

## Test Report

No.: SHHL1609054992MD

Date: OCT. 13, 2016

Page: 1 of 6

SHANDONG INTCO MEDICAL PRODUCTS CO., LTD

QIWANG ROAD, NAOSHAN INDUSTRY PARK, QINGZHOU, SHANDONG, CHINA

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

Sample Description : DISPOSABLE NITRILE MEDICAL EXAMINATION GLOVES  
 SGS Ref. No. : QDHL1609006834OT  
 Style/ Item No. : S、M、L、XL  
 Sample Receiving Date : SEP. 18, 2016  
 Testing Period : SEP. 18, 2016 TO OCT. 13, 2016  
 Test Performed : SELECTED TEST(S) AS REQUESTED BY APPLICANT  
 Test Requested : EN 455-2-2015 MEDICAL GLOVES FOR SINGLE USE – PART 2:  
 REQUIREMENTS AND TESTING FOR PHYSICAL PROPERTIES  
 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



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### Test Conducted

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

Number of test sample	:	78 pcs
Type	:	examination/procedure gloves
The manufacturing batch code	:	/
Size	:	S, M, L, XL
Defects observed before testing	:	No defect
Test Result	:	Pass

Clause	Test Items	Result	Note
4	Dimensions	Pass	#1
5	Strength	Pass	#2, #3
7	Labeling	N/C	#4

Notes : # 1 See result 1  
# 2 See result 2  
# 3 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.  
# 4 N/C means not conducted as per client's requirement.



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## Test Result:

### 1. Dimensions

Sample Quantity: 52 pcs

Size	S												
Length(mm)	242	240	241	245	241	241	242	240	242	240	240	242	240
Width(mm)	85	85	86	86	85	86	86	86	85	85	85	84	85

Median value:

Length (mm): 241

Width (mm): 85

Size	M												
Length(mm)	244	243	240	243	245	243	241	240	244	245	240	244	246
Width(mm)	98	97	98	98	96	97	98	97	98	98	98	98	98

Median value:

Length (mm): 243

Width (mm): 98

Size	L												
Length(mm)	243	247	249	250	245	245	247	253	250	250	243	250	245
Width(mm)	105	109	106	109	107	108	107	108	103	108	108	108	105

Median value:

Length (mm): 247

Width (mm): 108

Size	XL												
Length(mm)	250	256	250	258	255	250	265	252	250	250	248	252	260
Width(mm)	117	117	115	120	117	117	117	118	117	116	114	117	117

Median value:

Length (mm): 252

Width (mm): 117

Requirements: see table 1&2



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**Table 1 Dimensions for surgical gloves**

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

**Table 2 Dimensions for  
examination/procedure gloves**

Size	Median length in mm	Median width in mm
Extra small	$\geq 240$	$\leq 80$
Small		$80 \pm 10$
Medium		$95 \pm 10$
Large		$110 \pm 10$
Extra Large		$\geq 110$



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### 2. Strength

Sample Quantity: 26 pcs

Size	M												
Force at break(N)	7.279	3.922	4.901	7.438	4.688	8.478	5.367	3.436	7.098	8.918	7.871	8.763	4.397
Force at break after challenge testing(N)	5.736	5.594	6.649	3.298	5.874	3.306	7.962	8.171	8.004	8.092	6.803	8.964	10.89

Median value:

Force at break during shelf life (N): 7.098

Force at break after challenge testing (N): 6.803

Requirements: see table 3

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).			



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### Sample Photo:

Received sample (Size S)



Received sample (Size M)



Received sample (Size L)



Received sample (Size XL)



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\*\*\*End of Report\*\*\*



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# Test Report

No.: QDHL1909015461OT

Date: SEP.25,2019

Page: 1 of 3

SHANDONG INTCO MEDICAL PRODUCTS CO., LTD

NO.9888, QIWANG ROAD, NAOSHAN INDUSTRY PARK, QINGZHOU, SHANDONG, CHINA

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

Sample Description : METRO/MAKRO PROFESSIONAL NITRILE GLOVES, NON-POWDERED, BLUE

Sample Receiving Date : SEP.12,2019

Testing Period : SEP.12,2019 TO SEP.25,2019

Test Performed : SELECTED TEST(S) AS REQUESTED BY APPLICANT

Test Requested : EN 455-2-2015 MEDICAL GLOVES FOR SINGLE USE – PART 2: REQUIREMENTS AND TESTING FOR PHYSICAL PROPERTIES

Test Result(s) : PLEASE REFER TO THE FOLLOWING PAGE(S)

Conclusion : THE SUBMITTED SAMPLE MET THE TEST REQUIREMENT.

Remark: Unless otherwise stated the results shown in this test report refer only to the sample(s) tested.

SGS-CSTC Standards  
Technical Services (Qingdao)  
Co., Ltd.




Zhou Xinkuan, SK  
Lab Manager



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# Test Report

No.: QDHL1909015461OT

Date: SEP.25,2019

Page: 2 of 3

## Test Conducted:

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

Number of test sample	:	26 Pieces
The type of gloves	:	examination/procedure gloves c)
Manufacturing batch code	:	/
Size	:	Examination/procedure gloves: M
Defects observed before testing	:	No defects

Clause	Test Items	Result	Note
5	Strength	---	---
5.2	Force at break	Pass	# 1
5.3	Force at break after challenge testing	Pass	# 1

Notes : #1 See result 1

## Test Result:

### 1. Strength

Sample Quantity: 13pcs

Size	M												
Force at break(N)	7.8	8.5	8.0	9.0	9.4	8.9	6.8	7.1	8.2	8.9	8.3	8.6	8.4
Force at break after challenge testing(N)	7.8	7.6	8.3	7.6	6.5	6.1	8.4	7.4	6.8	6.8	8.5	7.2	6.0

Median value:

Force at break during shelf life (N): 8.4

Force at break after challenge testing (N): 7.4



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## Test Report

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Date: SEP.25,2019

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Requirements: see table 3

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).			

### Sample Photo:

Received sample



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Material and Engineering Laboratory-Kaohsiung

## Test Report



Report No. : KV-18-11251

Page No. : 1 OF 2

Date of Report : Dec. 25, 2018

**Shandong Intco Medical Products Co., Ltd.**

**No.9888, Qiwang Road, Naoshan Industry Park, Qingzhou, Shandong, China**

**Product Name** Disposable Nitrile Glove (QDHL1811025521OT)

**Date of Sample Received** Dec. 10, 2018

**Date of Testing** Dec. 10, 2018~Dec. 25, 2018

**Remark** The information mentioned in the above section is provided  
by Client(Exclude Date of Sample Received and Date of Testing)

=====

The laboratory tests according to the test requests and samples provided by client, and the results are as follows:


Test Request : Aqueous Extractable Protein

Test Method : Refer to BS EN 455-3:2015 Medical gloves for single use —  
Part 3 : Requirements and testing for biological evaluation

Test Result : Please see attached pages

----- 1 -----

The required specification(s) offered in this test report is/are for reference only.  
The conformity judgment is at the Applicant's final verdict.

  
Signed for and on behalf of  
SGS Taiwan Ltd.

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## Test Report



Report No. : KV-18-11251

Page No. : 2 OF 2

Date of Report : Dec. 25, 2018

### Test Equipment :

Name	Brand	Model
UV-VISIBLE Spectrophotometer	SHIMADZU	UV-1700

### Lab. Environmental Conditions:

Ambient Temperature :  $(25 \pm 2) ^\circ\text{C}$

Relative humidity :  $(50 \pm 10) \%$

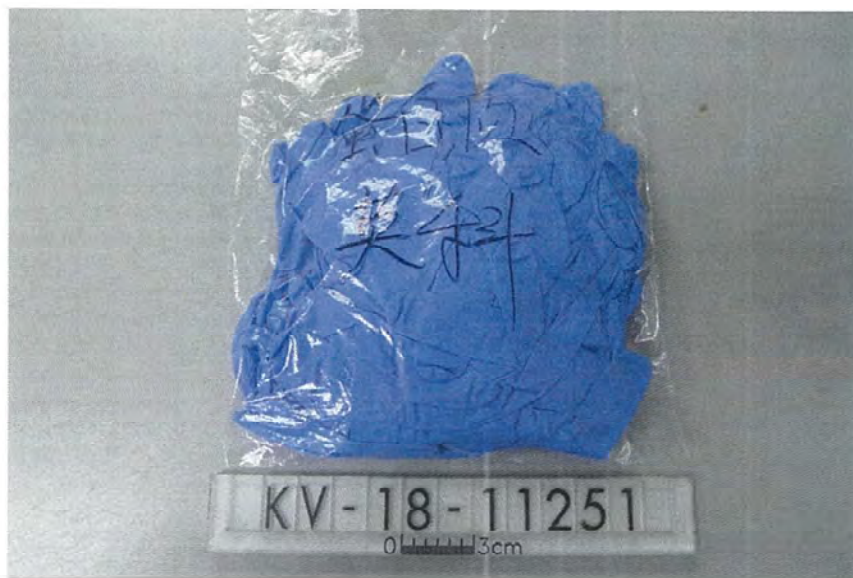
### Test Result :

INSPECTION ITEM	TEST RESULT
Aqueous Extractable Protein (ppm)	n.d.

Note: 1. n.d. = not detected.

2. MDL (METHOD DETECTION LIMIT):0.2ppm.

### Sample Photo :



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The required specification(s) offered in this test report is/are for reference only.

The conformity judgment is at the Applicant's final verdict.

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**Test Report No. 7191205302-EEC19-WBH**  
**dated 01 Mar 2019**



PSB Singapore

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**SUBJECT:**

Testing of Disposable Nitrile Glove submitted by  
Shandong Intco Medical Products Co., Ltd. on 18 Feb 2019.

**TESTED FOR:**

Shandong Intco Medical Products Co., Ltd  
No. 9888 Qiwan Road  
Naoshan Industry Park, Qingzhou, Shandong, China

**TEST DATE:**

25 Feb 2019

**DESCRIPTION OF SAMPLES:**

S/N	Product Description	Colour	Lot No.	Size	Sample received (pieces)	Manufacturer
1	Disposable Nitrile Glove	Blue	/	M	217	Shandong Intco Medical Products Co., Ltd

Lot size as specified by client: 35,001 to 150,000 pieces

**METHOD OF TEST:**

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



**Laboratory:**  
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**Test Report No. 7191205302-EEC19-WBH**  
dated 01 Mar 2019



PSB Singapore

**RESULTS:**


Sample: Disposable Nitrile Glove, Size M

Table: Results for EN 455-1:2000

Clause	Tests	Requirements	No. of non-compliers allowed (pieces)	Number tested (pieces)	Actual no. of non-compliers found (pieces)	Inferred results
4 5	Freedom from holes	Shall not leak	7	200	0	Passed

**REMARKS:**

1. The manufacturing lot no. was not provided by the client.

  
Yeo Poh Kwang  
Higher Associate Engineer

  
Wong Bee Hui  
Product Manager  
Medical Health Services (NAM)

**APPENDIX:**



Photo : Disposable Nitrile Glove, Size M



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