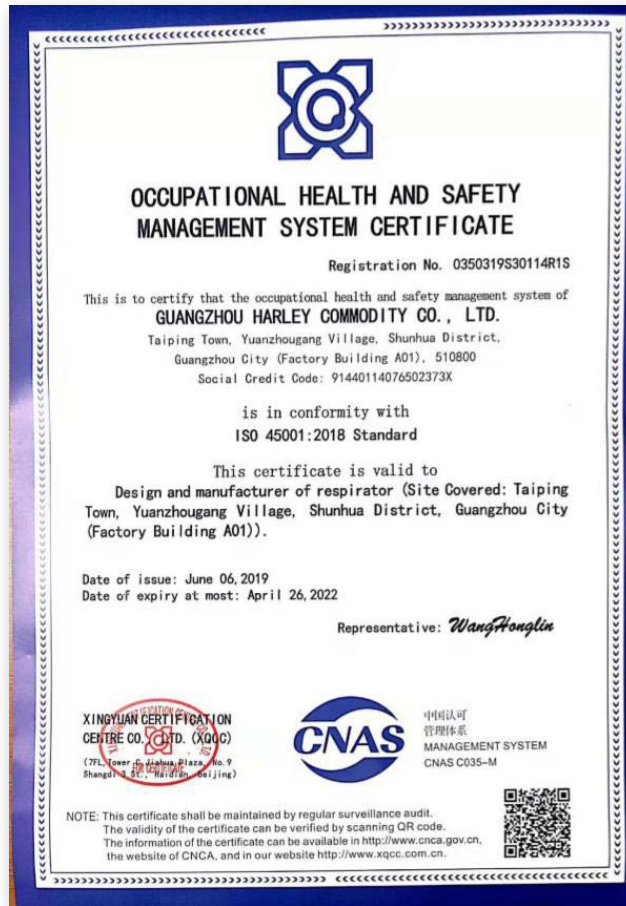
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NIOSH N95 Masks (Harley L-188): Certifications



ISO 45001

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Business Certificate

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Production License



Certificate of Safety Mark for Special Labor Protection Articles

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This proposal shall provide the relevant information in order to make decisions related to the procurement of Personal Protective Equipment (PPE).

Prior to the outbreak of COVID-19, Prepared was one of the largest clothing blank manufacturers in the market with substantial industrial manufacturing capabilities in China.

Prepared is not a broker or intermediary, we directly manufacture PPE and we have an active FDA initial import account.



Our warehouse in Alhambra, CA

When the retail clothing orders came to a halt in February, we shifted all of our manufacturing, logistics and financial resources to manufacturing and distributing PPE and masks.

Prepared currently has multiple FDA registered factories under production agreements and we are working to secure additional factory capacity in Indonesia, Vietnam, Thailand, Malaysia and China. We have quality control and logistics personnel working on the ground in China, in addition to logistics personnel in South Africa, Vietnam, Australia and at our headquarters in Alhambra, California. Our PPE products meet applicable standards set forth under FDA, SGS, ISO, and CE guidelines and we use Flexport as our freight forwarder.

The Principals of our firm have been in the soft goods manufacturing and exporting business for 25 years.

Prepared's CAGE # is 8KE87

Prepared's DUNS # is 115031892

Uniti Prepared LLC DBA Prepared

Customer and trade references available upon request

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145 Factories

145 Factories Linked to Prepared's FDA Import License.

20 Years

20 Years in the soft goods manufacturing and export/import business.

40 Countries

Prepared and it's parent company have delivered product to 40 Countries.

65 Million

65 Million Pieces of PPE Manufactured, Sold and Delivered in 2020.

24 Million

24 Million 3-Ply Masks in Stock in LA.

4.8 Million

4.8 Million KN95 Masks in Stock in LA.

175 Million

175 Million Weekly Nitrile Glove Production Capability.

60 Million

60 Million Isolation Gown Monthly Production Capability.

30 Million

30 Million 510k 3-Ply ASTM Level 1 and Level 2 Mask Weekly Production Capability.

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For More Information Please Contact:

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 **prepared.**

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