

Quick Details

Place of Origin: China
Model Number: S/M/L/XL
Properties: Examination/daily/Industry use
Stock: YES
Material: 100% Nitrile
Instrument classification: Class I

Brand Name: Palmwell
Disinfecting Type: Non-sterile
Size: 9"
Shelf Life: 2 years
Quality Certification: EN455/420/374
Safety standard: ISO13485/ GB4806



NITRILE GLOVE

Features

- 100% latex free--be made from durable nitrile, prevent allergic reaction
- Nearly same as latex or better in stretch, tactile sensitivity and other properties
- Designed to provide natural rubber feel-like
- Textured fingers ensure excellent grip in all situations
- Food safety, suitable for handling fatty goods such as olive or similar like that
- FDA 510(K) available
- AQL1.5

Technical details

- Type: Powder-free, unsterilized
- Material: Nitrile butadiene rubber (NBR)
- Model: Ambidextrous, with rolled rim
- Size: XS, S, M, L, XL
- Color: Blue
- Application: for medical use or daily use

Disposable Nitrile Gloves

No.	Level	Gram weight (g) (± 0.3)				Length (mm)	Width (± 10) (mm)	Thickness (mm)			Before Aging		After Accelerated Aging			
		S	M	L	XL			Cuff	Palm	Finger	European Union	America		European Union	America	
											Force at break (N)	Tensile Strength (Mpa)	Ultimate Elongation (%)	Force at break (N)	Tensile Strength (Mpa)	Ultimate Elongation (%)
1	3.0g	2.8	3.0	3.5	4.0	≥230	S: 80; M: 95; L: 110; XL: 120.	≥0.04	≥0.05	≥0.05	/	14	500	/	14	400
2	3.5g	3.0	3.5	4.0	4.5	≥230	S: 80; M: 95; L: 110; XL: 120.	≥0.04	≥0.06	≥0.07	6	14	500	6	14	400
3	4.0g	3.5	4.0	4.5	5.0	≥230	S: 80; M: 95; L: 110; XL: 120.	≥0.05	≥0.07	≥0.08	6	14	500	6	14	400
4	4.5	4.0	4.5	5.0	5.5	≥230	S: 80; M: 95; L: 110; XL: 120.	≥0.06	≥0.08	≥0.09	6	14	500	6	14	400
5	5.0	4.5	5.0	5.5	6.0	≥230	S: 80; M: 95; L: 110; XL: 120.	≥0.06	≥0.09	≥0.11	6	14	500	6	14	400

High Elasticity

Ultrathin

Super Fit



AUTHENTICATION-NITRILE GLOVE

SGS

Test Report No.: QDHL2006005727MD_EN Date: JUL.14.2020 Page 1 of 7

Client name : PUYANG LINSHI MEDICAL SUPPLIES CO., LTD
 Client address : NORTHEAST CORNER OF THE INTERSECTION OF PANJIN ROAD AND FUJIN ROAD IN PUYANG COUNTY, HENAN PROVINCE
 Sample Description : DISPOSABLE NITRILE EXAMINATION GLOVES
 Lot No. : 2020061102
 Lot Size : NOT PROVIDED
 Sample Quantity : M: 400PCS. L: 400PCS
 Manufacturer : PUYANG LINSHI MEDICAL SUPPLIES CO., LTD
 Manufacturer Date : 2020.06.11
 Storage Condition : AVOID LIGHT

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.

Sample Receiving Date : JUN.19.2020
 Final Sample Submission Date : JUL.13.2020
 Test Performing Date : JUN.19.2020 TO JUL.14.2020

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丁腈手套EN455 Test Report

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Test Report No.: QDHL2006005727MD_EN Date: JUL.14.2020 Page 2 of 7

Test Requested

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 M, L)	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, 5.2, 5.3) (For size M, L)	Pass
3. BS EN 455-3:2015 Medical Gloves for Single Use – Part 3: Requirements and Testing for Biological Evaluation (Clause 4.4) (Only for size L)	Pass

BS EN 455-3:2015 Medical Gloves for Single Use – Part 3: Requirements and Testing for Biological Evaluation (Clause 4.6) (For size M, L)

Note: -Unless otherwise stated the results shown in this test report refer only to the sample(s) tested. The test report shall only be used for clients' scientific research, teaching, internal quality control, product research and development, etc... and just for internal reference.

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

Jessica Gao
 Approved Signatory

QR Code: QDHL2006005727MD

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丁腈手套EN455 Test Report

AUTHENTICATION-NITRILE GLOVE

ARDL
AKRON RUBBER DEVELOPMENT LABORATORY, INC.

Testing, Development, Problem Solving.

January 19, 2021

TEST REPORT

PN 157407

PHARMACEUTICAL SERVICES

Prepared For:

Puyang Linshi Medical Supplies Co., Ltd.
East of Panjin Road and North of Fumin Road
Puyang County, Puyang City, Henan Province
China

Prepared By: *Tiffany Heller* / *de* Approved By: *Ana C Barbur* / *1th*
Tiffany Heller, Manager, Pharmaceutical Services
Ana C Barbur, M.S., Vice President, Analytical & Chemical Services

Rev 101218

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丁腈手套ASTMD6978 Test Report

ARDL
AKRON RUBBER DEVELOPMENT LABORATORY, INC.

Testing, Development, Problem Solving.

January 19, 2021

Puyang Linshi Medical Supplies Co., Ltd.

Page 2 of 5
PN 157407

SUBJECT: Permeation testing per ASTM D6978 on sample submitted by the above company.

RECEIVED: One (1) glove type identified as; Disposable Nitrile Examination Gloves, Lot Number 20120512, Date of production 20201205.

TEST CHEMICALS:
Table 1. List of the Testing Drugs and their Sources

TESTING CHEMOTHERAPY DRUGS	DRUG SOURCE
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	Sigma Aldrich; Batch# 000098912; Expiration 01/2022
Cisplatin, 1.0 mg/ml (1,000 ppm)	Accord; Lot# P2001296; Expiration 01/2022
Cyclophosphamide (Cytosan), 20.0 mg/ml (20,000 ppm)	Accord; Lot# 19112225; Expiration 10/2021
Dacarbazine, 10.0 mg/ml (10,000 ppm)	Teva; Lot# 31325414B; Expiration 09/2021
Doxorubicin HCl, 2.0 mg/ml (2,000 ppm)	WestWard; Lot# BJ0051; Expiration 06/2021
Etoposide, 20.0 mg/ml (20,000 ppm)	Teva; Lot# 31325485B; Expiration 07/2021
Fluorouracil, 50.0 mg/ml (50,000 ppm)	Accord; Lot# P2001167; Expiration 01/2022
Paclitaxel, 6.0 mg/ml (6,000 ppm)	Teva; Lot# 19K24KA; Expiration 11/2021
ThioTepa, 10.0 mg/ml (10,000 ppm)	USP; Lot # R11380; Expiration 01/2022

COLLECTION MEDIA:
Table 2. Collection Media for Test Drug

TEST DRUG AND CONCENTRATION	COLLECTION MEDIUM
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	10% Ethanol Aqueous Solution
Cisplatin, 1.0 mg/ml (1,000 ppm)	Distilled Water
Cyclophosphamide (Cytosan), 20.0 mg/ml (20,000 ppm)	Distilled Water
Dacarbazine, 10.0 mg/ml (10,000 ppm)	Distilled Water
Doxorubicin HCl, 2.0 mg/ml (2,000 ppm)	Distilled Water
Etoposide, 20.0 mg/ml (20,000 ppm)	Distilled Water
Fluorouracil, 50.0 mg/ml (50,000 ppm)	9.20 pH Sodium Hydroxide Solution
Paclitaxel, 6.0 mg/ml (6,000 ppm)	30% Methanol Aqueous Solution
ThioTepa, 10.0 mg/ml (10,000 ppm)	Distilled Water

*ARDL is ISO 17025 accredited by AZLA for the test methods listed on the certificates referenced on page one. Unless specified, the current specification version is used.
NOTE: Non-ISO 17025 accredited test methods are designated with the [^] symbol to differentiate from ISO 17025 accredited methods in the body of the test report.
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丁腈手套ASTMD6978 Test Report

AUTHENTICATION-NITRILE GLOVE





2015150662V





中国认可
国际互认
检测
TESTING
CNAS L0604

Test Report No. TAOHG2101193801 Date: 25 Mar 2021 Page 1 of 4

PUYANG LINSHI MEDICAL SUPPLIES CO.,LTD
EAST OF PANJIN ROAD AND NORTH OF FUMIN ROAD IN PUYANG COUNTY, PUYANG CITY, HENAN PROVINCE

The following sample(s) was/were submitted and identified on behalf of the clients as : DISPOSABLE NITRILE GLOVES

SGS Job No. : QDHL2103500879CW - QD
Date of Sample Received : 19 Mar 2021
Testing Period : 19 Mar 2021 - 25 Mar 2021
Test Requested : Selected test(s) as requested by client.
Test Method : Please refer to next page(s).
Test Results : Please refer to next page(s).

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

clair
Wang Bo, Claire
Approved Signatory



TAOHG2101193801




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2015150662V





中国认可
国际互认
检测
TESTING
CNAS L0604

Test Report No. TAOHG2101193801 Date: 25 Mar 2021 Page 2 of 4


Result Summary :

Test Requested	Comments
GB 4806.11-2016-Sensory(Appearance: Normal color, no smell, no dirty)	PASS
GB 4806.11-2016-Sensory (Marinate: Colorless, no turbidity, no precipitate, no smell, or other sensory deterioration)	PASS
GB 4806.11-2016-Overall migration	PASS
GB4806.11-2016-Potassium permanganate consumption	PASS
GB 4806.11-2016-Heavy metal (as Lead)	PASS

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



TAOHG2101193801



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AUTHENTICATION-NITRILE GLOVE

The screenshot shows the FDA's Establishment Registration & Device Listing page. At the top, there is a navigation bar with the FDA logo and the text 'U.S. FOOD & DRUG ADMINISTRATION'. To the right, there are links for 'Follow FDA | En Español' and a search bar with a 'SEARCH' button. Below the navigation bar, there is a menu with categories: Home, Food, Drugs, Medical Devices, Radiation-Emitting Products, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, and Tobacco Products. The main heading is 'Establishment Registration & Device Listing', with sub-links for 'FDA Home', 'Medical Devices', and 'Databases'. There are icons for printing, a plus sign, and an email icon. The main content area is titled 'New Search' and 'Back To Search Results'. It contains the following information:
Establishment:
PUYANG LINSHI MEDICAL SUPPLIES CO.,LTD
East Of Panjin Road And North Of Fumin Road In Puyang County
Puyang Henan, CN 457100
Status: Active; Awaiting Assignment Of Registration Number
Date Of Registration Status: 2021
Owner/Operator:
PUYANG LINSHI MEDICAL SUPPLIES CO.,LTD
East Of Panjin Road And North Of Fumin R
Puyang, Henan CN 457100
Owner/Operator Number: 10078898
Official Correspondent:
Ligong Shi
East Of Panjin Road And North Of Fumin R
Puyang, Henan CN 457100
Phone: 86-10-56335780
US Agent:
Wen Wu
4611 Maydew Mews Way
Ellicott, MD US 21042
Phone: 443 8968583 Ext
Email: Infor@Believe-Med.Com
At the bottom of the content area, there is a note: '* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set'. Below the content area, there is a footer with the text 'Page Last Updated: 12/21/2020' and a note: 'Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.' Below that, there is a list of languages: 'Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | ڊزسي | English'. At the very bottom, there is a navigation bar with the FDA logo and links for 'Accessibility', 'Contact FDA', 'Careers', 'FDA Basics', 'FOIA', 'No FEAR Act', 'Nondiscrimination', and 'Website Policies / Privacy'. Below the navigation bar, there is the text 'U.S. Food and Drug Administration' with the address '10903 New Hampshire Avenue, Silver Spring, MD 20993'. To the right, there is the text 'Combination Products Advisory Committees'. At the bottom right, there is the U.S. Department of Health & Human Services logo and text.

证书查询: <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm>,
输入 owner/operator number:
10078898, 点击search即可

美国FDA 注册 FDA registration