PRODUCT SPECIFICATION

Nitrile medical Gloves 3.5g (textured on half of finger)

SECTION 1: PRODUCT DESCRIPTION

1.1	Type	Nitrile medical Gloves Powder Free, Non-sterile
1.2	Material	1.Nitrile Polymers98% 2.Others 2%
1.3	Color	Violet / blue
1.4	Design and Features	Ambidextrous, textured on half of finger, beaded cuff
1.5	Powder	No powder lubricant added
1.6	Storage Conditions	5℃-35℃
1.7	Shelf-life	5 years from the date of manufacture with the above storage conditions.
1.8	Packing Style	100 pcs gloves* 10 boxes * 1 carton

SECTION 2: PERFORMANCE SPECIFICATION

2.1. Dimensions

	X-SMALL	SMALL	MEDIUM	LARGE	X-LARGE	TOLERANCE
Length (mm)	240	240	240	240	240	±5
Width of palm (mm)	75	85	95	105	114	±3
Weight per pc (g)	2.9	3.2	3.5	3.8	4.1	±0.2
Thickness of finger tip (mm)	0.08	0.08	0.08	0.08	0.08	±0.0.3
Thickness of palm (mm)	0.07	0.07	0.07	0.07	0.07	±0.0.3
Thickness of cuff (mm)	0.06	0.06	0.06	0.06	0.06	±0.0.3

2.2. Physical Properties

Description	Standard	
	Before Aging	After Aging
Elongation at Break (%)	≥ 500 %	≥ 400%
Tensile Strength (MPa)	≥ 14 MPa	≥ 14 MPa

201208153675

Test Report No. 20218965983ZH
dated 30 Apr 2023

Note: Note: This report is issued in accordance with the certification regulations of MB company and the general terms and conditions of business of MB private limited. In addition, this report is governed by the provisions set out in this report

SUBJECT

Testing of Gloves

CLIENT

Hebei Titans Hongsen Medical Technology Co.,Ltd

Eastern Industrial Zone，Nangong City, Xingtai City. Hebei Province, China

SAMPLE SUBMISSION DATE/ TEST DATE

16 Apr 2023 to 30 Apr 2023

DESCRIPTION OF SAMPLES

S/N	Product Description	Brand/ Model	Size	Colour	Lot No.	Expiry Date	Sample Received (pieces)	Manufacturer
1	Disposable Powder Free Nitrile Gloves (Blue)	--------	S	Blue	20230316	20250315	100	Hebei Titans Hongse Medical Technology Co.,Ltd
			M				100	
			L				100	

China Regional Office:
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TEL:0519-86380918
Email: Info@mbgls.com

Sweden Regional office:
MB Global Service AB
Prastgatan 68, 111 29 Stockholm, Sweden

METHOD OF TEST

The tests were conducted in accordance with the following test standards:

BS EN ISO 21420:2020 Protective gloves – General requirements and test methods
- Clause 4.2c pH value
- Clause 5.1 Sizing and measurement of gloves
- Clause 5.2 Dexterity

RESULTS

Sample: Disposable Powder Free Nitrile Gloves, Blue

<table>
<tr><th>Test</th><th colspan="2">BS EN ISO 21420: 2020 Requirements</th><th colspan="2">Results</th><th>Inferred Results</th></tr>
<tr><td>I. Determination of pH Value, pH value</td><td colspan="2">> 3.5 and < 9.5</td><td colspan="2">8.2</td><td>Passed</td></tr>
<tr><td rowspan="4">II. Sizing, minimum length of glove (mm)</td><td colspan="2" rowspan="4">-</td><td>Size</td><td>Results</td><td rowspan="4">(see remark 2)</td></tr>
<tr><td>S</td><td>245</td></tr>
<tr><td>M</td><td>245</td></tr>
<tr><td>L</td><td>250</td></tr>
<tr><td rowspan="6">III. Dexterity, level of performance</td><td>Level of performance</td><td>Smallest pin diameter fulfilling test conditions (mm)</td><td>Size</td><td>Results</td><td rowspan="6">(see remark 3)</td></tr>
<tr><td>1</td><td>11</td><td rowspan="2">S</td><td rowspan="2">5</td></tr>
<tr><td>2</td><td>9.5</td></tr>
<tr><td>3</td><td>8</td><td rowspan="2">M</td><td rowspan="2">5</td></tr>
<tr><td>4</td><td>6.5</td></tr>
<tr><td>5</td><td>5</td><td>L</td><td>5</td></tr>
</table>

REMARKS

1. 3 sizes were mixed for pH value as the glove are made from same material.

2. Sizes of gloves are defined with respect to the sizes of the hands they are to fit. If required for specific use (for example, gloves for welders and firefighters), the minimum glove length shall be defined in the relevant specific standards.

3. For Dexterity test, a glove should allow as much dexterity as possible given its purpose.

Afra

Chen Nuo
Associate Engineer

APPENDIX

Photo: Disposable Powder Free Nitrile Gloves,Blue

Please note that this Report is issued under the following terms :

1. This report applies to the sample of the specific product/equipment given at the time of its testing/calibration. The results are not used to indicate or imply that they are applicable to other similar items. In addition, such results must not be used to indicate or imply that MB approves, recommends or endorses the manufacturer, supplier or user of such product/equipment, or that MB in any way " guarantees" the later performance of the product/equipment. Unless otherwise stated in this report, no tests were conducted to de termine long term effects of using the specific product/equipment.
2. The sample/s mentioned in this report is/are submitted/supplied/manufactured by the Client. MB therefore assumes no responsibility for the accuracy of information on the brand name, model number, origin of manufacture, consignment or any information supplied.
3. Nothing in this report shall be interpreted to mean that MB has verified or ascertained any endorsement or marks from any other testing authority or bodies that may be found on that sample.
4. This report shall not be reproduced wholly or in parts and no reference shall be made by the Client to MB or to the report or results furnished by MB in any advertisements or sales promotion.
5. The tests carried out by MB and this report are subject to MB ' s General Terms and Conditions of Business and the Testing and Certification Regulations of the MB Group
6. This test is only responsible for incoming samples.

Test Report No. 7191237186-EEC20/01-WBH
dated 26 May 2020

PSB Singapore

Add value.
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SUBJECT:

Testing of Gloves submitted by Hebei Titans Hongsen Medical Technology Co., Ltd on 30 Apr 2020.

TESTED FOR:

Hebei Titans Hongsen Medical Technology Co., Ltd
Eastern Industrial Zone, Nangong City,
Hebei Province, China

TEST DATE:

15 May 2020 to 26 May 2020

DESCRIPTION OF SAMPLES:

S/N	Product Description	Colour	Lot No.	Size	Sample received (pieces)	Manufacturer
1	Disposable Nitrile Gloves	Blue	2020/04/18	S	5 boxes of 100 pcs for each size	Hebei Titans Hongsen Medical Technology Co., Ltd
2				M		
3				L		
4				XL		

TÜV SÜD PSB

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1 Science Park Drive, #02-01
Singapore 118221

PSB Singapore

METHOD OF TEST:

The tests were conducted in accordance with the following test standards:

EN ISO 374-1:2016 Protective gloves against dangerous chemicals and micro-organisms
Part 1: Terminology and performance requirements for chemical risks

- Clause 5.1 General requirements
  (Test method described in EN 420:2003+A1:2009 Protective gloves – General requirements and test methods)

- Clause 5.2 Penetration
  (Test method described in EN 374-2:2014 Protective gloves against dangerous chemicals and micro-organisms – Part 2: Determination of resistance to penetration)

- Clause 5.3 Degradation
  (Test method described in EN 374-4:2019 Protective gloves against chemicals and micro-organisms. Determination of resistance to degradation by chemicals)

- Clause 5.4 Permeation
  (Test method described in EN 16523-1:2015 Determination of material resistance to permeation by chemicals. Permeation by potentially hazardous liquid chemicals under conditions of continuous contact)

- Clause 6 Marking

- Clause 7 Information supplid by the manufacturer

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RESULTS:

Table 1: Results for tests according to EN ISO 374-1:2016 Clause 5.1-5.4

Sample: Disposable Nitrile Gloves, Lot No. 2020/04/18

Clause	Tests	Specification	Results			Inferred Result
5.1	General Requirement	Protective gloves against dangerous chemicals shall comply with the requirements given in EN 420:2009, Clause 4, Clause 5 and Clause 7.	Refer to Table 3 for results of EN 420:2009, Clause 4, Clause 5 The submitted glove and packaging not tested to EN 420 Clause 7 Marking and information as requested by client.			Complied Not tested
5.2	Penetration	Protective gloves shall not leak when tested according to EN 374-2:2014, 7.2 and 7.3. 7.2 Air leak test 7.3 Water leak test	Size		-	-
			S		No leakage for both tests	Complied
			M		No leakage for both tests	Complied
			L		No leakage for both tests	Complied
			XL		No leakage for both tests	Complied
5.3	Degradation	The degradation (DR) shall be determined according to EN 374-4 for each chemical claimed in the marking and reported in the user instruction. Tested Chemical: 40% Sodium Hydroxide	Degradation Results (%)			NA
			Size S	Glove 1	-35.0	
				Glove 2	-33.4	
				Glove 3	-31.3	
				Average	-33.2	
				Standard Deviation	1.8	
			Size M	Glove 1	-27.4	NA
				Glove 2	9.2	
				Glove 3	1.1	
				Average	-5.7	
				Standard Deviation	19.3	
			Size L	Glove 1	-4.0	NA
				Glove 2	-31.4	
				Glove 3	-31.0	
				Average	-22.1	
				Standard Deviation	15.7	
			Size XL	Glove 1	-15.9	NA
				Glove 2	-24.3	
				Glove 3	-31.6	
				Average	-23.9	
				Standard Deviation	7.8	

RESULTS (cont'd):

Table 1: Results for tests according to ISO 374-1:2016 (cont'd)

Sample: Disposable Nitrile Gloves, Lot No. 2020/04/18

Clause	Tests	Specification	Results		Inferred Result
5.4	Permeation	Each combination of protective glove/test chemical shall be classified according to Table A (see remark 4), using the results as given in EN 16523-1:2015, 8.5.1.1 or 8.5.1.3 for the normalized breakthrough time. Tested Chemical: 40% Sodium Hydroxide	Breakthrough Time (mins)		Complied
			Glove 1	251	
			Glove 2	289	
			Glove 3	251	
			Mean Value	264	
			Lowest Value	251	
			The breakthrough time occurred after 240 mins, the tested glove is classified as Level 5. No color change was observed on the glove test specimen after the test. *The gloves palm area were taken randomly from any size of "S, M, L and XL." Type of glove: Type C The permeation performance at least level 1 against one test chemical		

Table 2: Results for tests according to ISO 374-1:2016 Clause 6 and 7

Clause	Tests	Specification	Results
6	Marking	Protective gloves against dangerous chemicals shall be marked in accordance with the requirements for protective gloves in EN 420 and with the following: 6.3 Marking of Type C gloves (The permeation level shall be at least Class 1 against minimum of one test chemical): The tested chemical shall be identified by its code letter which shall be marked under the pictogram and a reference to ISO 374-1:2016/ Type C.	NT NT
		Inferred results	Not tested

RESULTS (cont'd):

Table 2: Results for tests according to ISO 374-1:2016 Clause 6 and 7 (cont'd)

Sample: Disposable Nitrile Gloves, Lot No. 2020/04/18

Clause	Tests	Specification	Results
7	Labelling	The information supplied by the manufacturer shall be in accordance with the requirements as defined in EN 420 and the following warnings shall be added in the user instructions:	NT
		- "This information does not reflect the actual duration of protection in the workplace and the differentiation between mixtures and pure chemicals."	NT
		- "The chemical resistance has been assessed under laboratory conditions from samples taken from the palm only (except in cases where the glove is equal to or over 400 mm – where the cuff is tested also) and relates only to the chemical tested. It can be different if the chemical is used in a mixture."	NT
		- "It is recommended to check that the gloves are suitable for the intended use because the conditions at the workplace may differ from the type test depending on temperature, abrasion and degradation."	NT
		- "When used, protective gloves may provide less resistance to the dangerous chemical due to changes in physical properties. Movements, snagging, rubbing, degradation caused by the chemical contact etc. may reduce the actual use time significantly. For corrosive chemicals, degradation can be the most important factor to consider in selection of chemical resistant gloves"	NT
		- "Before usage, inspect the gloves for any defect or imperfections."	NT
		For reusable gloves, the manufacturer shall provide the relevant instructions for decontamination.	NT
		If there is no information about decontamination, then it is intended for single use only and the following warning shall be added: "For single use only."	NT
		Inferred result	Not tested

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RESULTS (cont'd):

Table 3: Results for EN 420:2003+A1:2009

Sample: Disposable Nitrile Gloves, Lot No. 2020/04/18

Test	EN 420:2003+A1:2009 Requirements		Results		Inferred Results
I. Determination of pH Value, pH value	Size	> 3.5 and < 9.5	-		-
	S		7.0		Passed
	M		7.0		Passed
	L		7.0		Passed
	XL		7.0		Passed
II. Sizing, minimum length of glove (mm)	Size	Minimum length of glove (mm)	-		-
	S (6)	220	250		Passed
	M (7)	230	250		Passed
	L (8)	240	260		Passed
	XL (9)	250	270		Passed
III. Dexterity, level of performance	Level of performance	Smallest pin diameter fulfilling test conditions (mm)	-		-
	1	11	Size	-	
	2	9.5	S	5	
	3	8	M	5	
	4	6.5	L	5	
	5	5	XL	5	

REMARKS:

1. For Clause 5.2 Penetration, the test sample will be four gloves of each size, with an overall minimum of 16 gloves per performed test (Air leak test and Water leak test). If one sample fails the penetration test, the test shall be reported as having failed.

2. For Clause 5.3 Degradation, the test specimens for each size will be 3 gloves and 6 specimens will be cut from each glove. For each glove, 3 specimens will be exposed to the challenge chemical (40% Sodium Hydroxide) and 3 specimens will be unexposed. After prepare the specimens, and exposed to 40% Sodium Hydroxide for 1 hour, puncture the specimen and record the peak force required.

3. For Clause 5.4 Permeation, The palm area of the glove sample was mounted between two halves of a test cell. The test cell consisted of a two-compartment cell with 40% Sodium Hydroxide on glove's normal outside surface and Ultrapure Water on the glove's normal inside surface. Testing were carried out at ambient temperature (23°C ± 2°C). The collecting medium were sampled and analysed for 40% Sodium Hydroxide at 10 min (level 1), 30 min (level 2), 60 min (level 3), 120 min (level 4) , 240 min (level 5) and 480 min (level 6). The extracts were then analysed by Ion Chromatography. The results were used to calculate the permeation rate of 40% Sodium Hydroxide through the glove material. Based on the result, the minimum rate of sampling was determined. The tests were repeated at 10 min, 30 min, 60 min, 120 min, 240 min and the sampling interval of 11 min and collected until 480 mins. The extracts were then analysed by Ion Chromatography for the Normalised Permeation Rate. A blank test was carried out exactly with the same procedure except Ultrapure Water was used.

   Note: Chemical transfer referred to the quantity of chemical which had passed through per cm^2 of glove sample at the termination of the test. The thickness of the glove is 0.04mm.

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REMARKS (cont'd):

4. Table A Classification of Glove Levels According to Breakthrough Time for Clause 5.4 Permeation

Breakthrough Time (mins) *	Permeation performance level
> 10	1
> 30	2
> 60	3
> 120	4
> 240	5
> 480	6

* The breakthrough time is deemed to have occurred when the analytical equipment detects a permeation rate of 1 $\mu g/cm^2/min$.

5. NA: Not applicable for the submitted sample.

6. NT: Not tested.

Lee Dai Yi
Engineer

Wong Bee Hui
Product Manager
Medical Health Services (NAM)

APPENDIX:

Photo 1: Disposable Nitrile Gloves, Lot No. 2020/04/18

Photo 2: Packaging Artwork

PSB Singapore

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5. Unless otherwise stated, the tests were carried out in TÜV SÜD PSB Pte Ltd, No.1 Science Park Drive Singapore 118221.

July 2011

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	**HEBEI TITANS HONGSEN MEDICAL TECHNOLOGY CO., LTD**
CLIENT ADDRESS	EASTERN INDUSTRIAL ZONE, NANGONG CITY, HEBEI PROVINCE, CHINA
TEST PERIOD	30-Apr-2020~13-May-2020
TEST REQUEST	Penetration of Phi-X174 Bacteriophage Test - with reference to ISO 16604-2004, BS EN ISO 374-5:2016

Prepared By **Authorized By**

Bella Xu
(Bella Xu)
Report Drafter

Leo liu
(Leo Liu)
Authorized Signatory

Note: (1) General Terms & Conditions as mentioned overleaf. (2) The results relate only to the items tested.(3) The test report shall not be reproduced except in full without the written approval of the laboratory.(4) Without the agreement of the laboratory , the client is not authorized to use the test results for unapproved propaganda.

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No.151 Heng Tong Road Shanghai
200 070 P.R.China

RECEIPT DATE / TEST DATE

30-Apr-2020/ 30-Apr-2020

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

Sample Name: Disposable Nitrile Gloves
Batch No./Date: LOT:20/04/18; 2020/04/18
Manufacturer: Hebei Titans Hongsen Medical Technology Co., Ltd

SAMPLE NO.	SAMPLE SPECIFICATION	DESCRIPTION	PHOTOGRAPH
721654161-1	Color: blue Size: S	Gloves	
721654161-2	Color: blue Size: M	Gloves	
721654161-3	Color: blue Size: L	Gloves	
721654161-4	Color: blue Size: XL	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

Chemical/Microbiology Laboratory:
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Regional Head Office:
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No.151 Heng Tong Road Shanghai
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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)℃ 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 laboratry 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±1)x10^8 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 laboratry 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-XI74 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(+)	$1.9x10^8$	$1.9x10^8$	None Seen	Seen	-	-	Acceptable
	Control(-)	$1.9x10^8$	$1.9x10^8$	None Seen	None Seen	None Seen	<1	Acceptable
	721654161 -1①	$1.9x10^8$	$1.9x10^8$	None Seen	None Seen	None Seen	<1	Pass
	721654161 -1②	$1.9x10^8$	$1.9x10^8$	None Seen	None Seen	None Seen	<1	Pass
	721654161 -1③	$1.9x10^8$	$1.9x10^8$	None Seen	None Seen	None Seen	<1	Pass
	721654161 -2①	$1.9x10^8$	$1.9x10^8$	None Seen	None Seen	None Seen	<1	Pass
	721654161 -2②	$1.9x10^8$	$1.9x10^8$	None Seen	None Seen	None Seen	<1	Pass
	721654161 -2③	$1.9x10^8$	$1.9x10^8$	None Seen	None Seen	None Seen	<1	Pass
	721654161 -3①	$1.9x10^8$	$1.9x10^8$	None Seen	None Seen	None Seen	<1	Pass
	721654161 -3②	$1.9x10^8$	$1.9x10^8$	None Seen	None Seen	None Seen	<1	Pass
	721654161 -3③	$1.9x10^8$	$1.9x10^8$	None Seen	None Seen	None Seen	<1	Pass
	721654161 -4①	$1.9x10^8$	$1.9x10^8$	None Seen	None Seen	None Seen	<1	Pass
	721654161 -4②	$1.9x10^8$	$1.9x10^8$	None Seen	None Seen	None Seen	<1	Pass
	721654161 -4③	$1.9x10^8$	$1.9x10^8$	None Seen	None Seen	None Seen	<1	Pass

Note:
1.PFU: Plaque Forming Unit.
2.This report is for internal use only such as internal scientific research ,education, quality control, product R&D.

-END OF THE TEST REPORT-

Chemical/Microbiology Laboratory:
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TÜV SÜD Certification and Testing (China) Co., Ltd.
No.151 Heng Tong Road Shanghai
200 070 P.R.China

Test Report

No.: QDHL2005003787MD_EN Date: MAY.21,2020 Page: 1 of 5

Client name	:	HEBEI TITANS HONGSEN MEDICAL TECHNOLOGY CO.,LTD.
Client address	:	EASTERN INDUSTRIAL ZONE, NANGONG CITY, XINGTAI CITY, HEBEI, CHINA
Sample Description	:	SINGLE-USE NITRILE PATIENT EXAMINATION GLOVES (THIN)
Lot No.	:	NOT PROVIDED
Lot Size	:	NOT PROVIDED
Sample Quantity	:	S: 200PCS, M: 200PCS, L: 200PCS, XL: 200PCS
Style/ Item No.	:	S, M, L, XL
Manufacture	:	HEBEI TITANS HONGSEN MEDICAL TECHNOLOGY CO.,LTD.
Country of Origin	:	CHINA
Country of Destination	:	EUROPE & USA

As above test item and its relevant information regarding to the submission are provided and confirmed by the applicant. SGS is not liable to either the test item or its relevant information, in terms of the accuracy, suitability, reliability or/and integrity accordingly.

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Sample Receiving Date	:	MAY.06,2020
Test Performing Date	:	MAY.06,2020 TO MAY.21,2020
SGS Ref. No.	:	TJHL2004002165MD

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Test Requested	Result
1. BS EN 455-1:2000 MEDICAL GLOVES FOR SINGLE USE – PART 1: REQUIREMENTS AND TESTING FOR FREEDOM FROM HOLES (CLAUSE 5.1) (FOR SIZE S ONLY)	Pass
2. BS EN 455-2:2015 MEDICAL GLOVES FOR SINGLE USE – PART 2: REQUIREMENTS AND TESTING FOR PHYSICAL PROPERTIES (CLAUSE 4.2, 4.3) (FOR SIZE L ONLY)	Pass
3. BS EN 455-2:2015 MEDICAL GLOVES FOR SINGLE USE – PART 2: REQUIREMENTS AND TESTING FOR PHYSICAL PROPERTIES (CLAUSE 5.2, 5.3) (FOR SIZE XL ONLY)	Pass
4. BS EN 455-3:2015 MEDICAL GLOVES FOR SINGLE USE—PART 3: REQUIREMENTS AND TESTING FOR BIOLOGICAL EVALUATION (CLAUSE 4.4) (FOR SIZE M ONLY)	Pass

Remark: - Unless otherwise stated the results shown in this test report refer only to the sample(s) tested. This document cannot be used for publicity, without prior written approval of the SGS.

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

scan to see the report

QDHL2005003787MD

Jessica Gao
Approved Signatory

Test Conducted:

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

Number of test sample	:	200 Pieces
Sample size	:	S
Number of non-conforming gloves	:	0

Clause	Test Items	Result
5	Watertightness test for detection of holes	---
5.1	Referee testing	Pass (See note 1)

Note : 1 Sample quantity: 200pcs, AQL:1.5, Ac:7, Re:8, Found:0.
The sample selecting amount for this clause is deviated to 200 pcs as assessed by SGS.

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

Number of test sample	:	26 Pieces
Type	:	Examination/procedure gloves b)
Size	:	Examination/procedure gloves: L, XL

Clause	Test Items	Result
4	Dimensions (for size L only)	---
4.2	Length	Pass (See result 1)
4.3	Width	Pass (See result 1)
5	Strength (for size XL only)	---
5.2	Force at break	Pass (See result 2)
5.3	Force at break after challenge testing	Pass (See result 2)

Result 1: Dimensions

Size	L	
No.	Length (mm)	Width (mm)
1	242	108
2	249	109
3	242	109
4	245	108
5	244	109
6	241	109
7	244	109
8	244	109
9	245	109
10	246	109
11	245	109
12	247	110
13	244	110
Standard requirement	≥240	110±10
Median value	244	109

Result 2: Strength

Size: XL			
Force at break (N)			
Before aging		After aging	
No.	/	No.	/
1	8.3	1	7.9
2	7.5	2	7.3
3	8.3	3	8.0
4	7.7	4	7.5
5	7.2	5	6.7
6	7.0	6	6.9
7	8.3	7	7.5
8	8.2	8	7.3
9	8.1	9	7.2
10	7.7	10	7.3
11	8.0	11	7.8
12	7.0	12	6.6
13	7.7	13	7.2
Standard requirement	≥6.0	Standard requirement	≥6.0
Median value	7.7	Median value	7.3

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

Number of test sample	:	5 Pieces
Sample size	:	M
Finishes of gloves	:	Powdered-free gloves other than surgeon's gloves

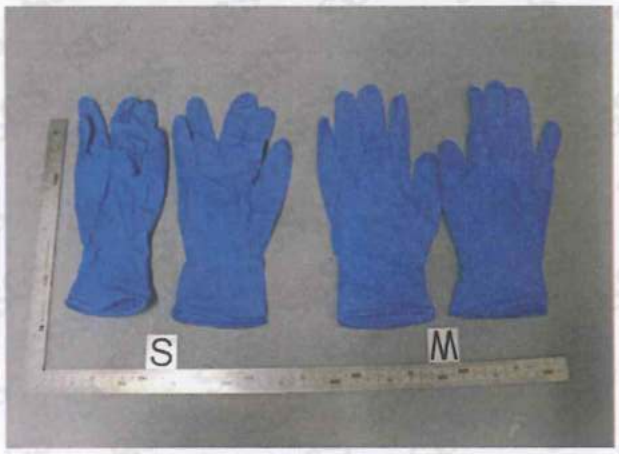
Clause	Test Items	Result
4.4	Powder-free gloves	Pass (See note 1)

Note : 1 Test according to EN ISO 21171:2006, the average mass of powder per glove is 0.10mg. (Requirement: ≤2mg per powder-free glove)

Remark: The declaration of conformity is only based on the actual value of laboratory activity, measurement uncertainty of the results not take into account.

Sample Photo:

Received Sample



Received Sample

SGS authenticate the photo on original report only

End of Report

Inspection report

No:HS001

Company	Hebei Titans Hongsen Medical Technology Co.,Ltd Eastern Industrial Zone, Nangong City, Xingtai City. Hebei Province, China				
Sample information	single use examination nitrile glove ----------				
Nature of inspection	testing	Test start date	9/1/2021	Date of report	12/9/2021
Judgment basis	EN 455-4 2009 《Storage and measurement test and requirements》				
Conclusion of comprehensive test	---				

Inspection and testing

Test items	Judgment basis	determine
pinhole	EN 455-1 2020	qualified
size	EN 455-2 2015	qualified
Breaking strength	EN 455-2 2015	qualified

remarks	The inspection and testing items in this report are carried out under the environmental conditions specified in the corresponding standards (except for those noted). The copy or duplicate is invalid without the confirmation seal of the report.

常州沐邦检测技术有限公司
Changzhou Mubang Testing Technology Co., Ltd
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Room 922, building 72, Xihu garden, No.2, Xihu Road, Wujin national high tech Industrial Development Zone

Sample picture

No:HS001

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Attached page of the first batch inspection report

Test date: 9/1/2021

NO:HS001

Inspection and testing project	requirement	Disqualification allowed (number)	Number of tests (number)	The actual quantity is unqualified (found)	determine	remarks
● pinhole	No leakage	12	500	0	qualified	
project	**Test**	**requirement**	**Number of tests (number)**	**result**	**determine**	**remarks**
● size	length (mm)	≥240	13	243	qualified	
	width (mm)	≥110	13	114	qualified	
● Breaking strength	Breaking force (N)	≥6	13	7.5	qualified	
	After using the breaking force Test (n) 7 days (70 ± 2) Centigrade	≥6	13	7.3	qualified	

1.A total of 3000 samples were selected and divided into 3 batches. The detection cycle was 7 days.

2.The experiment was carried out in our laboratory. The test temperature is 70 ℃ ± 2 ℃ (t he laboratory environment temperature and humidity are controlled)

remarks	(this column is blank)

End of this report

常州沐邦检测技术有限公司
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Attached page of the second batch inspection report

Test date: 9/8/2021

NO:HS001

Inspection and testing project	requirement	Disqualification allowed (number)	Number of tests (number)	The actual quantity is unqualified (found)	determine	remarks
● pinhole	No leakage	12	500	1	qualified	

Inspection and testing project	test	requirement	Number of tests (number)	result	determine	remarks
● size	length (mm)	≥240	13	243	qualified	
	width (mm)	≥110	13	113	qualified	
● Breaking strength	Breaking force (N)	≥6	13	7.2	qualified	
	After using the breaking force Test (n) 7 days (50 ± 2) Centigrade	≥6	13	6.9	qualified	

1. A total of 2800 samples were selected and divided into three batches. The detection cycle was 45 days.
2. The experiment was carried out in our laboratory. The test temperature is 50 ℃ ± 2 ℃ (the laboratory environment temperature and humidity are controlled)

remarks	(this column is blank)

——— End of this report ———

常州沐邦检测技术有限公司
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Attached page of the third batch inspection report

Test date: 10/23/2021

NO: HS001

Inspection and testing project	requirement	Disqualification allowed (number)	Number of tests (number)	The actual quantity is unqualified (found)	determine	remarks
● pinhole	No leakage	12	500	1	qualified	
Inspection and testing project	**test**	**requirement**	**Number of tests (number)**	**result**	**determine**	**remarks**
● size	length (mm)	≥240	13	241	qualified	
	width (mm)	≥110	13	110	qualified	
● Breaking strength	Breaking force (N)	≥6	13	7.0	qualified	
	After using the breaking force Test (n) 7 days (50 ± 2) Centigrade	≥6	13	6.8	qualified	

1. A total of 2600 samples were selected and divided into three batches. The detection cycle was 45 days.
2. The experiment was carried out in our laboratory. The test temperature is 50 ℃ ± 2 ℃ (the laboratory environment temperature and humidity are controlled)

remarks	This test is only responsible for the incoming samples.

常州沐邦检测技术有限公司 检验检测专用章

—— End of this report——

常州沐邦检测技术有限公司
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