

Test Report

No.: QDHL1806013113OT

Date: JUN.26,2018

Page: 1 of 2

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 : DISPOSABLE NITRILE GLOVE

SGS Ref. No. : SL218022415598TX

Sample Receiving Date : JUN.19,2018

Testing Period : JUN.19,2018 TO JUN.26,2018

Test Requested
pH Value

Result
Pass

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

Approved by:



Zhou Xinkuan, SK
Lab Manager



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Test Report

No.: QDHL1806013113OT

Date: JUN.26,2018

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Test Result

pH Value

Test Method: According to EN 1413:1998

pH value

Conclusion

Notes:

- Requirement of EN 420:2003+A1:2009: greater than 3.5 and less than 9.5

Sample Description : (A) Disposable nitrile glove: in purple
(B) Disposable nitrile glove: in white
(C) Disposable nitrile glove: in black

Sample Photo:



SGS authenticate the photo on original report only

End of Report



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SUBJECT Microbiological Analysis

TEST LOCATION TÜV SÜD China

TÜV SÜD Products Testing (Shanghai) Co., Ltd.
B-3/4, No.1999 Du Hui Road, Minhang District
Shanghai 201108, P.R. China

CLIENT NAME Shandong Intco Medical Products Co., Ltd

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

TEST PERIOD 26-Nov-2018~10-Dec-2018

TEST REQUEST Penetration of Phi-X174 Bacteriophage Test - with reference to ISO 16604-2004, BS EN ISO 374-5:2016

Prepared By

(Gao Ju)
Report Drafter

Authorized By



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RECEIPT DATE / TEST DATE

26-Nov-2018/ 26-Nov-2018

THE FOLLOWING SAMPLE(S) WAS/WERE SUBMITTED

BY/ ON BEHALF OF THE CLIENTS AS:

Sample Name: Disposable Nitrile Gloves

Sample Specification: /

Batch No./Date: /

Manufacturer: /

SAMPLE NO.	DESCRIPTION	PHOTOGRAPH
721642857-2	Gloves	

TEST METHOD(S)

Penetration of Phi-X174 Bacteriophage Test

- in accordance with BS EN ISO 374-5:2016 Protective gloves against dangerous chemicals and micro-organisms Part 5: Terminology and performance requirements for micro-organisms risks, 5.3 Protection against viruses. Test method with reference to ISO 16604-2004 Clothing for protection against contact with blood and body fluids -Determination of resistance of protective clothing materials to penetration by blood-borne pathogens — Test method using Phi-X174 bacteriophage

REQUIREMENT

- Exposure Procedure: B

Sampling Size: 75mm×75mm

Negative control: Polyethylene material

Positive control: 0.04 µm microporous membrane

Prior to testing, condition all test specimens and controls for a minimum of 24 hours at (21±5)°C and 30%~80% relative humidity.

TEST ORGANISM(S)

Bacteriophage ATCC 13706-B1

PROCEDURE

1. Compatibility testing
 - 1.1. Test three specimens representing each material type to be tested.
 - 1.2. With the sterile cell placed horizontally on the laboratory bench, insert the specimen in the test cell with the back of the hand and the palm of the hand toward the cell reservoir.
 - 1.3. Assemble the test cell. Torque the bolts in the test cell to 13.6 N·m each.

- 1.4. With the cell remaining in the horizontal position on the laboratory bench, place a 2.0 µL aliquot of the Phi-X174 bacteriophage in bacteriophage nutrient broth, containing a total of 900-1200 PFU, near the middle of each piece of test specimen.
 - 1.5. Prepare a control by adding a 2.0 µL aliquot from the same suspension directly into 5.0 mL of sterile bacteriophage nutrient broth.
 - 1.6. After 60 min, quantitatively assay by adding 5.0mL of sterile bacteriophage nutrient broth onto the surface of the specimen.
 - 1.7. Calculate the ratio of the control assay titer to the test material assay titer using the following equation:
$$\text{ratio} = \frac{\text{control assay titer (PFU/mL)}}{\text{test material assay titer (PFU/mL)}} = 1.1$$
 - 1.8. Record the initial titer of the Phi-X174 bacteriophage challenge suspension used for the test . ($(2 \pm 1) \times 10^8$ PFU/mL times the ratio calculated.)
2. Test procedure
- 2.1. Prepare the bacteriophage challenge suspension (40-44 mN/m) for the test.
 - 2.2. With the sterile cell placed horizontally on the laboratory bench, insert the specimen in the test cell with the back of the hand and the palm of the hand toward the cell reservoir.
 - 2.3. Assemble the test cell. Torque the bolts in the test cell to 13.6 N·m each.
 - 2.4. Mount the test cell in the test apparatus in a vertical position and close the drain valve.
 - 2.5. Penetration test: If liquid appears to penetrate through the test specimens at anytime during the test, terminate the test.
 - (1) Carefully fill the test cell reservoir with approximately 60 mL of the Phi-X174 bacteriophage challenge suspension
 - (2) Step1: Observe for 5 min at 0 psi.
Step2: Slowly increase the pressure to 2.0 psi at the rate of no more than 0.5 psi/s, keep the pressure at 2.0 psi, observe for 1 min.
Step3: Slowly decrease the pressure to 0 psi at the rate of no more than 0.5 psi/s, observe for 54 min.
 - (3) At the end of the time period, open the drain valve and drain the test cell of the bacteriophage challenge suspension. Dilute and assay the bacteriophage concentration.
 - 2.6. Specimen surface assay procedure
 - (1) With the sterile cell placed horizontally on the laboratory bench. Slowly add 5.0 mL of sterile bacteriophage nutrient broth onto the exposed surface of the specimen.
 - (2) Gently swirl the test cell for approximately 1 min. Assay the liquid soon after collecting.
 - 2.7. Remove the specimen from the test cell and prepare the test cell for sterilization.
3. Test controls
- 3.1. The negative control was negative for bacteriophage penetration.
 - 3.2. The positive control was positive for bacteriophage penetration.
 - 3.3. Record the final titer of the bacteriophage challenge at the conclusion of the 60 min test.



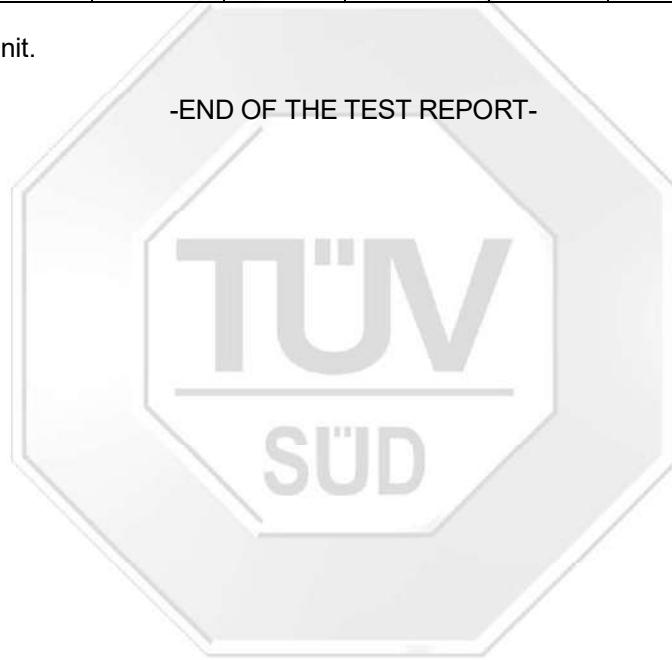
TEST RESULT(S)

Test Items		Initial titer PFU/ml	Final titer PFU/ml	Test Results				
				Step1	Step2	Step3	Assay titer (PFU/ml)	Pass/Fail
Penetration of Phi-X174 Bacteriophage	Control(+)	1.6x10 ⁸	1.5x10 ⁸	None Seen	Seen	-	-	Acceptable
	Control(-)	1.6x10 ⁸	1.5x10 ⁸	None Seen	None Seen	None Seen	<1	Acceptable
	-1	1.6x10 ⁸	1.5x10 ⁸	None Seen	None Seen	None Seen	<1	Pass
	-2	1.6x10 ⁸	1.5x10 ⁸	None Seen	None Seen	None Seen	<1	Pass
	-3	1.6x10 ⁸	1.5x10 ⁸	None Seen	None Seen	None Seen	<1	Pass

Note:

PFU: Plaque Forming Unit.

-END OF THE TEST REPORT-





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TESTING
CNAS L0604

Test Report

No. SL218023033763TX

Date: Dec 13, 2018

Page 1 of 5

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 on behalf of the client as:

Sample Description : (A) Disposable nitrile glove: in blue
(B) Disposable nitrile glove: in purple
(C) Disposable nitrile glove: in white
(D) Disposable nitrile glove: in black

SGS Internal Ref.No. : QDHL1812026344OT

Test Performed : Selected test(s) as requested by applicant against:
EN 420:2003+A1:2009

* * * *

Sample Receiving Date : Dec 07, 2018

Testing Period : Dec 07, 2018- Dec 13, 2018

Test Result(s) : Unless otherwise stated the results shown in this test report refer only to the sample(s) tested. For further details, please refer to the following page(s).

Summary of test results:

Chemical tests

(A)
pH Value Pass

EN 420:2003+A1:2009

(A)	Test	Result	Level of performance
5.1 & 6.1 Sizing (mm)		See Result	-
5.2 & 6.2 Dexterity		5	5
(B)	Test	Result	Level of performance
5.2 & 6.2 Dexterity		5	5
(C)	Test	Result	Level of performance
5.2 & 6.2 Dexterity		5	5
(D)	Test	Result	Level of performance
5.2 & 6.2 Dexterity		5	5

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

Tina Cui

Tina Cui (Account Executive)



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Test Report

No. SL218023033763TX

Date: Dec 13, 2018

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Test Result

● Chemical test

pH Value

Test Method: According to ISO 3071:2005; 0.1 mol/l KCL extraction

pH value

Conclusion

Result

(A)

7.5

Pass

Note:

- Requirement of EN 420:2003+A1:2009: greater than 3.5 and less than 9.5



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Clause 5.1.2 & 6.1 Sizing

(A)

Size of glove	Length of glove (mm)	Requirement	Conclusion
XS	230	-	-
S	240	-	-
M	243	-	-
L	242	-	-
XL	252	-	-

Note: Sizes of hands (reference only)

Hand size	Hand circumference (20 mm from the crotch between thumb and index finger)	Hand length (mm)
6	152	160
7	178	171
8	203	182
9	229	192
10	254	204
11	279	215

Note: Sizes of gloves

Glove size	Fit	Minimum length of glove
6	Hands size 6	220
7	Hands size 7	230
8	Hands size 8	240
9	Hands size 9	250
10	Hands size 10	260
11	Hands size 11	270

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Clause 5.2 Dexterity
(A)

Specimen	Smallest diameter of pin fulfilling test conditions (mm)	Level of performance (#)
1	5	5
2	5	
3	5	
4	5	

(B)

Specimen	Smallest diameter of pin fulfilling test conditions (mm)	Level of performance (#)
1	5	5
2	5	
3	5	
4	5	

(C)

Specimen	Smallest diameter of pin fulfilling test conditions (mm)	Level of performance (#)
1	5	5
2	5	
3	5	
4	5	

(D)

Specimen	Smallest diameter of pin fulfilling test conditions (mm)	Level of performance (#)
1	5	5
2	5	
3	5	
4	5	

Remark: # = The performance level is defined as the smallest diameter of pin that can be picked up.

Note: Levels of performance – finger dexterity test

Level of performance	Smallest diameter of pin fulfilling test condition (mm)
1	11
2	9.5
3	8
4	6.5
5	5



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Sample Photo



*** End of Report ***



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TEST REPORT

Report No. : CH:TX:6420076491

DATE : 24/12/2015



QDHG1511005851CO

SHANDONG INTCO MEDICAL PRODUCTS CO., LTD.
QIWANG ROAD, NAOSHAN INDUSTRIAL PARK. QINGZHOU,
SHANDONG,
P.R.CHINA
A/C SGS-CSTC HARDGOODS SERVICES.,
CONTACT PERSON : --

THE FOLLOWING SAMPLE(S) WAS/WERE SUBMITTED AND IDENTIFIED BY/ON BEHALF OF THE CUSTOMER AS :

SAMPLE DESCRIPTION GLOVES
NITRILE GLOVES

PHOTO APPENDIX.



SAMPLE RECD ON 22/12/2015 TESTING PERIOD : 22/12/2015 - 24/12/2015

Summary of Test Results

Test Method	Test Name	Status / Performance Level
EN 374-1:2003	Minimum Liquid Proof Length	
	Size XS,S,M,L,XL	Pass

Per pro SGS India Private Ltd.

K. Pachaiyappan

K. PACHAIYAPPAN
SECTION INCHARGE

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TEST REPORT

Report No. : CH:TX:6420076491

DATE : 24/12/2015



QDHG1511005851CO

RESULTS

EN 374-1 : 2003 Protective Gloves against Chemicals and Micro Organisms – Minimum Liquid Proof Length

Clause	Test Name	Result		Average	Requirements as per EN 420: 2003 (5.1.2)	Status
5.1	Minimum Length of Glove Declared Size XS	242	235	238.5	Min : 220 mm	Pass
	Declared Size S	242	241	241.5	Min : 230 mm	Pass
	Declared Size M	240	240	240.0	Min : 240 mm	Pass
	Declared Size L	253	255	254.0	Min : 250 mm	Pass
	Declared Size XL	260	261	260.5	Min : 260 mm	Pass

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

TEST REPORT

Report No. : CH:TX:6420074520

DATE : 19/12/2015



QDHG1512006001OT

SHANDONG INTOCO MEDICAL PRODUCTS CO., LTD.
QIWANG ROAD, NAOSHAN INDUSTRIAL PARK. QINGZHOU,
SHANDONG,
P.R.CHINA
A/C SGS-CSTC HARDGOODS SERVICES.,
CONTACT PERSON : --

THE FOLLOWING SAMPLE(S) WAS/WERE SUBMITTED AND IDENTIFIED BY/ON BEHALF OF THE CUSTOMER AS :

SAMPLE DESCRIPTION GLOVES
NITRILE GLOVES
COLOUR BLUE
PHOTO APPENDIX.



SAMPLE RECD ON

14/12/2015

TESTING PERIOD : 14/12/2015 - 19/12/2015

Summary of Test Results

Test Method	Test Name	Status / Performance Level
EN 420 : 2003+A1: 2009	General requirements and test methods	
	Sizing	Refer enclosed pages
	Dexterity	Performance Level 5
	pH Value	Pass

Per pro SGS India Private Ltd.



K. PACHAIYAPPAN
SECTION INCHARGE

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TEST REPORT

Report No. : CH:TX:6420074520

DATE : 19/12/2015



QDHG1512006001OT

RESULTS

EN 420 : 2003+A1: 2009 Protective Gloves – General requirements and test methods

Clause	Test Name	Result				Average	Standard sizing
5.1	Sizing Declared size XS						
	Circumference (mm)	159	157			158.0	6
	Length (mm)	240	242			241.0	
	Declared size S						
	Circumference (mm)	171	173			172.0	6½
	Length (mm)	239	245			242.0	
	Declared size M						
	Circumference (mm)	197	199			198.0	7½
	Length (mm)	244	242			243.0	
	Declared size L						
	Circumference (mm)	217	219			218.0	8½#
	Length (mm)	246	243			244.5	
	Declared size XL						
	Circumference (mm)	237	239			238.0	9
	Length (mm)	256	260			258.0	
5.2	Dexterity Smallest Pin Diameter (mm)	5	5	5	5	5	Performance level 5

--> Fit for special purpose

pH VALUE

With reference to ISO 3071:2005/Analysis by pH meter

Extraction Solution : KCL

NITRILE GLOVES – BLUE

Value 6.9

3.5 - 9.5

Note : pH value of extraction medium : 5.0 – 7.5

Temperature of the extraction solution : 25±2°C

Note: Requirements given as per EN 420:2003 +A1:2009 (Clause: 4.3.2).

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