鸿锐集团
Hongray®

VINYL/NITRILE BLENDED GLOVE

Dedicated to the glove industry for more than 20 years

Vinyl/Nitrile Blended glove containing no natural latex protein, causing no allergies, and offering affordable and effective safety and hygiene in various work environments for both medical and industrial applications.

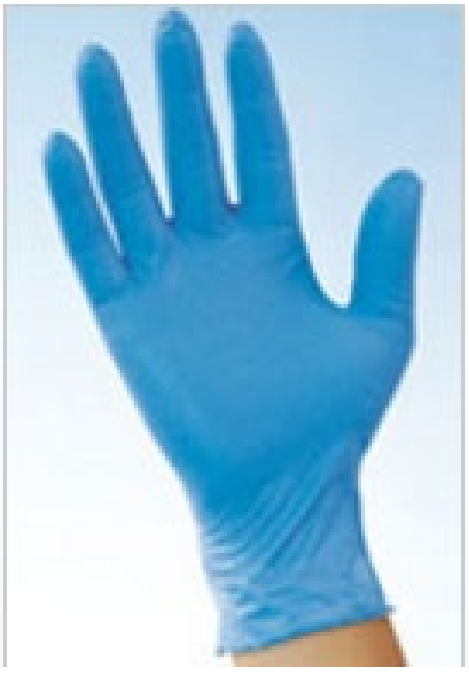
PRODUCT DESCRIPTION AND PICTURES

Product Name: Disposable Vinyl/Nitrile Blended Examination Gloves
Single use, non-sterile, no measuring, Latex free
Sizes: XS、S、M、L、XL、XXL
Color: Blue, Green
Structure: 5 fingers, beaded cuff for easy donning, ambidextrous
Surface: Smooth

The Vinyl/Nitrile Blended glove is a new type of synthetic glove that was developed based on the vinyl glove production technology. Its material is compounded with PVC paste and Nitrile latex, so the finished production has the advantage of both PVC and Nitrile gloves.
Comparing with the vinyl gloves, the Vinyl/Nitrile Blended glove can better satisfy the user's demands, it feels softer, more flexible and more comfortable when wearing.

Intended purpose: The examination glove is disposable non-sterile device intended for medical purpose that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Pictures:



资质证书目录

Qualification Certificate List

1、医疗器械质量管理体系EN ISO13485证书、ISO9001质量管理体系证书
Medical Device Quality Management System EN ISO 13485 Certificate, ISO 9001 Quality Management System Certificate

2、FDA注册信息
FDA Registration Information

3、产品510K
Product 510K

4、生物兼容测试报告
Biocompatibility Test Report

5、欧盟CE 证书（DOC、技术文件评审报告）
EU CE Certificate (DOC, Technical Documentation Review Report

6、产品规格单 (EU/US)
Product Specification (EU/US)

7、ASTM D 5250测试报告
ASTM D 5250 test report

8、EN455测试报告
EN455 test report

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Shijiazhuang Hongray Group Co., Ltd.
South Tongda Rd., East Dist.
Jinzhou
052260 Hebei
P.R. China

has established and applies a quality management system for medical devices for the following scope:

Manufacture and Distribution of Patient Examination Gloves

(see attachment for sites included)

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2020-04-16
Certificate Registration No.:	SX 60148697 0001
An audit was performed. Report No.:	16801058 009
This Certificate is valid until:	2020-10-25

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date 2020-04-16

Jing Zhang

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

TÜVRheinland®

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60148697 0001
Report No.: 16801058 009

Organization:
Shijiazhuang Hongray
Group Co., Ltd.
South Tongda Rd., East Dist.
Jinzhou
052260 Hebei
P.R. China

Scope:

Sites included:

Shijiazhuang Hongray Group Co.,Ltd.
South Tongda Rd., East Dist., Jinzhou, 052260 Hebei, China

Distribution of Patient Examination Gloves

Syntex Healthcare Products Co., Ltd.
No.1 Fanjiazhuang Industrial Zone,
Xinji City, 052360, Hebei, China

Manufacture of Patient Examination Gloves

Grand Work Plastic Products Co., Ltd.
Donggao Industrial Zone, Zanhuang, 050000, Hebei, China

Manufacture of Patient Examination Gloves

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH

Date: 2020-04-16

Jing Zhang

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60148697 0001
Report No.: 16801058 009

Organization:
Shijiazhuang Hongray
Group Co., Ltd.
South Tongda Rd., East Dist.
Jinzhou
052260 Hebei
P.R. China

Scope:

Sites included:

Shijiazhuang Jiahe Plastic Glove Co., Ltd
Western Jiafeng Road, Mining Area, Shijiazhuang,
050100, Hebei, China

Manufacture of Patient Examination Gloves

Ever Light Plastic Products Co., Ltd.
Donggao Industrial Zone, Zanhuang, Shijiazhuang,
050000, Hebei, China

Manufacture of Patient Examination Gloves

Better Care Plastic Technology Co., Ltd.
Fuqian Xi Road, West district of Shenze Industrial Base,
Shenze County, 050000, Hebei,China

Manufacture of Patient Examination Gloves

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date: 2020-04-16

Jing Zhang

TÜVRheinland®

Doc. 3/3, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: SX 60148697 0001
Report No.: 16801058 009

Organization:
Shijiazhuang Hongray
Group Co., Ltd.
South Tongda Rd., East Dist.
Jinzhou
052260 Hebei
P.R. China

Scope:

Sites included:

Hong Di Plastic Products Co., Ltd.
Donggao Industrial Zone, Zanhuang, 050000, Hebei, China

Manufacture of Patient Examination Gloves

Shanxi Hongjin Plastic Technology Co., LTD
Coal Bed Gas Industrial Zone, Qu'e Town, Daning County,
Linfen City, 042300,Shanxi,China

Manufacture of Patient Examination Gloves

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Date: 2020-04-16

Jing Zhang

TÜVRheinland®
LGA
Precisely Right.

Business Stream Products
Certification Department

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

Shijiazhuang Hongray
Group Co., Ltd.
South Tongda Rd., East Dist.
Jinzhou
052260 HEBEI
P.R. CHINA

Contact

Tel. +49 911 655-5225
Mail service@de.tuv.com

Date April 16, 2020

Application for : QMS
Certificate No. : SX 60148697 Sheet 0001
Device : Only for QM-System audit
Test requirement : EN ISO 13485:2016

Dear Madame or Sir,

Enclosed please find the
new certificate No. SX 60148697 0001
replacing the previous certificate.

Kind regards

Certification body

Jing Zhang

Test sample: no, documentation available

TÜV Rheinland
LGA Products GmbH

Tillystraße 2
90431 Nürnberg

Tel. +49 911 655-5225
Fax +49 911 655-5226
Mail service@de.tuv.com
Web www.tuv.com/safety

Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1732303**

Certificate Holder: **Shijiazhuang Hongray Group Co., Ltd.**
Unified Social Credit Code: 91130100728799919R
Registration Address: South Tongda Rd., East Dist.,
Jinzhou City, 052260 Hebei, P. R. China
Operation Address: same as above

including the locations according to annex

Scope: Manufacture and Distribution of Patient Examination Gloves

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

Validity: The certificate is valid from 2020-04-10 until 2020-10-19.
It remains valid subject to satisfactory surveillance audits.
First certification 2017

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

2020-04-14

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

www.tuv.com

DAkkS Deutsche Akkreditierungsstelle D-ZM-16031-01-00

TÜVRheinland®
Precisely Right.

Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1732303**

No.	Location	Scope
/01	Shijiazhuang Hongray Group Co., Ltd. Unified Social Credit Code: 91130100728799919R Registration Address: South Tongda Rd., East Dist., Jinzhou City, 052260 Hebei, P. R. China Operation Address: same as above	Distribution of Patient Examination Gloves
/02	Syntex Healthcare Products Co., Ltd. Unified Social Credit Code: 91130181734364356G Registration Address: Southern No. 307 National Highway Rd., Western Fanjiazhuang Village, Xinji City, 052360 Hebei, P. R. China Operation Address: same as above	Manufacture and Distribution of Patient Examination Gloves
/03	Grand Work Plastic Products Co., Ltd. Unified Social Credit Code: 91130100752433415G Registration Address: Donggao Industrial Zone, Zanhuang, 050000 Hebei, P. R. China Operation Address: same as above	Manufacture and Distribution of Patient Examination Gloves

Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1732303**

/06	Shijiazhuang Jiahe Plastic Glove Co., Ltd. Unified Social Credit Code: 91130107563240147C Registration Address: Northern Jiandi Village, Western Jiafeng Road, Mining Area, Shijiazhuang City, 050100 Hebei, P. R. China Operation Address: same as above	Manufacture and Distribution of Patient Examination Gloves
/07	JinZhou XinRui Plastic Products Co., Ltd. Unified Social Credit Code: 911301835795985148 Registration Address: South Tongda Rd., East Dist., Jinzhou City, 052260 Hebei, P. R. China Operation Address: same as above	Manufacture and Distribution of Patient Examination Gloves
/08	Purtech Cleanroom Products Co., Ltd. Unified Social Credit Code: 91130181777701957N Registration Address: Fanjiazhuang Industrial Zone, Xinji City, 052360 Hebei, P. R. China Operation Address: same as above	Manufacture and Distribution of Patient Examination Gloves
/09	Ever Light Plastic Products Co., Ltd. Unified Social Credit Code: 91130100784064765D Registration Address: Donggao Industrial Zone, Zanhuang, 050000 Hebei, P. R. China Operation Address: same as above	Manufacture and Distribution of Patient Examination Gloves

Annex to certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1732303**

/10	Better Care Plastic Technology Co., Ltd. Unified Social Credit Code: 911301286920575093 Registration Address: Shenze Industrial Base (Fuqian Xi Road), Shenze County, 050000 Hebei, P. R. China Operation Address: same as above	Manufacture and Distribution of Patient Examination Gloves
/11	Shijiazhuang Hongzan Plastic Technology Co., Ltd. Unified Social Credit Code: 91130129567387090Y Registration Address: Donggao Industrial Zone, Zanhuang, 050000 Hebei, P. R. China Operation Address: same as above	Manufacture and Distribution of Patient Examination Gloves
/12	Shanxi Hongjin Plastic Technology Co., Ltd. Unified Social Credit Code: 91141030MA0HDY6R5D Registration Address: Coal Bed Gas Industrial Zone, Qu'e Town, Daning County, Linfen City, 042300 Shanxi, P. R. China Operation Address: same as above	Manufacture and Distribution of Patient Examination Gloves

2020-04-14

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

FDA ANNUAL REGISTRATION INFORMATION

Name: Grand Work Plastic Products Co., Ltd.

Address: Donggao Industrial Zone, Zanhuang, Hebei, 050000, China

The factory has completed the Establishment Registration and Device Listing with the US Food & Drug Administration for 2020 and the registration will be valid through Dec 31, 2020.

Registration Number: 3004168786

Current Status: Active

Products: Vinyl Patient Examination Gloves

Product Code: 80 LYZ

Regulatory Class: Class I

Holds 510(k) premarket notification

All information is available at the following address:

https://www.fda.gov/

Date of Verification: Oct 10, 2019

Date of Expiration: Dec. 31, 2020

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

December 5,2014

Grand Work Plastic Products Company Limited
C/O Ms. Kathy Liu
Hongray USA Medical Products Incorporated
3973 Schaefer Avenue
Chino, CA 91710

Re: K142409
Trade/Device Name: Vinyl Co-Polymer Powder-free Examination Gloves, Blue Color
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LYZ
Dated: October 31, 2014
Received: November 5, 2014

Dear Ms. Liu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Consumer Product Testing Co.

EST. 1973

FINAL REPORT

CLIENT: Grand Work Plastic Products Co., Ltd.
Donggao Industrial Zone
Zanhuang, Hebei, China 050000

AUTHORIZING AGENT: Kathy Liu

TEST: Primary Dermal Irritation in Rabbits (ISO)

TEST ARTICLE: Vinyl Co-Polymer Powder Free Examination Gloves, Blue Color; Size: M; Lot#: 1405F4A3-PF

EXPERIMENT REFERENCE NUMBER: T14-2583-1

4/13/14

Steven Nitka
Vice President
Laboratory Director

70 New Dutch Lane • Fairfield, New Jersey 07004-2514 • (973) 808-7111 • Fax (973) 808-7234

Consumer Product Testing Co.

EST. 1973

QUALITY ASSURANCE UNIT STATEMENT

Study No.: T14-2583-1

The objective of the Quality Assurance Unit (QAU) is to monitor the conduct and accurate reporting of non-clinical laboratory studies. This study has been performed under Good Laboratory Practice Regulations (21 CFR Part 58) and in accordance with CPTC Standard Operating Procedures (SOP's) and applicable standard protocols. The QAU maintains copies of study protocols and SOP's and has inspected this study on the date(s) indicated below. The findings of these inspections have been reported to CPTC Management and the Study Director.

Date(s) of inspection(s): 6/6/14, 7/8/14, 8/12/14

Date(s) finding(s) reported to CPTC Management and the Study Director: 7/15/14

Quality Unit Certified By Christine Henduck Date: 8/13/14

70 New Dutch Lane • Fairfield, New Jersey 07004-2514 • (973) 808-7111 • Fax (973) 808-7234
Clinical • Toxicology • Analytical Chemistry • Microbiology

Consumer Product Testing Co.
EST. 1975

Final Report Summary

CLIENT: Grand Work Plastic Products Co., Ltd.
STUDY NO.: T14-2583-1
REFERENCE: K. Liu
TEST ARTICLE: Vinyl Co-Polymer Powder Free Examination Gloves, Blue Color; Size: M; Lot#: 1405F4A3-PF
TEST ARTICLE RECEIPT DATE: May 23, 2014
EXPERIMENTAL INTERVAL: July 8, 2014 to July 22, 2014

Primary Dermal Irritation in Rabbits (ISO)

Method: Three (3) New Zealand White rabbits each received a single dermal application of 25 mm x 25 mm of the test article on two (2) test sites, both non-abraded. Each animal also had two (2) control sites. The negative control site consisted only of gauze moistened with physiological saline. The positive control site consisted of a dosage of sodium dodecyl sulfate at two and one-half (2.5) percent. The test sites were semi-occluded for four (4) hours and were observed individually for erythema, edema, and other effects one (1), 24, 48 and 72 hours after unwrapping. If irritation persisted, the sites were observed again on days seven (7) and fourteen (14). The primary irritation index was determined as detailed on page six (6) of this report. The test article, in one (1) inch squares, was moistened with distilled water upon dosing and applied so that the inside of the glove test article contacted the skin of three (3) test sites and the outside of the glove test article contacted the skin of the remaining three (3) test sites.

Results: Primary Irritation Indices:* 0.00 (Test Article)
2.77 (Positive Control)
0.00 (Negative Control)

Conclusion: This test article elicited a negligible dermal response in rabbits under the conditions of this test.

*Refer to Table 2 for specific evaluation.

Primary Dermal Irritation in Rabbits (ISO)

Objective:

This test was designed to assess the potential of the test article to produce irritation on rabbit skin according to the International Organization for Standardization standards.[1]

Test Article:

The test article arrived at this facility as blue gloves. The intended use and/or application of the test article is thought, by this facility, to be that of standard examination gloves.

Test System:

Three (3), female, New Zealand White rabbits, about three (3) months of age, weighing at least two (2) kilograms, were used for the test article. The animals were obtained through a suitably licensed dealer. They were of a single strain from a single recognized source. They were checked carefully upon receipt for diarrhea and dehydration, respiratory difficulties, postural deficiencies, skin lesions, and general condition.

The animals were acclimated for at least 13 days prior to test initiation. They were individually housed in stainless steel cages, in a temperature controlled room, with a 12 hour light/dark cycle and identified through individual markings on the outer ear of each animal, as well as a cage label. The room temperature was controlled to comply with Animal Welfare Regulations with an approximate range of 65° to 72° F. The humidity was also monitored. Diet consisted of Lab Diet Certified High Fiber Diet #5325 at 100 grams per day per animal. Water was provided *ad libitum*. There are no known contaminants that are reasonably expected to be present in animal feed or water at levels sufficient to interfere with this study.

Method:

The study director did not anticipate a well-defined irritation response from the test article, therefore one (1) animal was not dosed initially. Three (3) animals were dosed in the following manner:

[1]The International Organization for Standardization (ISO 10993-10 Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Sensitization, Reference Number ISO 10993-10:2010)

Method (continued):

Twenty-four (24) hours prior to test initiation, the animals were reexamined. Any animals in poor condition and particularly animals with skin eruptions or dermal lesions, were not used. The animals were prepared for testing by close-clipping the hair of the mid-dorsal area of the trunk, between the scapulae and the pelvis, using an Oster® small animal clipper equipped with a #40 (surgical) head. Care was taken to avoid abrasion of the skin during clipping. The following day, initial weights were recorded for each animal.

For the test article, samples 25 mm by 25 mm were applied directly to the skin on each side of each rabbit (see Figure 1). The negative control (physiological saline at 100%) and the positive control (sodium dodecyl sulfate, at two and one-half (2.5) percent in physiological saline) were applied, each on one (1) site of each animal, in an identical manner (Figure 1). The test article was moistened sufficiently with distilled water, to ensure good contact with the skin. The sites were then covered by 25 millimeter by 25 millimeter, gauze sponges and a Kendall Webril® pad. Three (3) inch 3M Micropore™ tape was used to wrap the sites semi-occlusively. Elizabethan collars were used to preclude the animals from interfering with the articles and wrapping.

The wrapping was removed four (4) hours following application and the position of the sites were marked on the skin. Residual article was removed by appropriate means. The sites were then carefully dried.

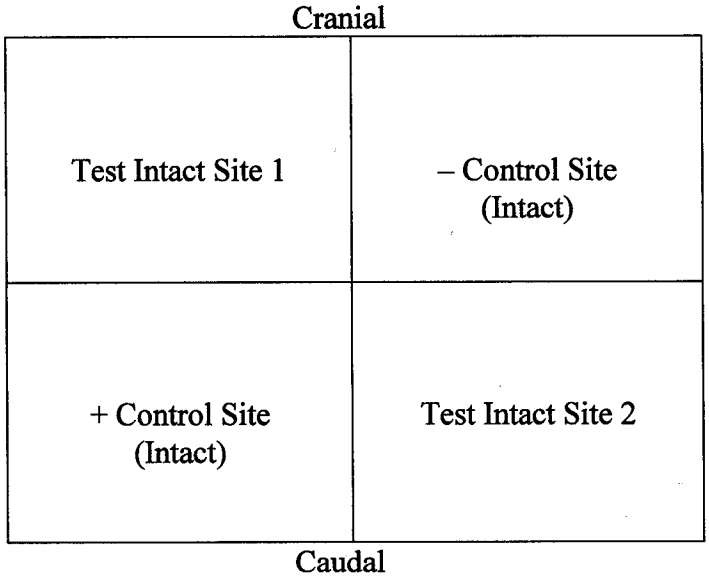


Figure 1 – Location of Skin Application Sites

Method (continued):

Each test site was scored individually 60 minutes after unwrapping, for erythema and edema using the Draize skin scoring scale (refer to the appended table). Test sites were re-examined 24, 48 and 72 hours after unwrapping for the same parameters. The presence of effects not listed in the scoring scale, such as fissuring, ulceration, vesiculation, etc., were noted separately if observed. Observation continued until all irritation subsided or irritation present was confirmed to be irreversible (14 days maximum).

The Primary Irritation Index was determined for the test article as follows:

Only the 24, 48 and 72 hour scores were used in these calculations. For each animal, the Primary Irritation Scores for the test article for both erythema and edema at each time specified were added together. This sum was then divided by the total number of observations (six (6): two (2) sites at each time specified). As a negative control was used, the Primary Irritation Score for the negative controls was also calculated. That score was subtracted from the score for the test article to obtain the Primary Irritation Score for each animal.

The scores for each animal were then added together. This sum was divided by the total number of animals. The resultant figure was the Primary Irritation Index. Observations made prior to 24 hours or after 72 hours, to monitor recovery, were not used in this determination.

Record Retention:

All records and documents pertaining to the conduct of this study shall be retained in the CPTC archives for a minimum of ten (10) years. At any time prior to the completion of the tenth archival year, a Sponsor may submit a written request to the CPTC QA Department to obtain custody of study records once the CPTC archive period has been completed. This transfer shall be performed at the Sponsor's expense. In the absence of a written request, study-related records shall be destroyed at the end of the CPTC archive period in a manner that renders them useless.

Professional personnel involved:

Steven Nitka, B.S.	-	Vice President Laboratory Director (Study Director)
Lillian Vazquez, B.S.	-	Laboratory Supervisor
Christine Hendricks	-	Quality Assurance Group Leader

Primary Dermal Irritation in Rabbits (ISO)

The scoring and irritant classification scales used are presented in Tables 1 and 2 respectively. The individual test results are presented in Table 3.

Characterization of the test article was not performed by this facility. All materials and data pertinent to this study will be stored in the archive facilities utilized by Consumer Product Testing Company.

Summaries of all results are found preceding the text.

Table 1

Scoring Criteria for Skin Reactions

ERYTHEMA FORMATION	
No erythema	0
Very slight erythema (barely perceptible)	1
Well-defined erythema	2
Moderate to severe erythema	3
Severe erythema (beet redness) to slight eschar formation (injuries in depth)	4

Total possible erythema score = 4

EDEMA FORMATION	
No edema	0
Very slight edema (barely perceptible)	1
Slight edema (edges of area well-defined by definite raising)	2
Moderate edema (area raised approximately 1 mm)	3
Severe edema (area raised more than 1 mm and extending beyond area of exposure)	4

Total possible edema score = 4

Total possible primary irritation score = 8

Table 2

Dermal Irritation Response Categories in the Rabbit

Response Category	Mean Score
Negligible	0.0 to 0.4
Slight	0.5 to 1.9
Moderate	2.0 to 4.9
Severe	5.0 to 8.0

Table 3

Primary Skin Irritation – Rabbit

Summary of Scores for Skin Irritation

Vinyl Co-Polymer Powder Free Examination Gloves, Blue Color;
Size: M; Lot#: 1405F4A3-PF

Dose = 25 mm x 25 mm (moist with distilled water) Date: 7/8/14

Animal # - Sex	Initial Wgt (kg)	T/C*	Scores @ 1 Hr.	24 Hrs.	48 Hrs.	72 Hrs.	Day 7	Day 14
1 (111F)	2.31	T(I)	0/0	0/0	0/0	0/0	0/0	---
		T(I)	0/0	0/0	0/0	0/0	0/0	---
		C^1	0/0	0/0	0/0	0/0	0/0	---
		C^2	2/1	2/1	2/0	2/0	0/0S	---
2 (113F)	2.35	T(I)	0/0	0/0	0/0	0/0	0/0	0/0
		T(O)	0/0	0/0	0/0	0/0	0/0	0/0
		C^1	0/0	0/0	0/0	0/0	0/0	0/0
		C^2	2/2	2/1	2/1	2/1	1/0S	0/0
3 (123F)	2.11	T(O)	0/0	0/0	0/0	0/0	0/0	0/0
		T(O)	0/0	0/0	0/0	0/0	0/0	0/0
		C^1	0/0	0/0	0/0	0/0	0/0	0/0
		C^2	2/1	2/1	2/1	2/1S	1/0S	0/0S

Raw Data Page: 161791

Scores = Erythema/Edema
*T = Test article site; (I) = inside of glove contacted skin, (O) = outside of glove contacted skin
* C^1 = Negative control site (physiological saline at 100%)
* C^2 = Positive control site (sodium dodecyl sulfate, at two and one-half (2.5) percent in physiological saline)
All sites were intact
S = Scaling

Consumer Product Testing Co.

EST. 1975

FINAL REPORT

CLIENT: Grand Work Plastic Products Co., Ltd.
Donggao Industrial Zone
Zanhuang, Hebei, China 050000

AUTHORIZING AGENT: Kathy Liu

TEST: Guinea Pig Closed Patch Sensitization Test (ISO)

TEST ARTICLE: Vinyl Co-Polymer Powder Free Examination Gloves, Blue Color; Size: M; Lot#: 1405F4A3-PF

EXPERIMENT REFERENCE NUMBER: T14-2583-2

8/13/14

Steven Nitka
Vice President
Laboratory Director

Consumer Product Testing Co.

EST. 1975

QUALITY ASSURANCE UNIT STATEMENT

Study No.: T14-2583-2

The objective of the Quality Assurance Unit (QAU) is to monitor the conduct and accurate reporting of non-clinical laboratory studies. This study has been performed under Good Laboratory Practice Regulations (21 CFR Part 58) and in accordance with CPTC Standard Operating Procedures (SOP's) and applicable standard protocols. The QAU maintains copies of study protocols and SOP's and has inspected this study on the date(s) indicated below. The findings of these inspections have been reported to CPTC Management and the Study Director.

Date(s) of inspection(s): 6/6/14, 6/25/14, 8/12/14

Date(s) finding(s) reported to CPTC Management and the Study Director: 6/30/14

Quality Unit Certified By: Christine Hendricks Date: 8/13/14

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Clinical • Toxicology • Analytical Chemistry • Microbiology

Consumer Product Testing Co.
EST. 1975

Final Report Summary

CLIENT: Grand Work Plastic Products Co., Ltd.
STUDY NO.: T14-2583-2
REFERENCE: K. Liu
TEST ARTICLE: Vinyl Co-Polymer Powder Free Examination Gloves, Blue Color; Size: M; Lot#: 1405F4A3-PF
TEST ARTICLE RECEIPT DATE: May 23, 2014
EXPERIMENTAL INTERVAL: June 25, 2014 to July 30, 2014

Guinea Pig Closed Patch Sensitization Test (ISO)

Method: Ten (5M:5F) Hartley-strain guinea pigs, 320 - 358 grams, were utilized as the test group. An additional five (2M:3F) Hartley-strain guinea pigs, 302 - 366 grams, were utilized as the control group. For induction, each animal in the test group received nine (9), six (6) hour topical applications of the test article, made, up to three (3) times per week, during consecutive weeks. The control group animals were similarly dosed, but with the wrapping alone, moistened with physiological saline. Approximately two (2) weeks after the last topical induction application, the challenge application was made. These six (6) hour challenge applications of the test article were made to virgin sites on the flank of each animal in the test and control groups. Observations of erythema, edema and other effects were recorded 24 and 48 hours after the challenge applications. The test article was used as received and moistened with saline upon dosing and applied so that the inside of the glove test article contacted the skin of approximately one-half of the animals in each group and the outside of the glove test article contacted the skin of approximately one-half of the animals in each group.

Results:

	Challenge	
Index:	Incidence	Severity
Group	Test/Control	Test/Control
Scoring Interval:		
24 Hours:	0.00/0.00	0.00/0.00
48 Hours:	0.00/0.00	0.00/0.00

Conclusion: This test article did not elicit a sensitization reaction in guinea pigs under the conditions of this test.

Incidence Index = Number of animals exhibiting a 1 or greater erythema score divided by the number of animals observed at challenge.
Severity Index = The sum of the erythema scores divided by the number of animals observed at challenge.

Guinea Pig Closed Patch Sensitization Test (ISO)

Objective:

This test was designed to assess the potential of a medical glove test article to produce skin sensitization in guinea pigs according to the International Organization for Standardization standards.[1] The method is essentially that of Buehler.[2,3]

Test Articles:

The test article arrived at this facility as blue gloves. The intended use and/or application of the test article is thought, by this facility, to be that of standard examination gloves.

Test System:

Fifteen, albino, Hartley-strain guinea pigs, male and female, approximately four to six (4-6) weeks of age and between 300 and 500 grams at the start of the test, were used. The animals were obtained through a suitably licensed dealer. The number of animals and the species used are those specified in the quoted regulation. Guinea pigs have a history of use in topical sensitization testing. They were of a single strain from a single recognized source. They were carefully checked upon receipt and prior to test initiation for respiratory or intestinal disease, skin eruptions, mucosal membrane irritation, postural difficulties and general condition. Females were nulliparous and not pregnant. Guinea pig sensitization reactions are well documented in the scientific literature and guinea pigs have been used extensively in studies of this type.

The animals were acclimated for seven (7) days prior to test initiation. They were housed in stainless steel cages in a temperature controlled room with a 12 hour light/dark cycle and were identified through individual markings as well as a cage label. The room temperature was controlled to comply with USDHHS guide with an approximate range of 64° to 79° F. The humidity was also monitored. Diet consisted of Lab Diet Certified Guinea Pig Diet #5026, as well as water, *ad libitum*. There are no known contaminants that are reasonably expected to be present in animal feed or water at levels sufficient to interfere with this study.

[1]The International Organization for Standardization (ISO 10993-10 Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Sensitization, Reference Number ISO 10993-10:2010)
[2]E.V. Buehler, "Delayed Contact Hypersensitivity in the Guinea Pigs," *Arch Derma*, 91, (1965), pp. 171 - 175.
[3]H.L. Ritz & E.V. Buehler, "Planning, Conduct and Interpretation of Guinea Pig Sensitization Patch Tests", in *Current Concepts in Cutaneous Toxicity*, V.A. Drill and P. Lazar, (Eds.), Academic Press 1980 pp. 25 - 41.

Method:

All shaving procedures were carried out the day prior to treatment using an Oster® small animal clipper equipped with a #40 (surgical) head. During all shaving procedures, care was taken to avoid abrading the skin.

SUMMARY

Because the test article was dosed as received, no screening procedures were carried out. The study had the following two (2) phases:

1. The induction phase, which consisted of nine (9), six (6) hour topical applications of the test article, made up to three (3) times per week during consecutive weeks, using the test group animals. Another group was also treated topically in the same manner, without the test article and served as a control for local irritation.
2. The challenge phase, which involved a single topical primary application of the test article, made to a naïve (previously untreated) site on the induced, test group animals and on the control group animals.

For each of the above mentioned phases of the study, the same test system, the same amount and method of test article application and the same method of test site observation were used.

INDUCTION

For induction, 15 guinea pigs were weighed. Ten (5M:5F) animals were used for the test group and five (2M:3F) animals were used for the control group. The animals were designated so that the inside of the glove test article would contact the skin of approximately one-half of the animals in each group and the outside of the glove test article would contact the skin of approximately one-half of the animals in each group. The sites and animals were then examined grossly. Animals showing dermal lesions, irritation, improper weight or ill health, were replaced. All animals were shaved at site 1 (Fig. 1). One (1) square inch of the test article (25 mm x 25 mm), moistened with saline, was applied to the shaven site one (1), on all animals in the test group. The article was applied to each site via a 25 mm Hilltop Chamber. The animals were occlusively wrapped after dosing, with a piece of three (3) inch Tensoplast® elastic tape (BSN medical S.A.S., Vibraye, France), that had been lined on the adhesive side with a three (3) inch wide strip of Hygenic® Dental Dam. The control group animals were similarly dosed but without the test article. They were exposed only to the Hilltop Chamber moistened with physiological saline under the occlusive wrap. The wraps were removed after six (6) hours of exposure. Approximately seven (7) and twenty-four hours after application, each test site was examined and scored.

CHALLENGE

Thirteen days after the ninth induction application, all animals in both groups were shaved on site 3. The next day, each test and control animal received a single occluded challenge application of the test article, prepared as in the induction phase, at site 3. The occlusive wrap, as previously stated, was removed after six (6) hours of exposure.

At 24 hours (± 2 hrs) after the challenge dosage, all challenge sites, as well as the surrounding areas, were shaved. After a minimum of two (2) hours after hair removal, each test site was examined and scored according to Table 1. The sites were again graded 48 hours (± 2 hrs) after removal of the challenge patch. For reporting purposes, the first and second gradings are designated as 24 and 48 hour readings respectively.

All animals appeared healthy and gained weight during the course of the study.

This facility will also be reporting the results of a positive control test conducted within six (6) months of this test. Initial and terminal body weights were recorded for all animals. All animals appeared healthy and gained weight during the course of the study.

Evaluation of Results:

Grades of one (1) or greater in the test group generally indicate sensitization, provided grades of less than one (1) are seen on control animals. If grades of one (1) or greater were noted on control animals, then the reactions of test animals which exceed the most severe control reaction would be presumed to be due to sensitization.

Two (2) indices were calculated from the challenge erythema scores, one (1) to evaluate the incidence of erythema (reaction) and the other to evaluate the severity of erythema. The indices for incidence and severity were calculated for both groups from all scoring intervals. The incidence index was calculated by counting the number of animals showing an erythema response (1 or greater), for a specified time period and by dividing that number by the number of test sites (animals) examined at that time period (# responses/# per group). The severity index was calculated by adding the erythema scores for a specified time period and dividing that sum by the number of scores added (sum of irritation scores/# scores added). The two (2) indices were used to assist in evaluating the sensitization potential of the test article.

Record Retention:

All records and documents pertaining to the conduct of this study shall be retained in the CPTC archives for a minimum of ten (10) years. At any time prior to the completion of the tenth archival year, a Sponsor may submit a written request to the CPTC QA Department to obtain custody of study records once the CPTC archive period has been completed. This transfer shall be performed at the Sponsor's expense. In the absence of a written request, study-related records shall be destroyed at the end of the CPTC archive period in a manner that renders them useless.

Guinea Pig Closed Patch Sensitization Test (ISO)

The scoring scale used is presented in Table 1. The site configuration is presented in Figure 1. Individual test group results are presented in Table 2. Individual control group results are presented in Table 3.

Characterization of the test article was not performed by this facility. All materials and data pertinent to this study will be stored in the archive facilities utilized by Consumer Product Testing Company.

Professional personnel involved:

Steven Nitka, B.S.	-	Vice President Laboratory Director (Study Director)
Lillian Vazquez, B.S.	-	Laboratory Supervisor
Christine Hendricks	-	Quality Assurance Group Leader

Summaries of all results are found preceding the text.

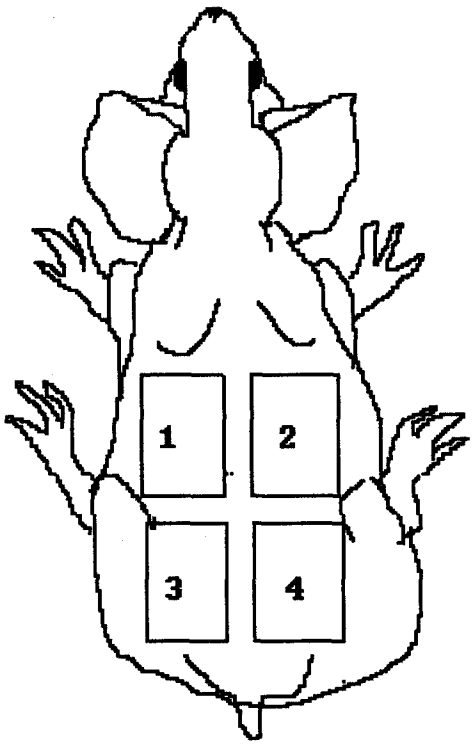
TABLE 1

Scoring Criteria for Skin Reactions
Magnusson and Kligman Scale

Patch Test Reaction	Grading Scale
No visible change	0
Discrete or patchy erythema	1
Moderate and confluent erythema	2
Intense erythema and swelling	3

FIGURE 1

GUINEA PIG SENSITIZATION



Induction Sites

Challenge Sites

APPLICATION SITES

Table 2

Guinea Pig Closed Patch Sensitization Test - Individual Results

Vinyl Co-Polymer Powder Free Examination Gloves, Blue Color; Size: M; Lot#: 1405F4A3-PF

Test Group

Dosage: 1 sq", moist w/saline, using a 25 mm Hilltop Chamber

	Time After Application	Animal Number/Sex 1M	2M	3M	4M	5M
Initial Bdwts. (grams):		358	320	344	342	334
Induction						
1	7 Hours	0	0	0	0	0
	24 Hours	0	0	0	0	0
2	7 Hours	0	0	0	0	0
	24 Hours	0	0	0	0	0
3	7 Hours	0	0	0	0	0
	24 Hours	0	0	0	0	0
4	7 Hours	0	0	0	0	0
	24 Hours	0	0	0	0	0
5	7 Hours	0	0	0	0	0
	24 Hours	0	0	0	0	0
6	7 Hours	0	0	0	0	0
	24 Hours	0	0	0	0	0
7	7 Hours	0	0	0	0	0
	24 Hours	0	0	0	0	0
8	7 Hours	0	0	0	0	0
	24 Hours	0	0	0	0	0
9	7 Hours	0	0	0	0	0
	24 Hours	0	0	0	0	0
Challenge	24 Hours	0	0	0	0	0
	48 Hours	0	0	0	0	0
Terminal Bdwts. (grams):		568	542	572	600	596

Raw Data Page: 161753
Animals #1 -3 were exposed to the inside of the glove and #4 – 5 were exposed to the outside of the glove.

Table 2 (continued)

Guinea Pig Closed Patch Sensitization Test - Individual Results

Vinyl Co-Polymer Powder Free Examination Gloves, Blue Color; Size: M; Lot#: 1405F4A3-PF

Test Group

Dosage: 1 sq", moist w/saline, using a 25 mm Hilltop Chamber

	Time After Application	Animal Number/Sex 6F	7F	8F	9F	10F
Initial Bdwts. (grams):		350	348	350	346	332
Induction						
1	7 Hours	0	0	0	0	0
	24 Hours	0	0	0	0	0
2	7 Hours	0	0	0	0	0
	24 Hours	0	0	0	0	0
3	7 Hours	0	0	0	0	0
	24 Hours	0	0	0	0	0
4	7 Hours	0	0	0	0	0
	24 Hours	0	0	0	0	0
5	7 Hours	0	0	0	0	0
	24 Hours	0	0	0	0	0
6	7 Hours	0	0	0	0	0
	24 Hours	0	0	0	0	0
7	7 Hours	0	0	0	0	0
	24 Hours	0	0	0	0	0
8	7 Hours	0	0	0	0	0
	24 Hours	0	0	0	0	0
9	7 Hours	0	0	0	0	0
	24 Hours	0	0	0	0	0
Challenge	24 Hours	0	0	0	0	0
	48 Hours	0	0	0	0	0
Terminal Bdwts. (grams):		512	564	544	552	516

Raw Data Page: 161753
Animals #6 -7 were exposed to the inside of the glove and #8 – 10 were exposed to the outside of the glove.

Table 3

Guinea Pig Closed Patch Sensitization Test - Individual Results

Vinyl Co-Polymer Powder Free Examination Gloves, Blue Color; Size: M; Lot#: 1405F4A3-PF

Control Group

Dosage: Induction - saline blank using a 25 mm Hilltop Chamber
Challenge – 1 sq" test article, moist w/saline, using a 25 mm Hilltop Chamber

	Time After Application	Animal Number/Sex 1M	2M	3F	4F	5F
Initial Bdwts. (grams):		362	356	302	354	366
Induction						
1	7 Hours	0	0	0	0	0
	24 Hours	0	0	0	0	0
2	7 Hours	0	0	0	0	0
	24 Hours	0	0	0	0	0
3	7 Hours	0	0	0	0	0
	24 Hours	0	0	0	0	0
4	7 Hours	0	0	0	0	0
	24 Hours	0	0	0	0	0
5	7 Hours	0	0	0	0	0
	24 Hours	0	0	0	0	0
6	7 Hours	0	0	0	0	0
	24 Hours	0	0	0	0	0
7	7 Hours	0	0	0	0	0
	24 Hours	0	0	0	0	0
8	7 Hours	0	0	0	0	0
	24 Hours	0	0	0	0	0
9	7 Hours	0	0	0	0	0
	24 Hours	0	0	0	0	0
Challenge	24 Hours	0	0	0	0	0
	48 Hours	0	0	0	0	0
Terminal Bdwts. (grams):		700	628	462	510	532

Raw Data Page: 161754
Animals #1, 3 & 4 were exposed to the inside of the glove and #2 & 5 were exposed to the outside of the glove.

CE DECLARATION OF CONFORMITY

Manufacturer,

Name: Grand Work Plastic Products Co., Ltd.

Address: Donggao Industrial Zone, Zanhuang, Hebei, 050000, China.

Declares that the MDD described hereafter

Products name and Model:

Disposable Vinyl/Nitrile Blended Examination Gloves

XS, S, M, L and XL

Meet the provisions of the Council Directive 93/42/EEC as amended by 2007/47/EEC and Provisions of the Regulation (EU) 2017/745 which apply to them.

Examination gloves are classified as Class I medical devices in accordance with the rules set out in Annex VIII.

Applied harmonized standards: EN455-1:2000, EN455-2:2015, EN455-3:2015, EN ISO 14971:2012, EN ISO 13485:2016.

Conformity assessment procedure: Annex VII of Medical Device Directive 93/42/EEC as amended by 2007/47/EEC and Article 52 in MDR 2017/745.

The CE declaration of conformity is issued under the sole responsibility of Shijiazhuang Hongray Group Co. Ltd.

The products can be placed the following CE mark.

CE

Signature: Wumin

Date: March 03, 2019

Regulatory Authority

CE TECHNICAL DOCUMENTATION REVIEW REPORT

Company Name:	Grand Work Plastic Products Co., Ltd.
Address:	Donggao Industrial Zone, Zanhuang, Hebei, 050000, China
Review Intention:	Review the completeness of the Technical Documentation according to the requirements of Medical Devices Directive 93/42/EEC Annex VII & the Regulation (EU) 2017/745 Annex II and III
Product(s):	Vinyl / Nitrile Blended Examination Gloves
Type(s) / Model(s):	Powder Free / XS, S, M, L, XL
Classification:	Class I (According to Annex IX Section III 1.1 and 1.4 of the Medical Devices Directive 93/42/EEC & Annex VIII Chapter III 4.1 rule 1 of Medical Device Regulations 2017/745)
Review period:	June 06, 2019
Review Result:	During the examination of the Technical Documentation (No: GW-JSWJ-002, Revision: C, Dated 2019-05-10), no non-compliance according to the requirements of Medical Devices Directive 93/42/EEC Annex VII & the Regulation (EU) 2017/745 Annex II and III was detected.

Signature: Wu Min

Date: June 06, 2019

Regulatory Authority

ONLY FOR EUROPEAN MARKET!

SHIJIAZHUANG HONGRAY GROUP

South Tongda Rd., East Dist. Jinzhou City, Hebei, 052260, China
TEL: 86-311-66179668
FAX: 86-311-66179676
www.hongray.com

SPECIFICATION FOR VINYL/NITRILE BLENDED EXAMINATION GLOVE

1.0 Product: Vinyl/Nitrile Blended, Powder Free, 9″ length, for examination use

2.0 Dimensions:

Size	Median Length (mm)	Median Width (mm)	Thickness (mm) (min)	
			Palm	Finger
XS	240	75±5	0.08	0.09
S	240	85±5	0.08	0.09
M	240	95±5	0.08	0.09
L	240	105±5	0.08	0.09
XL	240	115±5	0.08	0.09

3.0 Strength:
Force at break: 3.8N (Median)

4.0 Water Leakage Testing:
For exam gloves, according to ISO2859, G-I, Single Sampling Plan, AQL1.5

5.0 Powder Residues:
For powder free gloves, not more than 2mg per glove.

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TEL: 86-311-66179668
FAX: 86-311-66179676
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SPECIFICATION FOR VINYL/NITRILE BLENDED EXAMINATION GLOVE

1.0 Product: Vinyl/Nitrile Blended, Powder Free, 9″ length, examination use

2.0 Physical Dimensions:

Size	Length (mm) (min)	Width (mm)	Thickness (mm) (min)	
			Palm	Finger
XS	230	75±5	0.08	0.09
S	230	85±5	0.08	0.09
M	230	95±5	0.08	0.09
L	230	105±5	0.08	0.09
XL	230	115±5	0.08	0.09

3.0 Physical Requirements:
Before Aging:
Tensile Strength: 14 MPA (min); Elongation: 400% (min)

After Accelerated Aging:
Tensile Strength: 14 MPA (min); Elongation: 350% (min)

4.0 Freedom from holes:
According to ISO 2859, G-II, multiple sampling plan for normal inspection, AQL 1.5

5.0 Powder Residues:
For powder free gloves, not more than 2mg per glove.

Testing Report

Company Name: Grand Work Plastic Products Co., Ltd

Address: Donggao Industrial Zone, Zanhuang, Hebei, 050000, China

Test Date: Dec 16, 2019

Product Description: Powder Free Vinyl/Nitrile Blended Examination Gloves

Size: S, M, L, XL

Test Standards: ASTM D 5250-19 Standard Specification for Poly(vinyl chloride) Gloves for Medical Application

ASTM D412 Test Methods for Vulcanized Rubber and Thermoplastic Elastomers—Tension

ASTM D573 Test Method for Rubber—Deterioration in an Air Oven

ASTM D3767 Practice for Rubber—Measurement of Dimensions

ASTM D5151 Test Method for Detection of Holes in Medical Gloves

ASTM D6124 Test Method for Residual Powder on Medical Gloves

Specification:

<table>
<tr><th colspan="2">Item</th><th>Requirements</th><th>Inspection Level & AQL</th></tr>
<tr><td colspan="2">Length (mm)</td><td>≥230mm</td><td rowspan="11">S-2, AQL4.0</td></tr>
<tr><td colspan="2" rowspan="4">Width (mm)</td><td>S 85±5</td></tr>
<tr><td>M 95±5</td></tr>
<tr><td>L 105±5</td></tr>
<tr><td>XL 115±5</td></tr>
<tr><td rowspan="2">Thickness (mm)</td><td>Finger</td><td>0.08</td></tr>
<tr><td>Palm</td><td>0.08</td></tr>
<tr><td rowspan="2">Tensile Strength, MPa</td><td>Before Aging</td><td>11</td></tr>
<tr><td>After Accelerated Aging</td><td>11</td></tr>
<tr><td rowspan="2">Ultimate Elongation, %</td><td>Before Aging</td><td>300</td></tr>
<tr><td>After Accelerated Aging</td><td>300</td></tr>
<tr><td colspan="2">Powder Free Residue</td><td><2mg /glove</td><td>N=5</td></tr>
<tr><td colspan="2">Freedom from holes</td><td>G-I, AQL2.5</td><td>G-I, AQL2.5</td></tr>
<tr><td colspan="4">Notes:
1. Condition of sampling testing: Temperature: 23±2℃, Humidity: 50±5%
2. Specimen shall be conditioned at least 16 hours before testing.
3. Challenge testing condition: 70±2 h at a temperature of 70±2℃ in an oven.</td></tr>
</table>

Test Results: Please refer to the follows

Testing Report

1. Dimensions and Physical Properties

Test Method: ASTM D5250, ASTM D3767, ASTM D412, ASTM D573
Test Condition: 22℃, 51%
Tested by: Ma Huina

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Tensile Strength, MPa		Ultimate Elongation, %	
			Palm	Finger		Before Aging	After Aging	Before Aging	After Aging
1	S	230	0.08	0.10	86	15.6	14.4	400	340
2	S	231	0.08	0.09	86	15.5	15.7	390	370
3	S	232	0.08	0.09	87	16.7	15.0	380	360
4	S	230	0.08	0.10	86	15.8	14.9	370	370
5	S	231	0.08	0.09	85	15.2	15.2	390	350
6	S	232	0.08	0.10	86	16.4	16.0	400	390
7	S	232	0.08	0.10	87	15.7	15.4	370	360
8	S	233	0.08	0.09	86	15.0	14.6	390	370
9	S	237	0.08	0.10	86	15.9	14.4	400	350
10	S	240	0.08	0.10	87	15.9	13.2	380	340
11	S	236	0.08	0.09	86	14.5	15.4	370	370
12	S	232	0.08	0.10	86	15.1	15.1	390	360
13	S	235	0.08	0.09	86	16.8	15.7	410	350
Test Result		Pass							
1	M	235	0.08	0.09	96	14.7	14.9	410	350
2	M	230	0.08	0.10	96	16.5	15.7	370	370
3	M	232	0.08	0.09	97	15.7	15.0	380	340
4	M	231	0.08	0.09	96	14.8	15.9	370	370
5	M	234	0.08	0.09	97	15.2	15.2	400	340
6	M	232	0.08	0.10	96	16.4	14.0	390	390
7	M	230	0.08	0.09	97	15.7	15.4	380	360
8	M	234	0.08	0.09	96	15.0	15.6	370	370
9	M	237	0.08	0.10	96	15.9	16.4	390	350
10	M	240	0.08	0.09	96	14.9	14.2	400	320
11	M	235	0.08	0.09	96	15.5	15.5	390	370
12	M	232	0.08	0.10	97	15.1	15.1	390	340
13	M	231	0.08	0.09	96	15.8	15.7	400	350
Test Result		Pass							

Testing Report

1	L	230	0.08	0.10	106	14.6	16.4	400	340
2	L	231	0.08	0.09	106	15.5	15.7	390	350
3	L	232	0.08	0.09	107	15.7	15.0	380	360
4	L	231	0.08	0.10	106	15.8	14.9	370	370
5	L	235	0.08	0.09	105	15.2	14.2	390	350
6	L	232	0.08	0.10	106	15.4	14.0	400	350
7	L	230	0.08	0.09	106	15.7	14.4	380	360
8	L	234	0.08	0.09	106	15.0	14.6	380	360
9	L	237	0.08	0.10	106	15.9	15.4	410	340
10	L	240	0.08	0.09	107	14.9	14.2	390	350
11	L	236	0.08	0.09	106	16.5	15.4	380	360
12	L	234	0.08	0.10	106	15.1	15.1	400	340
13	L	235	0.08	0.10	105	15.4	14.7	390	350
Test Result		Pass							
1	XL	235	0.08	0.10	116	15.3	14.0	400	370
2	XL	231	0.08	0.09	116	15.5	15.7	400	350
3	XL	238	0.08	0.09	115	15.7	15.2	400	360
4	XL	231	0.08	0.10	116	15.8	14.9	390	370
5	XL	234	0.08	0.10	115	15.2	15.2	410	340
6	XL	232	0.08	0.10	116	14.4	16.1	390	390
7	XL	236	0.08	0.09	117	16.7	15.4	380	360
8	XL	234	0.08	0.09	116	15.0	14.7	370	350
9	XL	237	0.08	0.09	116	14.9	16.4	390	350
10	XL	235	0.08	0.10	115	14.2	14.2	380	380
11	XL	236	0.08	0.09	116	15.5	16.4	380	360
12	XL	237	0.08	0.10	116	15.1	15.3	390	370
13	XL	239	0.08	0.10	116	14.5	15.5	410	340
Test Result		Pass							

2. Freedom from Holes

Test Method: ASTM D5151

Sample Size: ISO2859, Inspection Level: G-1, AQL=2.5, 125pcs (Ac=7, Re=8)

Tested by: An Lijuan Ma Huina

Size	Sample Count (pcs)	Pinhole (pcs)	Test Result
S	125	1	Pass

Testing Report

M	125	1	Pass
L	125	2	Pass
XL	125	3	Pass

3. Powder Free Residue

Test Method: ASTM D6124
Sample Size: 5 pieces of gloves were sampled.
Tested by: Ma Huina

Size	Average Powder (mg/glove)	Test Result
S	0.41	Pass
M	0.43	Pass
L	0.45	Pass
XL	0.47	Pass

Conclusion:

The Powder Free Vinyl/Nitrile Blended Examination Gloves met the test requirements ASTM D5250-19 Standard Specification for Poly (vinyl chloride) Gloves for Medical Application.

Signed By: Zhang Li

Quality Manager

Testing Report

Company Name: Grand Work Plastic Products Co., Ltd

Address: Donggao Industrial Zone, Zanhuang, Hebei, 050000, China

Test Date: Dec 06, 2019

Product Description: Powder Free Vinyl/Nitrile Blended Examination Gloves

Size: XS, S, M, L, XL

Test Standards: EN 455-1:2000 Medical Gloves for Single Use-Part 1: Requirements and Testing For Freedom from Holes

EN 455-2:2015 Medical Gloves for Single Use-Part 2: Requirements and Testing For Physical Properties

EN 455-3:2015 Medical Gloves for Single Use-Part 3: Requirements and Testing For Biological Evaluation Clause 4.4 &4.6

Specification:

Item		Criteria	Quantity and Acceptance Criteria
Length (mm)		≥240mm	13 pieces, median
Width (mm)		XS: ≤80	13 pieces, median
		S:80±10	13 pieces, median
		M: 95±10	13 pieces, median
		L: 110±10	13 pieces, median
		XL: ≥110	13 pieces, median
Thickness (mm)	Middle Fingertip t^f	$t^f/t^x \geq 0.9$	13 pieces
	Test piece t^x		
Force at Break (N) (Before and After Aging)		≥3.6N	13 pieces, median
Water tightness		G-I, AQL1.5	200 pieces (Ac7, Re 8)
Powder		EN 455-3 Clause 4.4	<2mg /glove
Labelling		EN 455-3 Clause 4.6	Conform to EN 455-3 Clause 4.6

Notes:
1. Condition of sampling testing: Temperature: 23±2℃, Humidity: 50±5%
2. Specimen shall be conditioned at least 16 hours before testing.
3. Challenge testing condition: seven days at a temperature of 70±2℃ in an oven.

Test Results: Please refer to the follows

Testing Report

1. Dimensions and Physical Properties

Test Standard and Method: EN 455-2

Test Condition: 22℃, 51%

Tested by: Ma Huina

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)	
			Test Piece	Middle Fingertip		Before Aging	After Aging
1	XS	242	0.08	0.09	76	3.8	3.8
2	XS	241	0.08	0.09	77	3.5	3.9
3	XS	242	0.08	0.09	76	3.6	3.6
4	XS	240	0.08	0.09	76	3.9	3.8
5	XS	240	0.08	0.09	75	3.7	3.8
6	XS	242	0.08	0.10	76	3.5	3.7
7	XS	245	0.08	0.10	76	3.8	3.6
8	XS	244	0.08	0.09	76	3.6	3.5
9	XS	242	0.08	0.09	76	3.5	3.8
10	XS	243	0.08	0.09	76	3.7	3.8
11	XS	240	0.08	0.09	75	3.6	3.7
12	XS	241	0.08	0.10	76	3.7	3.5
13	XS	243	0.08	0.09	75	3.8	3.9
Median Value		242	0.08	0.09	76	3.8	3.8
Test Result		Pass					
1	S	240	0.08	0.10	86	3.8	3.7
2	S	241	0.08	0.10	86	3.9	3.8
3	S	242	0.08	0.09	85	3.9	3.9
4	S	241	0.08	0.09	86	3.7	3.6
5	S	240	0.08	0.09	86	3.6	3.8
6	S	242	0.08	0.09	86	3.8	3.4
7	S	242	0.08	0.09	86	3.7	3.8
8	S	244	0.08	0.09	85	3.7	3.8
9	S	241	0.08	0.09	86	4.0	3.9
10	S	240	0.08	0.09	86	3.8	3.6
11	S	241	0.08	0.09	86	3.7	3.7
12	S	244	0.08	0.10	86	3.6	3.8
13	S	242	0.08	0.09	86	3.8	3.6
Median Value		241	0.08	0.09	86	3.8	3.8
Test Result		Pass					

Testing Report

Serial No.	Size	Length (mm)	Thickness (mm)		Palm Width (mm)	Force at Break (N)	
			Test Piece	Middle Fingertip		Before Aging	After Aging
1	M	242	0.08	0.09	96	3.9	3.7
2	M	241	0.08	0.10	96	3.6	3.8
3	M	243	0.08	0.09	96	3.7	3.9
4	M	241	0.08	0.09	96	3.8	3.6
5	M	240	0.08	0.10	95	3.5	3.5
6	M	242	0.08	0.09	97	3.7	3.8
7	M	240	0.08	0.09	97	3.8	3.6
8	M	244	0.08	0.10	96	3.6	3.8
9	M	243	0.08	0.10	96	3.9	3.9
10	M	243	0.08	0.09	96	3.4	3.7
11	M	241	0.08	0.10	96	3.8	3.6
12	M	240	0.08	0.10	96	3.8	3.8
13	M	240	0.08	0.10	96	3.9	3.9
Median Value		241	0.08	0.10	96	3.8	3.8
Test Result		Pass					
1	L	242	0.08	0.10	105	3.8	3.8
2	L	241	0.08	0.09	105	3.9	3.9
3	L	243	0.08	0.09	106	3.7	3.6
4	L	241	0.08	0.10	105	3.5	3.8
5	L	243	0.08	0.10	105	3.6	3.5
6	L	242	0.08	0.10	107	3.5	3.8
7	L	242	0.08	0.09	106	4.0	3.6
8	L	244	0.08	0.09	106	3.8	3.5
9	L	242	0.08	0.10	106	3.6	3.8
10	L	240	0.08	0.09	107	3.6	3.6
11	L	242	0.08	0.09	106	4.0	3.6
12	L	241	0.08	0.10	106	3.8	3.8
13	L	242	0.08	0.10	106	3.9	3.9
Median Value		242	0.08	0.10	106	3.8	3.8
Test Result		Pass					
1	XL	244	0.08	0.10	117	3.9	3.9
2	XL	241	0.08	0.09	116	3.7	3.5
3	XL	243	0.08	0.09	116	3.7	3.8
4	XL	243	0.08	0.10	116	3.8	3.6

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5	XL	243	0.08	0.10	115	3.8	3.5
6	XL	244	0.08	0.10	116	3.6	3.8
7	XL	242	0.08	0.09	116	3.8	3.6
8	XL	244	0.08	0.09	116	3.9	3.8
9	XL	243	0.08	0.10	116	3.5	3.8
10	XL	242	0.08	0.09	117	3.6	3.6
11	XL	243	0.08	0.09	117	3.8	3.9
12	XL	240	0.08	0.09	116	3.6	3.8
13	XL	242	0.08	0.10	116	4.0	3.7
Median Value		243	0.08	0.09	116	3.8	3.8
Test Result		Pass					

2. Watertightness test

Test Standard and Method: EN 455-1

Sample Size: ISO2859, Inspection Level: G-1, AQL=1.5, 200pcs (Ac=7, Re=8)

Tested by: An Lijuan Ma Huina

Size	Sample Count (pcs)	Pinhole (pcs)	Test Result
XS	200	2	Pass
S	200	2	Pass
M	200	1	Pass
L	200	2	Pass
XL	200	3	Pass

3. Powder and Labeling

Test Standard and Method: EN 455-3 clause 4.4 &4.6

Sample Size: 5 pieces of gloves were sampled.

Tested by: Ma Huina

Size	Average Powder (mg/glove)	Labelling	Test Result
XS	0.40	Pass	Pass
S	0.41	Pass	Pass
M	0.43	Pass	Pass
L	0.45	Pass	Pass
XL	0.47	Pass	Pass

Conclusion:

The Powder Free Vinyl/Nitrile Blended Examination Gloves met the test requirements EN 455-1, EN 455-2 and EN455-3 Clause 4.4 &4.6.

Signed By: zhang Li

Quality Manager