



Test Report

No.: SHHG1511044686MD-01

Date: MAY 26, 2016

Page: 1 of 15

SHIJIAZHUANG WALLY PLASTIC CO., LTD

NO.78, TONGDA ROAD, JINZHOU CITY, HEBEI, CHINA

THE TEST REPORT IS TO SUPERSEDE THE TEST REPORT No.: SHHG1511044686MD

DATE: MAR. 01, 2016

The following sample(s) was/were submitted and identified by the client as:

Sample Description : EXAMINATION VINYL GLOVES
Style/ Item No. : XS, S, M, L, XL, XXL
Manufacturer : SHIJIAZHUANG WALLY PLASTIC CO., LTD
Supplier : SHIJIAZHUANG WALLY PLASTIC CO., LTD
Country of Origin : CHINA
Country of Destination : EUROPE
Sample Receiving Date : NOV. 23, 2015
Testing Period : NOV. 23, 2015 TO MAR. 01, 2016
Test Performed : SELECTED TEST(S) AS REQUESTED BY APPLICANT
Test Requested : 1. EN 455-1:2000 MEDICAL GLOVES FOR SINGLE USE
– PART 1: REQUIREMENTS AND TESTING FOR
FREEDOM FROM HOLES
2. EN 455-2: 2015 MEDICAL GLOVES FOR SINGLE USE
– PART 2: REQUIREMENTS AND TESTING FOR
PHYSICAL PROPERTIE
3. EN 455-3-2015 MEDICAL GLOVES FOR SINGLE
USE—PART 3:REQUIREMENTS AND TESTING FOR
BIOLOGICAL EVALUATION (EXCEPT CLAUSE 4.2
CHEMICALS)
Test Result(s) : FOR FURTHER DETAILS, PLEASE REFER TO THE
FOLLOWING PAGE(S)
Conclusion : THE SUBMITTED SAMPLE MET THE TEST
REQUIREMENT.

Signed for and on behalf of
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd.

Melody Zhang
Authorized Signatory



SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd.
Testing Center Harbin Branch

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Test Report

No.: SHHG1511044686MD-01

Date: MAY 26, 2016

Page: 2 of 15

Test Conducted:

- EN 455-1:2000 Medical gloves for single use – part 1: Requirements and testing for freedom from holes

Number of test sample : 200 Pieces
 The type of gloves : Examination/procedure gloves
 Manufacturing batch code : /
 Batch size : /
 Sample size : XS, S, M, L, XL, XXL
 Number of non-conforming gloves : None
 Defects observed before testing : No defects
 Test Result : Pass

Clause	Test Items	Result	Note
5	Watertightness test for detection of holes	---	---
5.1	Referee testing		# 1&2



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Test Report

No.: SHHG1511044686MD-01

Date: MAY 26, 2016

Page: 3 of 15

2. EN 455-2: 2015 Medical gloves for single use – part 2: Requirements and testing for physical properties

Number of test sample : 39 Pieces
 Type : Examination/procedure gloves
 The manufacturing batch code : /
 Size : XS, S, M, L, XL, XXL
 Defects observed before testing : No defects
 Test Result : Pass

Clause	Test Items	Result	Note
4	Dimensions	Pass	#3&4
5	Strength	Pass	#2&5
7	Labeling	Pass	/



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Test Report

No.: SHHG1511044686MD-01

Date: MAY 26, 2016

Page: 4 of 15

3. EN 455-3: 2015 Medical gloves for single use—Part 3:Requirements and testing for biological evaluation

Number of test sample : 1 bag+5pieces
 Finishes of gloves : Powdered-free gloves other than surgeon's gloves
 Defects observed before testing : No defects
 Test Result : Pass

Clause	Test Items	Result	Note
4.1	General	Pass	#6
4.2	Chemicals	N/C	#7
4.3	Endotoxins	N/A	#8
4.4	Powder-free gloves	Pass	#2&9
4.5	Proteins, leachable	N/A	#8
4.6	Labeling	Pass	/

Note:

- See result 1.
- As per client's declare, these gloves (four size: XS, S, M, L, XL, XXL) only size different, the material is the same, and only the glove of size L was tested.
- See result 2.
- As per client's request, the dimension requirement of size XXL was reference to size XL.
- See result 3.
- See result 4.
- N/C means not conducted as per client's request.
- N/A means not applicable for the design of product.
- Test according to EN ISO 21171-2006, the powder of gloves were 0.8mg<2.0mg.



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Test Report

No.: SHHG1511044686MD-01

Date: MAY 26, 2016

Page: 5 of 15

Test Results:

1. Watertightness test for detection of holes

Sample Quantity: 200pcs

AQL: 1.5 Accept: 7 Reject: 8 Found: 0

Remark:

- 1) The sample selecting amount for Watertightness test for detection of holes is deviated to 200 pcs as accessed by SGS.

2. Dimensions

Sample Quantity: 78pcs

Size	XS												
Length(mm)	249	248	247	249	248	249	247	248	249	248	247	248	249
Width(mm)	78	77	78	79	76	78	78	79	78	77	78	78	77

Median value:

Length (mm): 248

Width (mm): 78

Size	S												
Length(mm)	250	249	251	250	250	251	249	249	250	250	251	252	251
Width(mm)	88	87	87	88	85	86	87	88	88	87	86	86	87

Median value:

Length (mm): 250

Width (mm): 87

Size	M												
Length(mm)	246	245	247	246	245	246	247	247	246	245	246	245	245
Width(mm)	96	95	96	95	96	95	96	97	97	96	95	95	95

Median value:

Length (mm): 246

Width (mm): 96



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Test Report

No.: SHHG1511044686MD-01

Date: MAY 26, 2016

Page: 6 of 15

Size	L												
Length(mm)	248	248	247	247	248	248	247	247	246	247	248	247	248
Width(mm)	103	104	102	105	104	104	103	102	103	103	103	104	104

Median value:

Length (mm): 247

Width (mm): 103

Size	XL												
Length(mm)	247	248	247	248	247	247	247	248	247	247	248	248	248
Width(mm)	116	117	118	117	117	116	116	117	117	118	116	116	117

Median value:

Length (mm): 247

Width (mm): 117

Size	XXL												
Length(mm)	259	260	259	261	258	258	259	260	259	259	260	259	258
Width(mm)	122	121	121	120	122	123	122	122	123	122	122	123	121

Median value:

Length (mm): 259

Width (mm): 122



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Test Report

No.: SHHG1511044686MD-01

Date: MAY 26, 2016

Page: 7 of 15

Requirements: see table 1&2

Table 1 Dimensions for surgical gloves

Size	Median length in mm	Median width in mm
5	≥250	67 ±4
5.5	≥250	72 ±4
6	≥260	77 ±5
6.5	≥260	83 ±5
7	≥270	89 ±5
7.5	≥270	95 ±5
8	≥270	102 ±6
8.5	≥280	108 ±6
9	≥280	114 ±6
9.5	≥280	121 ±6

Table 2 Dimensions for examination/procedure gloves

Size	Median length in mm	Median width in mm
Extra small	≥240	≤80
Small		80 ±10
Medium		95 ±10
Large		110 ±10
Extra Large		≥110

3. Strength

Sample Quantity: 26pcs

Size	L												
Force at break(N)	8.53	8.35	8.13	7.98	8.50	8.37	8.78	7.81	8.24	8.52	8.64	8.23	8.37
Force at break after challenge testing(N)	7.80	9.01	8.53	9.13	7.92	8.24	8.41	8.78	8.69	8.98	8.76	8.74	8.43

Median value:

Force at break during shelf life (N): 8.37

Force at break after challenge testing (N): 8.69



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Requirements: see table 3

Table 3 — Median values of force at break

	Force at break in Newton		
	Surgical gloves	Examination/procedure gloves	
	a)	b)	c)
Throughout shelf life tested according to 5.2 and within 12 months of manufacture tested according to 5.3	≥ 9,0	≥ 6,0	≥ 3,6
a) Requirements for all surgical gloves. b) Requirements for all examination gloves, except gloves made from thermoplastic materials (e.g. polyvinylchloride, polyethylene).. c) Requirements for gloves made from thermoplastic materials (e.g. polyvinylchloride, polyethylene).			



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4. Attachment 1: Test for skin sensitization (Maximization test)

SUMMARY

A guinea pig maximization test of the test article, Examination Vinyl Gloves, was conducted to evaluate the skin sensitizing potential. This study was based on the International Organization for Standardization ISO 10993-10:2010: Biological evaluation of medical devices part 10: Tests for irritation and skin sensitization; ISO10993-12: 2012: Biological evaluation of medical devices Part 12: Sample preparation and reference materials.

The test article was extracted in 0.9% sodium chloride injection (SC) and cotton seed oil (CSO). Each extract was injected intradermally and patched occlusively to ten test guinea pigs (per extract) in an attempt to induce sensitization. The vehicle was similarly injected and patched occlusively to five reagent control guinea pigs (per vehicle). Following a recovery period, the test and reagent control animals were received a challenge patch of the appropriated test article extract and the reagent control. All sites were scored at 24 h and 48 h after patch removal.

Under the conditions of this study, the SC and CSO extracts of the test article showed no evidence of causing sensitization in the guinea pig.

MATERIALS

The test article was provided by the sponsor was identified and handled as follows:

- Test Article: Examination Vinyl Gloves
- Storage Conditions: Room temperature
- Extraction Vehicle: 0.9% sodium chloride injection (SC) Cotton seed oil (CSO)
- Test Article Preparation: According the requirement of the sponsor, the test articles were sterilized by ethylene oxide two weeks before the treatment. Based on the ISO ratio of 6 cm² :1 ml (Surface area of the test article to volume of extraction vehicle), 90 cm² of the test article was covered with 15 ml of extraction vehicle under aseptic conditions for preparing the SC and CSO test extract at 37 °C for 72 h respectively for each phase. The extracts were used after extraction.
- Reagent Control: The vehicles (without test article) were similarly prepared to serve as the reagent control.
- Condition of extracts: All the extract of the test and controls were clear.
- Additional materials: Freund's Complete Adjuvant (FCA) was mixed 50:50 (v/v) with the vehicle.
A 10% (w/w) sodium dodecyl sulphate suspension in paraffin.

In addition according ISO10993-10 requirement, 5% mercaptobenzothiazole (dissolved in DMSO) as a positive control was used previously for another study last three months. Complete data is traceable in laboratory records.

METHODS



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Test Report

No.: SHHG1511044686MD-01

Date: MAY 26, 2016

Page: 10 of 15

Test System

Species: Albino guinea pig
 Source: SHANGHAI SONGLIAN LAB ANIMAL-FEILD
 Sex: Male
 Body Weight Range: 309.7 g to 364.8 g
 Age: Young adult
 Number of animals: Thirty

Animal Management:

Husbandry: Conditions conformed to "Laboratory animal-Requirements of environment and housing facilities"; "ISO 10993-2:2006: Biological evaluation of medical devices Part 2: Animal welfare requirements".
 Food: Diet was provided from Shanghai Pu Lu Teng Biological Technology Co., Ltd.
 Housing: Healthy animals were acclimatized to the laboratory conditions for 5 days before the treatment, and then they were individually housed in stainless steel suspended cages identified by a card indicating the Identification No. of the test article and first treatment date.

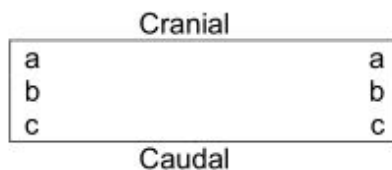
Environmental: The room temperature and humidity were monitored daily. The temperature range for the room was from 23 °C to 25 °C. The room humidity range was from 51 % to 61 %.

Personnel: Associates involved were appropriately qualified and trained.
 Selection: Only healthy, unused animals were selected.

Experimental Procedure:

1. Intradermal induction phase (induction I):

The day prior to treatment, the fur was clipped on all treatment sites with an electric clipper. The 1st day, the test animals were injected with the fresh extracts of test article and the control animals were injected with the reagent control. Three rows of intradermal injections (two per row) were given to each animal within an approximate 2 cm x 4 cm boundary of the fur clipped area as illustrated below:



Test Animals:

- a) 0.1ml of 50:50(v/v) mixture of FCA and the chosen vehicle
- b) 0.1ml of test extract
- c) 0.1ml of 50:50(v/v) mixture of a and b

Control Animals:

- a) 0.1ml of 50:50(v/v) mixture of FCA and the vehicle
- b) 0.1ml of vehicle
- c) 0.1ml of 50:50(v/v) mixture of a and b



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2. Topical induction phase (Induction II):

At 7th day after completion of the intradermal induction phase, the same area was clipped free of fur and treated with 10% sodium dodecyl sulphate suspension in paraffin. The suspension was massaged into the skin over the injection site to provoke a mild acute inflammation. The area was left uncovered.

At 8th day, a 20mm×40mm section of absorbent gauze patch, saturated with freshly prepared the extract of the test article, and then was topically applied to the previously injected sites of the test animals. The control animals were similarly patched with the appropriate reagent control. Each patch was secured with an occlusive dressing. The dressings and patches were removed after 48h.

3. Challenge phase

At 22nd days, the fur was removed from the left flank areas. At 23rd day, absorbent gauze patches were soaked with the corresponding solution at the concentration of site C, and patched on the left upper flank of each animal in test and reagent control group. Then the animals were secured with an occlusive dressing. The dressings and patches were removed after 24 h.

4. Observation of animals

The appearance of the challenge skin sites of the test and control animals was observed respectively at 24 h and 48 h after removal of the dressing. The skin reactions for erythema and swelling were described and graded in according with the criteria shown below:

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

If the grades of less than 1 are seen in reagent control animals, grades of 1 or greater in the test group were generally indicated sensitization.



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Test Report

No.: SHHG1511044686MD-01

Date: MAY 26, 2016

Page: 12 of 15

RESULTS

Clinical Observation:

All animals appeared clinically normal throughout the study.

Dermal Observations:

No evidence of sensitization was observed. Individual results of dermal scoring for the challenge phase shown below:

Time	Hours following patch removal			
	24 h		48 h	
Vehicle	SC	CSO	SC	CSO
Test article	0	0	0	0
Reagent Control	0	0	0	0

CONCLUSION

Under the conditions of this study, the SC and CSO extracts of the test article showed no evidence of causing sensitization in the guinea pig.

PHOTOGRAPH OF THE TEST ARTICL



Remark: Results and conclusions apply only to the test article sample tested provided by Client. Therefore, this Report contains the results obtained in the test of the provided samples only and do not express any opinion upon the lot from which the samples were drawn or any similar samples.



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Test Report

No.: SHHG1511044686MD-01

Date: MAY 26, 2016

Page: 13 of 15

Sample Photo:

Received sample (size XS)



Received sample (size S)



Received sample (size M)



Received sample (size L)



Received sample (size XL)



Received sample (XXL)



Label (size XS)

Examination Vinyl gloves
Powder free, Clear/Non sterile/Latex Free
Ambidextrous vinyl glove for single use only
Size: X-Small
LOT Number: EN150610

2015-06-10
 2020-06-10

Manufacturer: Shijiazhuang Wally Plastic CO., Ltd
NO. 78 Tongda Road, Jinzhou City, Hebei, China
Post code: 052260

Recommended Use
 These gloves are only for single use. Wash hands before and after glove use. Change gloves when moving to a new task or after handling soiled clothing. Avoid storing gloves above 140°F (40°C). Gloves should be stored away from direct sunlight, fluorescent lighting, moisture, X-rays and ozone chemicals. Some components used in making these gloves may cause allergic reactions in some users. Immediately discontinue use if reactions are suspected. Discontinue used if reddening or irritation occurs.

Label (size S)

Examination Vinyl gloves
Powder free, Clear/Non sterile/Latex Free
Ambidextrous vinyl glove for single use only
Size: Small
LOT Number: EN150610

2015-06-10
 2020-06-10

Manufacturer: Shijiazhuang Wally Plastic CO., Ltd
NO. 78 Tongda Road, Jinzhou City, Hebei, China
Post code: 052260

Recommended Use
 These gloves are only for single use. Wash hands before and after glove use. Change gloves when moving to a new task or after handling soiled clothing. Avoid storing gloves above 140°F (40°C). Gloves should be stored away from direct sunlight, fluorescent lighting, moisture, X-rays and ozone chemicals. Some components used in making these gloves may cause allergic reactions in some users. Immediately discontinue use if reactions are suspected. Discontinue used if reddening or irritation occurs.



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Label (size M)

Examination Vinyl gloves
Powder free, Clear/Non sterile/Latex Free
Ambidextrous vinyl glove for single use only
Size: Medium
LOT Number: EN150610

2015-06-10
 2020-06-10

Manufacturer: Shijiazhuang Wally Plastic CO., Ltd
NO. 78 Tongda Road, Jinzhou City, Hebei, China
Post code: 052260

Recommended Use
 These gloves are only for single use. Wash hands before and after glove use. Change gloves when moving to a new task or after handling soiled clothing. Avoid storing gloves above 140°F (40°C). Gloves should be stored away from direct sunlight, fluorescent lighting, moisture, X-rays and ozone chemicals. Some components used in making these gloves may cause allergic reactions in some users. Immediately discontinue use if reactions are suspected. Discontinue used if reddening or irritation occurs.

Label (size L)

Examination Vinyl gloves
Powder free, Clear/Non sterile/Latex Free
Ambidextrous vinyl glove for single use only
Size: Large
LOT Number: EN150610

2015-06-10
 2020-06-10

Manufacturer: Shijiazhuang Wally Plastic CO., Ltd
NO. 78 Tongda Road, Jinzhou City, Hebei, China
Post code: 052260

Recommended Use
 These gloves are only for single use. Wash hands before and after glove use. Change gloves when moving to a new task or after handling soiled clothing. Avoid storing gloves above 140°F (40°C). Gloves should be stored away from direct sunlight, fluorescent lighting, moisture, X-rays and ozone chemicals. Some components used in making these gloves may cause allergic reactions in some users. Immediately discontinue use if reactions are suspected. Discontinue used if reddening or irritation occurs.

Label (size XL)

Examination Vinyl gloves
Powder free, Clear/Non sterile/Latex Free
Ambidextrous vinyl glove for single use only
Size: X-Large
LOT Number: EN150610

2015-06-10
 2020-06-10

Manufacturer: Shijiazhuang Wally Plastic CO., Ltd
NO. 78 Tongda Road, Jinzhou City, Hebei, China
Post code: 052260

Recommended Use
 These gloves are only for single use. Wash hands before and after glove use. Change gloves when moving to a new task or after handling soiled clothing. Avoid storing gloves above 140°F (40°C). Gloves should be stored away from direct sunlight, fluorescent lighting, moisture, X-rays and ozone chemicals. Some components used in making these gloves may cause allergic reactions in some users. Immediately discontinue use if reactions are suspected. Discontinue used if reddening or irritation occurs.

Label (size XXL)

Examination Vinyl gloves
Powder free, Clear/Non sterile/Latex Free
Ambidextrous vinyl glove for single use only
Size: XX-Large
LOT Number: EN150610

2015-06-10
 2020-06-10

Manufacturer: Shijiazhuang Wally Plastic CO., Ltd
NO. 78 Tongda Road, Jinzhou City, Hebei, China
Post code: 052260

Recommended Use
 These gloves are only for single use. Wash hands before and after glove use. Change gloves when moving to a new task or after handling soiled clothing. Avoid storing gloves above 140°F (40°C). Gloves should be stored away from direct sunlight, fluorescent lighting, moisture, X-rays and ozone chemicals. Some components used in making these gloves may cause allergic reactions in some users. Immediately discontinue use if reactions are suspected. Discontinue used if reddening or irritation occurs.

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End of Report



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