

## Test Report

No.: SHHL1602007863MD-02

Date: APR. 08, 2016

Page: 1 of 8

SHIJIAZHUANG HONGRAY GROUP CO., LTD

SOUTH TONGDA RD., EAST DIST. JINZHOU CITY, HEBEI, 052260, CHINA

THE TEST REPORT IS TO SUPERSEDE THE TEST REPORT No.: SHHL1602007863MD-01

DATE: APR. 06, 2016

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

Sample Description : DISPOSABLE VINYL GLOVE  
Style/ Item No. : XS,S,M,L,XL  
Country of Origin : CHINA  
Sample Receiving Date : FEB. 29, 2016  
Testing Period : FEB. 29, 2016 TO MAR. 28, 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 CLAUSE 4.4 & 4.6  
Test Result(s) : FOR FURTHER DETAILS, PLEASE REFER TO THE  
FOLLOWING PAGE(S)  
Conclusion : THE SUBMITTED SAMPLE MET THE TEST REQUIREMENT.

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



Vincent Feng  
Technical Manager



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

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### 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  
 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

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

Number of test sample : 91 Pieces  
 Type : examination/procedure gloves  
 The manufacturing batch code : /  
 Size : XS, S, M, L, XL  
 Defects observed before testing : No defects  
 Test Result : Pass

Clause	Test Items	Result	Note
4	Dimensions	Pass	#3
5	Strength	Pass	#1&4
7	Labeling	Pass	/



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

Number of test sample : 5 Pieces  
 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
4.4	Powder	Pass	#1, 5&6
4.6	Labeling	Pass	/

#### Note:

- As per client's declare, these gloves (four size: XS, S, M, L, XL) only size different, the material is the same, and only the glove of size M was tested.
- See result 1.
- See result 2.
- See result 3.
- Test according to EN ISO 21171-2006.
- The powder of sample was 0.4mg < 2mg.



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## Test Results:

### 1. Watertightness test for detection of holes

Sample Quantity: 200pcs

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

### 2. Dimensions

Sample Quantity: 65pcs

Size	XS												
Length(mm)	243	244	243	244	242	242	245	244	243	242	244	243	242
Width(mm)	78	77	76	77	78	77	76	78	78	76	77	76	77

Median value:

Length (mm): 243

Width (mm): 77

Size	S												
Length(mm)	246	245	246	245	245	247	246	245	244	243	244	242	245
Width(mm)	88	87	86	85	85	86	87	88	87	85	86	85	86

Median value:

Length (mm): 245

Width (mm): 86

Size	M												
Length(mm)	248	248	249	248	247	248	249	249	250	248	247	246	247
Width(mm)	96	95	97	96	97	96	95	96	95	97	96	95	96

Median value:

Length (mm): 248

Width (mm): 96

Size	L												
Length(mm)	243	242	243	242	242	242	243	244	243	244	243	242	243
Width(mm)	106	105	106	104	105	106	107	106	105	106	107	105	104

Median value:

Length (mm): 243

Width (mm): 106



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Size	XL												
Length(mm)	255	252	254	252	254	253	252	254	253	252	253	254	253
Width(mm)	117	118	115	117	116	118	117	116	115	116	117	118	117

Median value:

Length (mm): 253

Width (mm): 117

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



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## 3. Strength

Sample Quantity: 26pcs

Size	M												
Force at break(N)	4.50	4.84	4.57	4.49	4.91	4.48	4.45	4.37	4.74	4.78	4.89	4.80	4.65
Force at break after challenge testing(N)	4.75	4.61	4.54	4.79	4.82	4.76	4.75	4.82	4.38	4.61	4.78	4.69	4.65

Median value:

Force at break during shelf life (N): 4.65

Force at break after challenge testing (N): 4.75

Table 3 — Median values of force at break

	Force at break in Newton		
	Surgical gloves a)	Examination/procedure gloves	
		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).			

Remark:

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



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### Sample Photo:

Received sample (size XS)



Received sample (size S)



Received sample (size M)



Received sample (size L)



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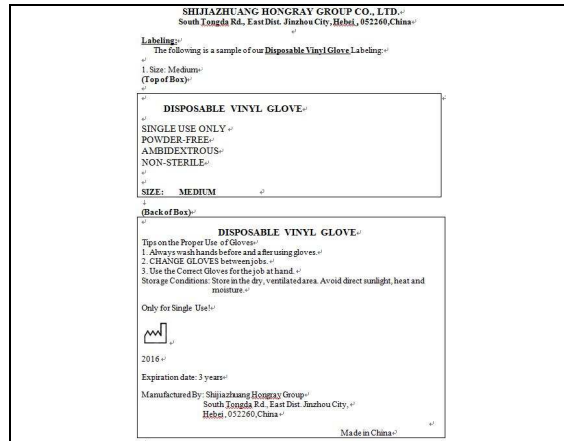
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