5000136413 - One Time Purchase Of Blue Nitrile Disposable Gloves For Jefferson Parish Public Works

Jefferson Parish Government

Jefferson Parish
State of Louisiana

Bid Number 50–00136413

One Time Purchase Of Blue Nitrile Disposable Gloves For Jefferson Parish Public Works

BID DUE: November 10, 2021 AT 11:00 AM

ATTENTION VENDORS!!!

Please review all pages and respond accordingly, complying with all provisions in the technical specifications and Jefferson Parish Instructions for Bidders and General Terms and Conditions. All bids must be received on the Purchasing Department's eProcurement site, www.jeffparishbids.net, by the bid due date and time. Late bids will not be accepted.

Jefferson Parish Purchasing Department
200 Derbigny Street
General Government Building, Suite 4400
Gretna, LA 70053
Buyer Name: BRENDA BELLOW – BUYER I
Buyer Email: bbellow@jeffparish.net
Buyer Phone: 504-364-2683

DATE: 11/05/2021

INVITATION TO BID
THIS IS NOT AN ORDER

BID NO.: 50-00136413

JEFFERSON PARISH

PURCHASING DEPARTMENT
P.O. BOX 9
GRETNA, LA. 70054-0009
504-364-2678

VENDOR: 27118 BLANK BID COPY VENDOR

BUYER: BBELLOW@jeffparish.net

Bids will be received until 11:00 AM, 11/10/2021 via online at www.jeffparishbids.net.

LATE BIDS WILL NOT BE ACCEPTED
NOTE: ONLY BIDS WRITTEN IN INK OR TYPEWRITTEN, AND PROPERLY SIGNED BY A MEMBER OF THE FIRM OR AUTHORIZED REPRESENTATIVE, WILL BE ACCEPTED. PENCIL AND/OR PHOTOSTATIC FIGURES OR SIGNATURES SHALL RESULT IN BID REJECTION. HOWEVER, ELECTRONIC SIGNATURES AS DEFINED IN LSA - R.S. 9:2602(8) ARE ACCEPTABLE. SIGNATURE MUST BE A SECURED DIGITAL SIGNATURE.

All bids submitted are subject to these instructions and general conditions and any special conditions and specifications contained herein, all of which are made part of this bid proposal reference. By submitting a bid, vendor agrees to comply with all provisions of Louisiana Law, as well be in compliance with the Jefferson Parish Code of Ordinances, Louisiana Code of Ethics, applicable Jefferson Parish ethical standards and Jefferson Parish Resolution No. 113646 and/or Resolution No. 113647 as amended. A copy of these resolutions may be obtained from the Office of the Parish Clerk, Suite 6700, Jefferson Parish General Government Building, 200 Derbigny Street, Gretna, LA 70053. You may also obtain a copy by visiting the Purchasing Department webpage at purchasing.jeffparish.net and clicking on On-line forms.

All vendors submitting bids should register as a Jefferson Parish vendor if not already yet registered. Registration forms may be downloaded from http://purchasing.jeffparish.net and by clicking on Vendor Information. Current W-9 forms with respective Tax Identification numbers and vendor applications may be submitted at any time; however, if your company is not registered and/or a current W-9 form is not on file, vendor registration is mandatory. Vendors may experience a delay in payment if your company is not a registered vendor with Jefferson Parish.

Jefferson Parish is exempt from paying sales tax under LSA-R.S. 47:301 (8)(c). All prices for purchases by Jefferson Parish of supplies and materials shall be quoted in the unit of measure specified and unless otherwise specified, shall be exclusive of state and local taxes. The price quoted for work shall be stated in figures. In the event there is a difference in unit prices and totals, the unit price shall prevail. Quotations shall be based on F.O.B. Delivered, anywhere within the Parish as designated by the Purchasing Department. JEFFERSON PARISH WILL ACCEPT ONE BID ONLY FROM EACH VENDOR. Items bid must meet specifications. JEFFERSON PARISH will accept one price for each item unless otherwise indicated. Two or more prices for one item will result in bid rejection. Bidders are required to complete, sign and return the bid form and/or complete and return the associated line item pricing forms as indicated. The price quoted for work shall be stated in figures. In the event there is a difference in unit prices and totals, the unit prices shall prevail

JEFFERSON PARISH reserves the right to award contracts or place orders on a lump sum or individual item basis, or such combination, as shall in its judgment be in the best interest of JEFFERSON PARISH. Every contract or order shall be awarded to the LOWEST RESPONSIVE and RESPONSIBLE BIDDER, taking into consideration the CONFORMITY WITH THE SPECIFICATIONS and the DELIVERY AND/OR COMPLETION DATE

PROTESTS: Only those vendors that submit bids in response to this solicitation may protest any element of the procurement, in writing to the Director of the Purchasing Department. Written protest must be received within 48 hours of the release of the bid tabulation by the Purchasing Department. After consultation, the Parish Attorney's Office will then respond to protests in writing. (For more information, please see Chapter 2, Article VII, Division 2, Sec. 2-914.1 of the Jefferson Parish Code of Ordinances.)

JEFFERSON PARISH reserves the right to cancel all or any part of an order if not shipped promptly. No charges will be allowed for parking or cartage unless specified in the quotation. The order must not be filled at a higher price than quoted. JEFFERSON PARISH reserves the right to cancel at any time and for any reason by issuing a THIRTY (30) day written notice to the contractor.

JEFFERSON PARISH requires all products to be new (current) and all work must be performed according to standard practices for the project. Unless otherwise specified, no aftermarket parts will be accepted. Unless otherwise specified, all workmanship and materials must have at least one (1) year guaranty, in writing, from the date of delivery and/or acceptance of the project. Any deviations or alteration from the specifications must be indicated on the bid form for each item and upon request, product data for same must be submitted by the time specified by the Purchasing Department.

If this bid requires a pre-bid conference (see Additional Requirements section), bidders are advised that such conference will be held to allow bidders the opportunity to identify any discrepancies in the bid specifications and seek further clarification regarding instructions. The Purchasing Department will issue a written response to bidders' questions in the form of an Addendum.

All formal Addenda require written acknowledgment on the bid form by the bidder by the bidder placing the Addendum number in the appropriate section. Failure to acknowledge an Addendum on the bid form shall cause the bid to be rejected; JEFFERSON PARISH reserves the right to award bid to next lowest responsive and responsible bidder in this event.

USE OF BRAND NAMES AND STOCK NUMBERS: Where brand names and stock numbers are specified, it is for the purpose of establishing certain minimum standards of quality. Bids may be submitted for products of equal quality, provided brand names and stock numbers are specified. Complete product data may be required prior to award.

Quantities listed are for bidding purposes only. Actual requirements may be more or less than quantities listed.

INSTRUCTIONS FOR BIDDERS AND GENERAL CONDITIONS

Bidders are not to exclude from participation in, deny the benefits of, or subject to discrimination under any program or activity, any person in the United States on the grounds of race, color, national origin, or sex; nor discriminate on the basis of age under the Age Discrimination Act of 1975, or with respect to an otherwise qualified handicapped individual as provided in Section 504 of the Rehabilitation Act of 1973, or on the basis of religion, except that any exemption from such prohibition against discrimination on the basis of religion as provided in the Civil Rights Act of 1964, or Title VI and VII of the Act of April 11, 1968, shall also apply. This assurance includes compliance with the administrative requirements of the Revenue Sharing final handicapped discrimination provisions contained in Section 51.55 (c), (d), (e), and (k)(5) of the Regulations. New construction or renovation projects must comply with Section 504 of the 1973 Rehabilitation Act, as amended, in accordance with the American National Standard Institute's specifications (ANSI Al 17.1-1961).

Jefferson Parish and its partners as the recipients of federal funds are fully committed to awarding a contract(s) to firm(s) that will provide high quality services and that are dedicated to diversity and to containing costs. Thus, Jefferson Parish strongly encourages the involvement of minority and/or woman-owned business enterprises (DBE's, including MBE's, WBE's and SBE's) to stimulate participation in procurement and assistance programs.

IN ACCORDANCE WITH STATE REGULATIONS JEFFERSON PARISH OFFERS ELECTRONIC PROCUREMENT TO ALL VENDORS

This electronic procurement system allows vendors the convenience of reviewing and submitting bids online. This is a secure site and authorized personnel have limited read access only. Bidders are to submit electronically using this free service; while the website accepts various file types, one single PDF file containing all appropriate and required bid documents is preferred. Bidders submitting uploaded images of bid responses are solely responsible for clarity. If uploaded images/documents are not legible, then bidder's submission will be rejected. Please note all requirements contained in this bid package for electronic bid submission.

Please visit our E-Procurement Page at www.jeffparishbids.net to register and view Jefferson Parish solicitations. For more information, please visit the Purchasing Department page at http://purchasing.jeffparish.net.

ADDITIONAL REQUIREMENTS FOR THIS BID

PLEASE MATCH THE NUMBERS PRINTED IN THIS BOX WITH THE CORRESPONDING INSTRUCTIONS BELOW.

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1. All bidders must attend the MANDATORY pre-bid conference and will be required to sign in and out as evidence of attendance. In accordance with LSA R.S. 38:2212(I), all prospective bidders shall be present at the beginning of the MANDATORY pre-bid conference and shall remain in attendance for the duration of the conference. Any prospective bidder who fails to attend the conference or remain for the duration shall be prohibited from submitting a bid for the project.

2. Attendance to this pre-bid conference is optional. However, failure to attend the pre-bid conference shall not relieve the bidder of responsibility for information discussed at the conference. Furthermore, failure to attend the pre-bid conference and inspection does not relieve the successful bidder from the necessity of furnishing materials or performing any work that may be required to complete the work in accordance with the specification with no additional cost to the owner.

3. Contractor must hold current applicable JEFFERSON PARISH licenses with the Department of Inspection and Code Enforcement. Contractor shall obtain any and all permits required by the JEFFERSON PARISH Department of Inspection and Code Enforcement. The contractor shall be responsible for the payment of these permits. All permits must be obtained prior to the start of the project. Contractor must also hold any and all applicable Federal and State licenses. Contractor shall be responsible for the payment of these permits and shall obtain them prior to the start of the project.

4. A LA State Contractor's License will be required in accordance with LSA R.S. 37-2150 et. seq. and such license number will be shown on the outside of the bid electronic envelope. Failure to comply will cause the bid to be rejected. When submitting the bid electronically, the license number must be entered in the appropriate field in the electronic procurement system. Failure to comply will cause the bid to be rejected.

INSTRUCTIONS FOR BIDDERS AND GENERAL CONDITIONS

5. It is the bidder's responsibility to visit the job site and evaluate the job before submitting a bid.

6. Job site must be clean and free of all litter and debris daily and upon completion of the contract. Passageways must be kept clean and free of material, equipment, and debris at all times. Flammable material must be removed from the job site daily because storage will not be permitted on the premises. Precaution must be exercised at all times to safeguard the welfare of JEFFERSON PARISH and the general public.

7. PUBLIC WORKS BIDS: All awards for public works in excess of $5,000.00 will be reduced to a formal contract which shall be recorded at the contractor's expense with the Clerk of Court and Ex-Officio Recorder of Mortgages for the Parish of Jefferson. A price list of recordation costs may be obtained from the Clerk of Court and Ex-Officio Recorder of Mortgages for the Parish of Jefferson. All awards in excess of $25,000.00 will require both a performance and a payment bond. Unless otherwise stated in the bid specifications, the performance bond requirements shall be 100% of the contract price. Unless otherwise state in the bid specifications, the payment bond requirements shall be 100% of the contract price. Both bonds shall be supplied at the signing of the contract.

8. NON-PUBLIC WORKS BIDS: A performance bond will be required for this bid. The amount of the bond will be 100% of the contract price unless otherwise indicated in the specifications. The performance bond shall be supplied at the signing of the contract.

9. NON-PUBLIC WORKS BIDS: A payment bond will be required for this bid. The amount of the bond will be 100% of the contract price unless otherwise indicated in the specifications. The payment bond shall be supplied at the signing of the contract.

10. All bidders must comply with the requirements stated in the attached "Standard Insurance Requirements" sheet attached to this bid solicitation. Failure to comply with this instruction will result in bid rejection.

11. A bid bond will be required with bid submission in the amount of 5% of the total bid, unless otherwise stated in the bid specifications. All sureties must be in original format (no copies). When submitting a bid online, vendors must submit an electronic bid bond through the respective online clearinghouse bond management system(s) as indicated in the electronic bid solicitation on Central Auction House. No scanned paper copies of any bid bond will be accepted as part of the electronic bid submission.

12. This is an as needed basis contract. JEFFERSON PARISH makes no representations on warranties with regard to minimum guaranteed quantities unless otherwise stated in the bid specifications.

13. Freight charges should be included in total cost when quoting. If not quoted FOB DELIVERED, freight must be quoted as a separate item. Bid may be rejected if not quoted FOB DELIVERED or if freight charges are not indicated on bid form.

14. PUBLIC WORKS BIDS - Completed, Signed and Properly Notarized Affidavits Required; This applies to all solicitations for construction, alteration or demolition of public buildings or projects, in conformity with the provisions contained in LSA-RS 38:2212.9, LSA-RS 38:2212.10, LSA-RS 38:2224, and Sec 2-923.1 of the Jefferson Parish Code of Ordinances. For bidding purposes, all bidders must submit with bid submission COMPLETED, SIGNED and PROPERLY NOTARIZED Affidavits, including: Non-Conviction Affidavit, Non-Collusion Affidavit, Campaign Contribution Affidavit, Debt Disclosures Affidavit and E-Verify Affidavit. For the convenience of vendors, all affidavits have been combined into one form entitled PUBLIC WORKS BID AFFIDAVIT. This affidavit must be submitted in its original format, and without material alteration, in order to be compliant and for the bid to be considered responsive. A scanned copy of the completed, signed and properly notarized affidavit may be submitted with the bid, however, the successful bidder must submit the original affidavit in its original format and without material alteration upon contract execution. Failure to comply will result in the bid submission being rejected as non-responsive. The Parish reserves the right to award bid to the next lowest responsive and responsible bidder in this event.

15. NON PUBLIC WORK BIDS - Completed, Signed and Properly Notarized Affidavits Required in conformity with the provisions contained in LSA – RS 38:2224 and Sec 2-923.1 of the Jefferson Parish Code of Ordinances. For bidding purposes, all bidders must submit with bid submission COMPLETED, SIGNED and PROPERLY NOTARIZED Affidavits, including: Non-Collusion Affidavit, Debt Disclosures Affidavit and Campaign Contribution Affidavit. For the convenience of vendors, all affidavits have been combined into one form entitled NON PUBLIC WORKS BID AFFIDAVIT. This affidavit must be submitted in its original format, and without material alteration, in order to be compliant and for the bid to be considered responsive. A scanned copy of the completed, signed and properly notarized affidavit may be submitted with the bid, however, the successful bidder must submit the original affidavit in its original format and without material alteration upon contract execution. Failure to comply will result in the bid submission being rejected as non-responsive. The Parish reserves the right to award bid to the next lowest responsive and responsible bidder in this event.

16. The ensuing contract for this bid solicitation may be eligible for FEMA reimbursement and/or Federal funding/reimbursement. As such, the referenced appendix will be applicable accordingly and shall be considered a part of the bid documents. All applicable certifications must be duly completed, signed and submitted with bid submission. Failure to submit applicable certifications with bid submission will result in bid rejection.

17. For this project, the Contractor shall not pay any state or local sales or use taxes on materials and equipment which are affixed and made part of the immovable property of the project or which is permanently incorporated in the project (hereinafter referred to as "applicable materials and equipment"). All purchases of applicable materials or equipment shall be made by the contractor on behalf of and as the agent of Jefferson Parish (Owner), a political subdivision of the State of Louisiana. No state and local sales and use taxes are owed on applicable materials and equipment under the provisions of Act 1029 of the 1991 Regular Session - Louisiana Revised Statute 47:301(8)(c). Owner will furnish to contractor a certificate form which certifies that Owner is not required to pay such state or local sales and use taxes, and contractor shall furnish a copy of such certificate to all vendors or suppliers of the applicable materials and equipment, and report to Owner the amount of taxes not incurred.

It shall be the duty of every parish officer, employee, department, agency, special district, board, and commission: and the duty of every contractor, subcontractor, and licensee of the parish, and the duty of every applicant for certification of eligibility for a parish contract or program, to cooperate with the Inspector General in any investigation, audit, inspection, performance review, or hearing pursuant to Jefferson Parish Code of Ordinances Section 2-155.10(19). By submitting a bid, vendor acknowledges this and will abide by all provisions of the referenced Jefferson Parish Code of Ordinances.

DATE: 11/05/2021

INVITATION TO BID
THIS IS NOT AN ORDER

BID NO.: 50-00136413

JEFFERSON PARISH

PURCHASING DEPARTMENT
P.O. BOX 9
GRETNA, LA. 70054-0009
504-364-2678

VENDOR: 27118 BLANK BID COPY VENDOR

BUYER: BBELLOW

As per LSA-RS 47:301 et seq., all governmental bodies are excluded from payment of sales taxes to any Louisiana taxing body. Quotations shall be based on F.O.B. Agency warehouse or jobsite, anywhere within the Parish as designated by the Purchasing Department.

JEFFERSON PARISH reserves the right to cancel all or any part of an order if not shipped promptly. No charges will be allowed for parking or cartage unless specified in quotation. The order must not be filled at a higher price than quoted. JEFFERSON PARISH reserves the right to cancel at any time and for any reason by issuing a THIRTY (30) day written notice to the contractor.

JEFFERSON PARISH is expecting all products to be new and all work to be done in workman-like manner, according to standard practices. Any deviations or alteration from the specifications must be indicated on the bid form for each item and upon request, product data for same must be submitted by the time specified by the Purchasing Department.

DELIVERY: FOB JEFFERSON PARISH

INDICATE DELIVERY DATE ON EQUIPMENT AND SUPPLIES: 7 days after receipt

INDICATE STARTING TIME (IN DAYS) FOR CONSTRUCTION WORK: _____

INDICATE COMPLETION TIME (IN DAYS) FOR CONSTRUCTION WORK: _____

In the event that addenda are issued with this bid, bidders MUST acknowledge all addenda on the bid form. Bidder must acknowledge receipt of an addendum on the bid form by placing the addendum number as indicated. Failure to acknowledge any addendum on the bid form will result in bid rejection.

Acknowledge Receipt of Addenda: NUMBER: _____

NUMBER: _____

NUMBER: _____

NUMBER: _____

LOUISIANA CONTRACTOR'S LICENSE NO.: (if applicable) _____

*** ALL BIDDERS MUST COMPLETE SECTION BELOW ***

FIRM NAME: Indo Trading, LLC	
SIGNATURE: (Must be signed here)	TITLE: Owner
PRINT OR TYPE NAME: Awfmar Sihotang	
ADDRESS: 2879 Metropolitan Pl	
CITY, STATE: Pomona, CA	ZIP: 91767
TELEPHONE: (909)906-1597	FAX: (909)906-1447
EMAIL ADDRESS: support@indotradingusa.com	

TOTAL PRICE OF ALL BID ITEMS: $ 6,250.00

INVITATION TO BID FROM JEFFERSON PARISH - continued

BID NO.: 50-00136413

SEALED BID

ITEM NUMBER	QUANTITY	U/M	DESCRIPTION OF ARTICLES	UNIT PRICE QUOTED	TOTALS
			ONE TIME PURCHASE OF BLUE NITRILE DISPOSABLE GLOVES FOR JEFFERSON PARISH PUBLIC WORKS	$6.25	$6,250.00
1	1,000.00	BX	0010 - GLOVES,BLUE NITRILE,DISPOSABLE, X-LARGE,AMBIDEXTROUS,TEXTURED,4 MIL, 9-1/2 IN LENGTH,POWDER FREE,100 GLOVES PER BOX,10 BOXES PER CASE,BOSS #1UH001X SK# 00-058038N DELIVER TO: JEFFERSON PARISH PUBLIC WORKS 1500 RIVER PARK BLVD BRIDGE CITY, LA 70094	**Brand**: Prince (Specification Sheets attached below)	

Give your staff & patients you care about,

THE ROYAL TREATMENT

4 MIL CHEMO RATED **NITRILE EXAM GLOVES**

PRINCE™ Premium +

100% USA LABORATORY TESTED

THE MOST PEDIGREED BRAND TO EMERGE SINCE THE PANDEMIC BEGAN

Prince™ Premium +
Nitrile Examination Gloves

Because you care about your staff and patients, you want to give them the royal treatment.

Meet the new royalty.

Prince Premium+ Nitrile Exam Gloves are one of the most independently tested exam gloves in the industry.

PRINCE™ Premium+

Nitrile Examination Gloves

Our Nitrile Gloves are also up to 3 times more puncture resistant than latex gloves. This makes them the preferred glove when there is risk of exposure to blood borne pathogens or other environmental contaminants. Prince Premium+ is Medical Grade, which means they have undergone a series of tests proving that they are suitable to be used in these environments. They are commonly used in laboratories, hospitals, and dentists and in the care environment but are also used in the automotive market where a thicker more puncture resistant nitrile glove is used to protect against oil and engine lubricants.

Prince Premium+ have been tested against 9 Chemotherapy drugs and have superior chemical resistance to other disposable gloves.

Prince Premium + is also powder free, further reducing the risk of allergens and dealing with messy powder. The gloves also have a chlorinated finish applied to the glove making donning & doffing easier, even when the hands are wet. This makes our gloves especially useful in situations such as food environments where frequent glove changes are required.

Due to the use of synthetic rubber Nitrile Gloves are not only used for strength and durability but also have enhanced flexibility making them the glove of choose when dexterity and sensitivity is required. Our gloves form to the shape of your hand making a comfortable fit and reducing hand fatigue, Nitrile Gloves also have a lower level of friction, meaning that these gloves can be worn for longer durations than other types of gloves.

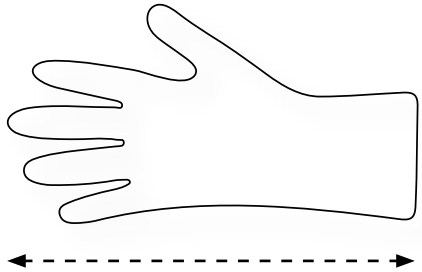
US and EU Testing:

ASTM D6978	ISO 10993-5
ASTM 6319-10	ISO 10993-10
ASTM F1671	ISO 10993-10
ASTM D5151	EN 16523-1
ASTM D6319	EN 455-1
ASTM D412	EN-455-2
ASTM D573	EN-455-4
ASTM 6124	EN-374-1
ASTM D6124	EN-374-2
ASTM D5712	EN-374-4
ASTM D6499	EN-374-5
ASTM D3578	ASTM D2712
ASTM D3767	ASTM D6499
ASTM D412	ASTM D573

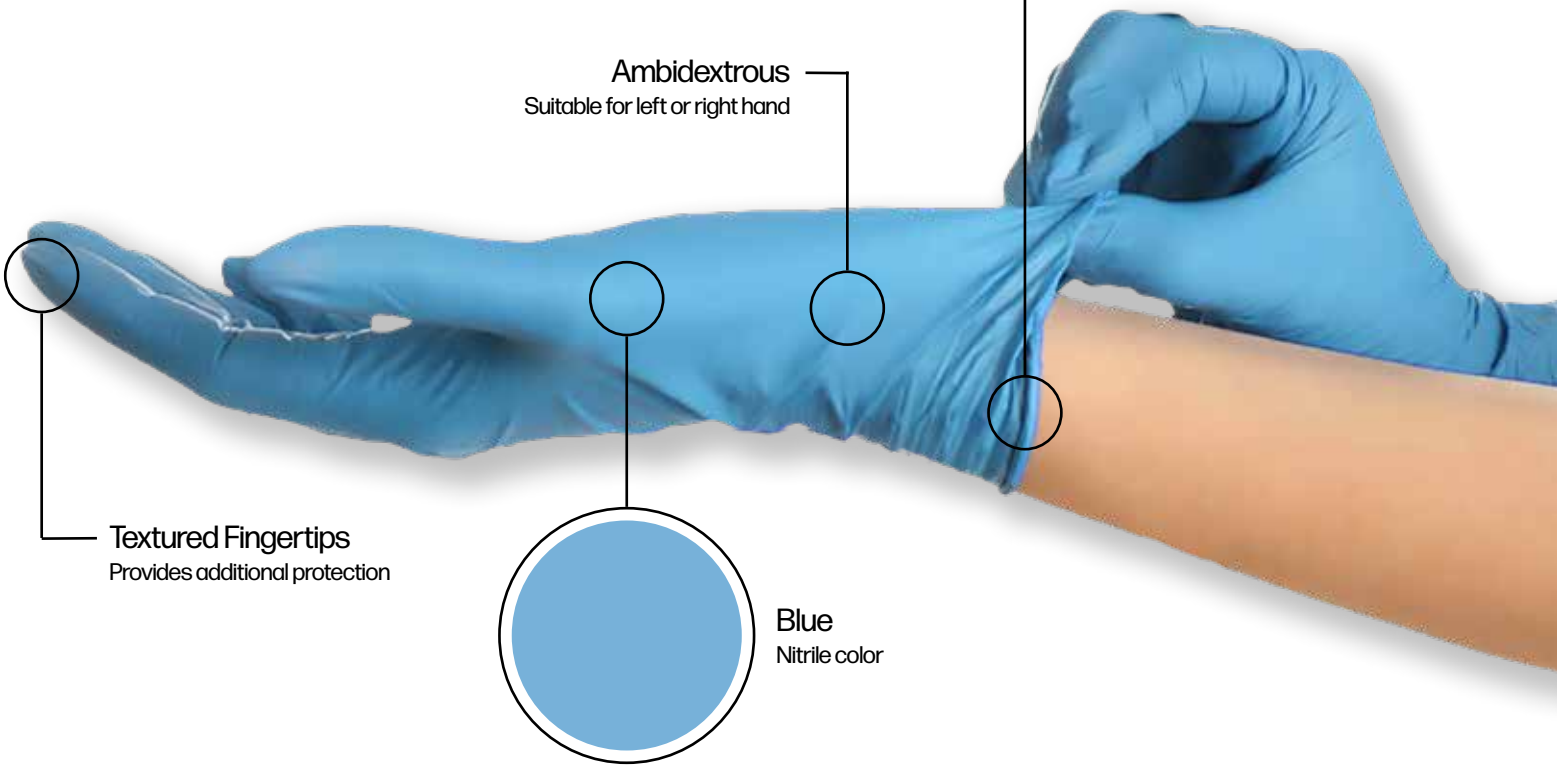
Chemotherapy Drug Permeation Resistance Testing per ASTM D6978

TEST CHEMOTHERAPY DRUGS	AVERAGE BREAKTHROUGH DETECTION TIME (Specimen 1/2/3) (Minutes)	AVERAGE STEADY STATE PERM. RATE (Specimen 1/2/3) (µg/cm²/minute)
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	43.7 (43.3,43.7,45.4)	0.5 (0.5,0.5,0.4)
Cisplatin, 1.0 mg/ml (1,000 ppm)	>240 min.	N/A
Cyclophosphamide (Cytoxan), 20. mg/ml (20,000 ppm)	>240 min.	N/A
Dacarbazine, 10.0 mg/ml (10,000 ppm)	>240 min.	N/A
Doxorubicin HCl, 2.0 mg/ml (2,000 ppm)	>240 min.	N/A
Etoposide, 20.0 mg/ml (20,000 ppm)	>240 min.	N/A
Fluorouracil, 50.0 mg/ml (50,000 ppm)	>240 min.	N/A
Paclitaxel, 6.0 mg/ml (6,000 ppm)	>240 min.	N/A
ThioTepa, 10.0 mg/ml (10,000 ppm)	98.6 (108.4,98.6,109.0)	0.2 (0.2,0.2,0.2)

PRINCE™ Premium



220mm (S) / 230mm (M, L, XL,) Min Length
as per ASTM D6319



Protective against dangerous chemicals and microorganisms

Nitirle gloves are a superior choice when it comes to puncture resistance, chemical/liquid/gas protection, strength and tactile sensitivity. Not only are these gloves very durable, but also comfortable. Ambidextrous design for either left or right hand usage and the textured fingertips are ideal for precision as needed. Powder-free to reduce any allergic reactions or skin sensitivity.

Available Sizes

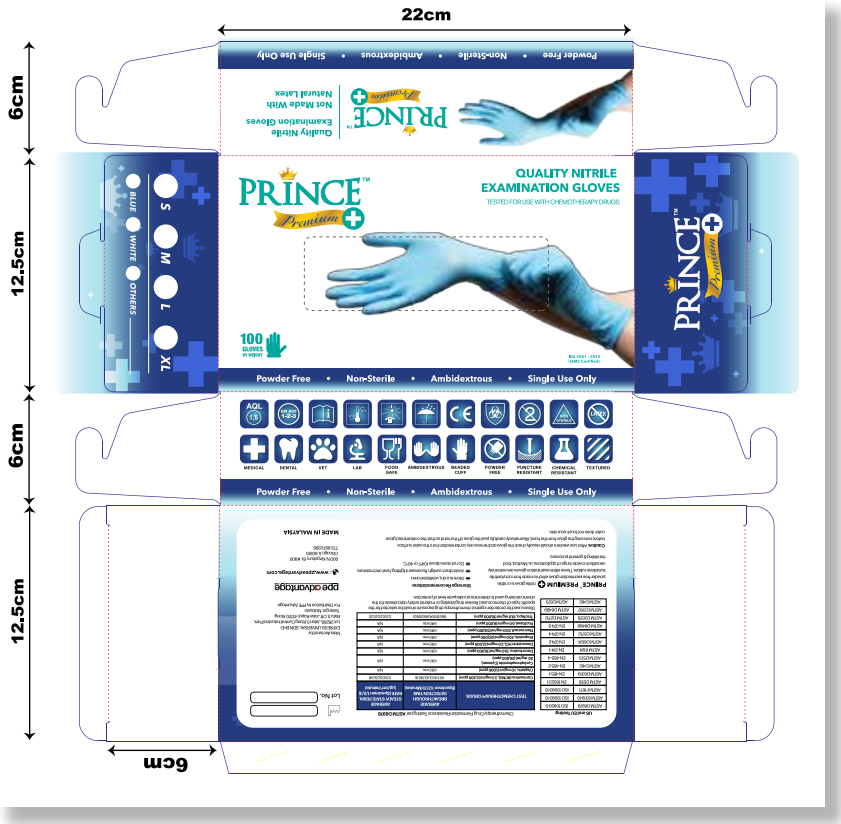
- Small
- Medium
- Large
- Extra-Large

PRINCE™ Premium

Length: 36cm | Height: 23cm | Width: 26cm

Length: 22cm | Height: 12.5cm | Width: 7cm

SIZE	CARTON KG	INNER BOX KG	CARTON LBS	INNER BOX LBS
SMALL	4.97	0.497	10.96	1.096
MEDIUM	5.40	0.540	11.91	1.191
LARGE	5.72	0.572	12.61	1.261
X-LARGE	6.04	0.604	13.32	1.332



40,000 boxes per container

Standard size ratio:

- 10% Small
- 40% Med
- 40% Large
- 10% Extra Large

PRINCE™ Premium

FDA

U.S. Food & Drug Administration

Establishment Registration & Device Listing

Proprietary Name:	Prince Premium+
Classification Name:	POLYMER PATIENT EXAMINATION GLOVE
Product Code:	LZA
Device Class:	1
Regulation Number:	880.6250
Medical Specialty:	General Hospital
Registered Establishment Name:	EXPRESS UNIVERSAL SDN BHD
Registered Establishment Number:	3018183243
Owner/Operator:	EXPRESS UNIVERSAL SDN BHD
Owner/Operator Number:	10080463
Premarket Submission Number:	K132354
Establishment Operations:	Manufacturer

NITRILE (POWDER-FREE)

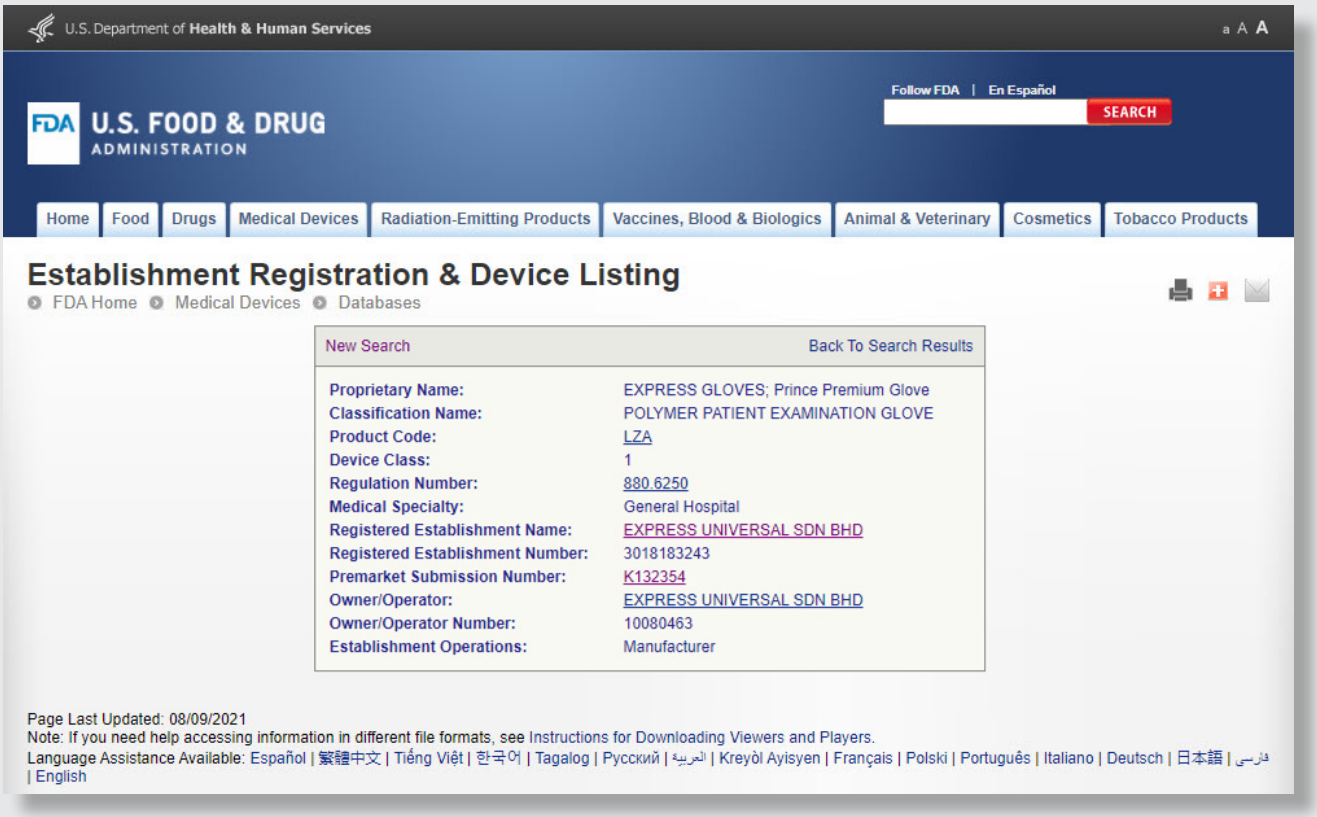
Name	Prince™ Premium +		
Type	Nitrile Examination Gloves	**Origin**	Malaysia
Size	S/M/L/XL	**Package**	100 pcs/box
Material	Acrylonitrile Butadiene	**Color**	Blue

Dimensions	**Standards**		
	Glove	**ASTM D3578**	**EN 455**
Length (mm)	Min 230 Min 240 300 ± 10	Min 220 (S) Min 230 (M,L,XL)	Min 240
Palm Width (mm) ▪ Small ▪ Medium ▪ Large ▪ Extra Large	84 ± 3 94 ± 3 105 ± 3 113 ± 3	80 ± 10 95 ± 10 110 ± 10 120 ± 10	80 ± 10 95 ± 10 110 ± 10 ≥ 110
Thickness: Single Wall (mm) ▪ Finger ▪ Palm	.10 +/- 2 .09 +/- 2	Min 0.05 Min 0.05	N/A N/A

Chemotherapy Drug Permeation Resistance Testing per **ASTM D6978**

TEST CHEMOTHERAPY DRUGS	**AVERAGE BREAKTHROUGH DETECTION TIME (Specimen 1/2/3) (Minutes)**	**AVERAGE STEADY STATE PERM. RATE (Specimen 1/2/3) (µg/cm²/minute)**
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	43.7 (43.3,43.7,45.4) min.	0.5 (0.5,0.5,0.4)
Cisplatin, 1.0 mg/ml (1,000 ppm)	>240 min.	N/A
Cyclophosphamide (Cytoxan), 20. mg/ml (20,000 ppm)	>240 min.	N/A
Dacarbazine, 10.0 mg/ml (10,000 ppm)	>240 min.	N/A
Doxorubicin HCl, 2.0 mg/ml (2,000 ppm)	>240 min.	N/A
Etoposide, 20.0 mg/ml (20,000 ppm)	>240 min.	N/A
Fluorouracil, 50.0 mg/ml (50,000 ppm)	>240 min.	N/A
Paclitaxel, 6.0 mg/ml (6,000 ppm)	>240 min.	N/A
ThioTepa, 10.0 mg/ml (10,000 ppm)	98.6 (108.4,98.6,109.0) min.	0.2 (0.2,0.2,0.2)

ESTABLISHMENT REGISTRATION & **DEVICE LISTING**



U.S. Department of Health & Human Services

a A A

FDA U.S. FOOD & DRUG ADMINISTRATION

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Establishment Registration & Device Listing

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Proprietary Name:	EXPRESS GLOVES; Prince Premium Glove
Classification Name:	POLYMER PATIENT EXAMINATION GLOVE
Product Code:	LZA
Device Class:	1
Regulation Number:	880.6250
Medical Specialty:	General Hospital
Registered Establishment Name:	EXPRESS UNIVERSAL SDN BHD
Registered Establishment Number:	3018183243
Premarket Submission Number:	K132354
Owner/Operator:	EXPRESS UNIVERSAL SDN BHD
Owner/Operator Number:	10080463
Establishment Operations:	Manufacturer

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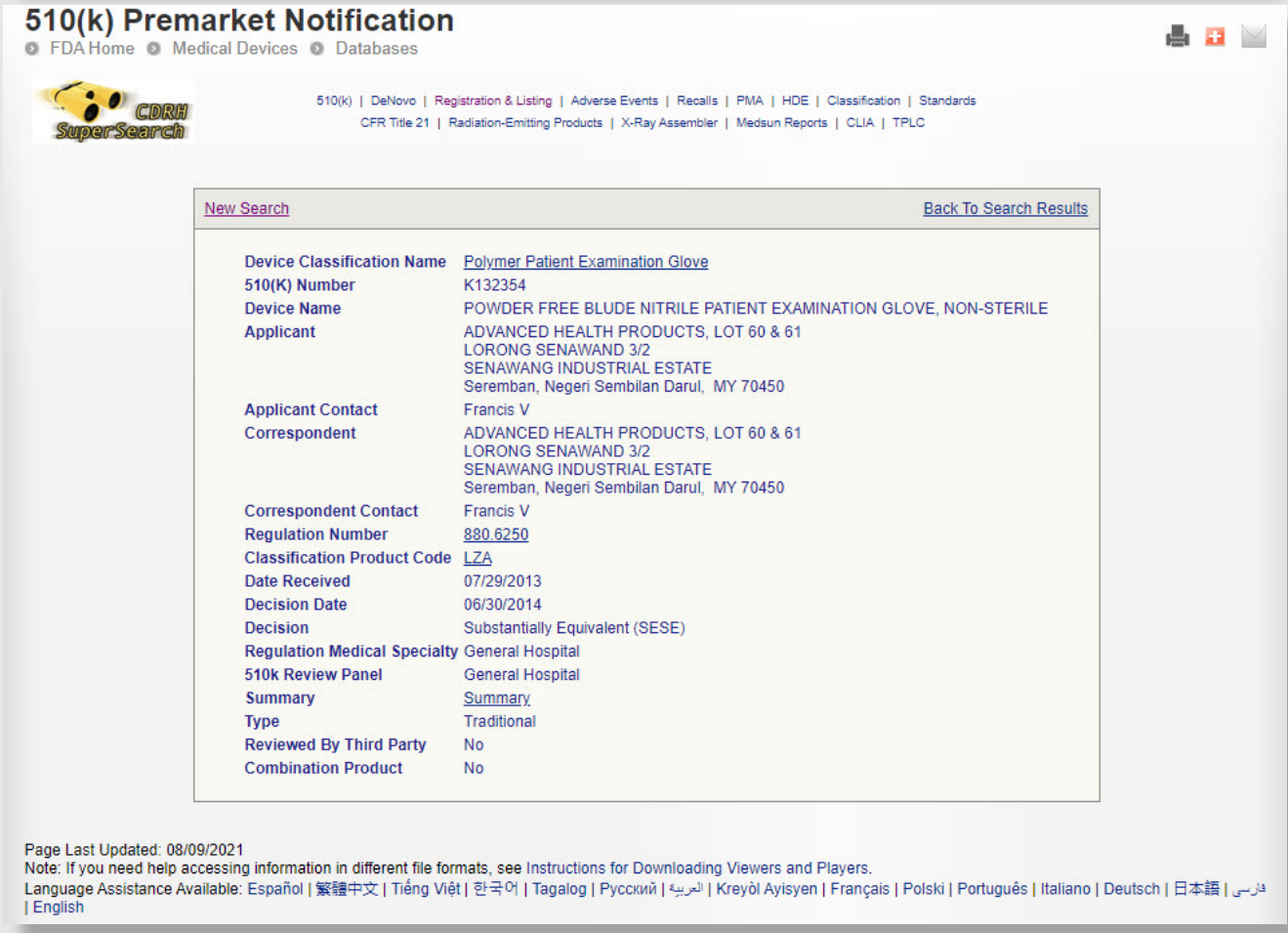

510(k) Premarket Notification

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Device Classification Name	Polymer Patient Examination Glove
510(K) Number	K132354
Device Name	POWDER FREE BLUDE NITRILE PATIENT EXAMINATION GLOVE, NON-STERILE
Applicant	ADVANCED HEALTH PRODUCTS, LOT 60 & 61 LORONG SENAWAND 3/2 SENAWANG INDUSTRIAL ESTATE Seremban, Negeri Sembilan Darul, MY 70450
Applicant Contact	Francis V
Correspondent	ADVANCED HEALTH PRODUCTS, LOT 60 & 61 LORONG SENAWAND 3/2 SENAWANG INDUSTRIAL ESTATE Seremban, Negeri Sembilan Darul, MY 70450
Correspondent Contact	Francis V
Regulation Number	880.6250
Classification Product Code	LZA
Date Received	07/29/2013
Decision Date	06/30/2014
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	General Hospital
510k Review Panel	General Hospital
Summary	Summary
Type	Traditional
Reviewed By Third Party	No
Combination Product	No

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k132354

510(k) SUMMARY

JUN 30 2014

1.0 Submitter:

Name: Mr. Francis V
Address: Advanced Healthcare Products Sdn Bhd
Lot 60 & 61, Lorong Senawang 3/2,
Senawang Industrial Estate,
70450 Seremban, Negeri Sembilan Darul Khusus,
Malaysia.
Phone No.: +60 6 678 4188
Fax No.: +60 6 678 4727

Date of Summary Prepared: June 27, 2014

2.0 Name of the device:

Powder Free Blue Nitrile Patient Examination Glove, Non-Sterile

Common Name: Patient Examination Glove

Classification Name: Patient Examination Gloves (21 CFR 880.6250 product code LZA)

Regulatory Class I

3.0 Identification of The Legally Marketed Devices that equivalency is claimed:

Dermagrip Ultra Powder Free Blue Nitrile Patient Examination Gloves Non-Sterile (and various brandnames)
510(k) : K110979
MDL : D133849
Regulatory Class I
Product Code : LZA

4.0 Description of The Device:

Predicate K110979	Current K132354
Dermagrip Ultra Powder Free Blue Nitrile Patient Examination Gloves Non-Sterile (and various brandnames) meets all the requirements of ASTM standard D6319-10 and FDA 21 CFR 880.6250.	Powder Free Blue Nitrile Patient Examination Glove, Non-Sterile meets all the requirements of ASTM standard D6319-10 and FDA 21 CFR 880.6250. The powder free nitrile examination glove is manufactured from synthetic rubber latex. Inner surface of gloves undergo surface treatment process to produce a smooth surface that assists the user in donning the gloves with ease without using any lubricant such as powder on the glove surface. The glove is ambidextrous; i.e. can be worn on right hand or left hand.

510(k) SUMMARY

5.0 Intended Use of the Device:

A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

6.0 Summary of the Technological Characteristics of the Device:

The Powder Free Blue Nitrile Patient Examination Glove, Non-Sterile are summarized with the following technological characteristics compared to ASTM D6319 or equivalent standards.

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE	
		Predicate K110979	Current K132354
Dimensions	ASTM D6319-10	Meets	Meets Length min 230mm Width min 95±10
Physical Properties	ASTM D6319-10	Meets	Meets **Before Aging** Tensile Strength min 14 MPa Ultimate Elongation Min 500% **After Aging** Tensile Strength min 14 MPa Ultimate Elongation Min 400%
Thickness	ASTM D6319-10	Meets	Meets Finger min 0.05mm Palm min 0.05mm
Powder Free	ASTM D6124-06 (Reapproved 2011)	Meets ≤ 2 mg/glove	Meets ≤ 2 mg/glove

510(k) SUMMARY

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE	
		Predicate K110979	**Current K132354**
Biocompatibility	Primary Skin Irritation – ISO 10993-10:2010(E) & Consumer Product Safety Commission, Tittle 16, Chapter II, Part 1500	Passes (Not a primary skin irritant) There was no erythema or oedema noted on abraded or non-abraded sites at 24±1 hours and 72±1 hours. The Primary Irritation Index (PII) of test material was "0".	Passes (Not a primary skin irritant) There was no erythema or oedema noted on abraded or non-abraded sites at 24±1 hours and 72±1 hours. The Primary Irritation Index (PII) of test material was "0".
	Dermal Sensitization - ISO 10993-10:2010(E) & Consumer Product Safety Commission, Tittle 16, Chapter II, Part 1500.3(c)(4)	Passes (Not a contact sensitizer) There was no positive allergic reaction observed during the challenge phase (at 0±2, 24±2 hours and 48±2 hours) in animals treated with the test material and negative control.	Passes (Not a contact sensitizer) There was no positive allergic reaction observed during the challenge phase (at 0±2, 24±2 hours and 48±2 hours) in animals treated with the test material and negative control.
Watertight (1000ml)	ASTM D5151-06 (Reapproved 2011)	Passes	Passes AQL 2.5
Intended Use	-	The powder free examination glove is a specialty medical glove which is a disposable device intended for medical purposes that is worn on the examiner's hand or forefinger to prevent contamination between examiner and patient bodily fluids, waste or environment.	A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

510(k) SUMMARY

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE	
		Predicate K110979	Current K132354
Material	ASTM D6319-10	Nitrile	Nitrile Sulphur Zinc Oxide Zinc Dibutyldithiocarbamate (ZDBC) Zinc Diethyldithiocarbamate (ZDEC) Phenolic Antioxidant Titanium Dioxide Blue Pigment
Color	-	Blue	Blue
Texture	-	Finger textured	Finger textured
Size	Medical Glove Guidance Manual – Labeling	Small Medium Large Extra Large	Extra Small Small Medium Large Extra Large
Single Use	Medical Glove Guidance Manual – Labeling	Single use	Single use
Manufacturer(s)	-	Advance Medical Products Sdn Bhd	Advanced Healthcare Products Sdn Bhd

7.0 Substantial Equivalent Based on Assessment of Non-Clinical Performance Data

The performance test data of the non-clinical tests that support a determination of substantial equivalence is the same as mentioned immediately above (ASTM Requirements).

8.0 Substantial Equivalent Based on Assessment of Clinical Performance Data

Not applicable - Clinical data is not needed for gloves or for most devices cleared by the 510(k) process.

510(k) SUMMARY

9.0 Conclusion

The conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device.
Powder Free Blue Nitrile Patient Examination Glove, Non-Sterile will perform according to the gloves performance standards such as ASTM standards, and FDA requirements for water leak test on pinhole AQL. Consequently, the device is substantially equivalent to currently marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 30, 2014

Advanced Healthcare Products Sdn Bhd
Mr. Francis V
Operations Manager
Lot 60 & 61, Lorong Senawang 3/2
Senawang Industrial Estate
70450 Seremban, Negeri Sembilan
Darul Khusus, MALAYSIA

Re: K132354
Trade/Device Name: Powder Free Blue Nitrile Patient Examination Gloves, Non-Sterile
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Gloves
Regulatory Class: 1
Product Code: LZA
Dated: May 20, 2014
Received: May 22, 2014

Dear Mr. Francis V:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K132354

Device Name
Powder Free Blue Nitrile Patient Examination Glove Non-Sterile

Indications for Use *(Describe)*

A patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Sreekanth Gutala -S

Digitally signed by Sreekanth Gutala -S
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ARDL
AKRON RUBBER DEVELOPMENT LABORATORY, INC.

Testing. Development. Problem Solving.

April 26, 2021

▪TEST REPORT▪

PN 159100A
PO cc

PHYSICAL TESTING DEPARTMENT

Prepared For:

Douglas Stein
PPE Advantage
900 North Kingsbury Street #900
Chicago, IL 60610

Prepared By: Sandy Jones Hamrick
Project Technician

Approved By: Melissa Martin
Physical Testing Manager

Rev 110119

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April 26, 2021
Douglas Stein
PPE Advantage

SUBJECT: Physical Testing on material submitted by the above company.

RECEIVED: Seven (7) boxes of gloves identified as Prince™ Premium+ Nitrile Examination Chemo Tested Powder Free Non-Sterile Ambidextrous Single Use Only Blue Size Large Lot 411128359

DECISION RULE: Rule #1

DIMENSIONS, ASTM D 6319
13 gloves tested

	LENGTH, mm	WIDTH, mm	FINGER, mm	PALM, mm
	235	107	0.109	0.096
	232	108	0.109	0.107
	242	107	0.104	0.096
	235	107	0.116	0.102
	237	108	0.122	0.096
	237	104	0.111	0.091
	230	106	0.118	0.105
	235	105	0.130	0.092
	240	107	0.130	0.097
	240	105	0.132	0.092
	240	104	0.132	0.105
	240	105	0.108	0.101
	235	104	0.129	0.118
Requirements	230 min.	**110 ± 10**	0.05 min	0.05 min.
Pass/Fail	Pass	Pass	Pass	Pass

WATER LEAKAGE, ASTM D 5151
Gloves were filled with 1000 mil. of tap water, then observed for two minutes for evidence of leakage.
500 gloves tested
AQL 2.5

	RESULTS	REQUIREMENTS	PASS/FAIL
Number of Failures	16	accept 21/ reject 22	Pass

**ARDL is ISO 17025 accredited by A2LA 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*

April 26, 2021
Douglas Stein
PPE Advantage

RESIDUAL POWDER, ASTM D 6124 PROCEDURE 1
Five glove specimens washed, the water was vacuumed through the filter then dried at 100°C to a constant weight.

	RESULTS	REQUIREMENTS	PASS/FAIL
Total Powder per Glove, mg	1.6	2 max.	Pass

SUMMARY OF THE TEST METHOD ASTM F1671 PROCEDURE B
Prior to testing, all test and control samples are conditioned in an environmental chamber for 24 h at 21 ± 5 °C and a relative humidity between 30-80%. Samples are then mounted onto the penetration cell chamber and challenged with a suspension of bacteriophage ΦX174 at a pressure of 13.8 kPa for 1 min and observed over an additional 54 minutes. After this time, the suspension is removed from the inner chamber, followed by the removal of the outer cover of the penetration cell chamber. Sterile broth is added to the outer chamber and swirled for 1 min before collecting and assaying for the presence of bacteriophage. Assays were performed in the presence of a retaining screen

Interpretation of results:
Test items that exhibit no detectable plaque forming units pass the test. In order for the test results to be valid, the following must be obtained:

(1) No background counts in any of the airborne contamination controls
(2) Negative control sample passes the test with no detectable phage counts
(3) Positive control sample fails the test with the visual observation of a fluid leak or the presence of plaque forming units

ASTM F1671 Viral Penetration Test Results

Results:

Test Article ID: Prince ™ Premium+ Nitrile, Examination, Chemo Tested, Powder Free, Non-Sterile, Ambidextrous, Single use only, Blue, Size large, Lot# 411128359

Date Received: 4-16-2021

Test Article Side Tested: Outside

Test Article Preparation: Samples were cut from the Palm/wrist area of the glove.

Test Article Sealed: Silicone Gaskets

Exposure Procedure: B Retaining Screen

Support Screen: Fiberglass Mesh

Compatibility Ratio: 1.2

Environmental Plate Results: PASS

Number Test Articles Tested: 3

Number Test Articles Passed: 3

April 26, 2021
Douglas Stein
PPE Advantage

Test Article Identification	Sample Mass (gm)	Average Thickness (mm)	Pre-Challenge PFU	Post-Challenge PFU	Assay Titer (PFU/ml)	Visual Leak Observation	Test Result
Negative Control - Silicone Film	21.53	1.957	4.9×10^5	4.5×10^5	<1[a]	None Seen	Pass
Blue gown, Positive Control	0.51	0.077	4.9×10^5	4.5×10^5	TMTC**	None Seen	Pass
Prince ™ Premium+ Nitrile, Examination, Chemo Tested, Powder Free, Non-Sterile, Ambidextrous, Single use only, Blue, Size large, Lot# 411128359	0.38	0.096	4.9×10^5	4.5×10^5	<1[a]	None Seen	Pass
	0.36	0.095	4.9×10^5	4.5×10^5	<1[a]	None Seen	Pass
	0.39	0.107	4.9×10^5	4.5×10^5	<1[a]	None Seen	Pass

aA value of <1 PFU/ml = plates showing no plaques.
**TMTC = PFUs that are Too Many To Count

ASSAY PROCEDURE:

Sample Extractions. The samples were measured, weighed, and cut prior to extraction within a polypropylene extraction vessel. The extraction buffer used was 50 mM phosphate pH 7.4 at a ratio of 5 ml of buffer per gram of sample. The extractions were carried out at room temperature for two hours with agitation. The samples were removed and the extracts centrifuged at >500 xg for 15 minutes to pellet particulates. The cleared extracts were then used in the assay.

ASTM D5712 Assay. Proteins are precipitated from the extract by the addition of a DOC-PTA-TCA (DeOxyCholate, PhosphoTungstic Acid, Tri-Chloroacetic Acid) solution and centrifugation. This precipitation step concentrates the proteins and removes substances that may interfere in the assay. The proteins are resuspended in 0.2 N NaOH and then transferred to each of two plates where they are incubated with a (1) copper tartrate solution and (2) an alkaline tartrate solution. Folin Ciocalteu's phenol reagent is added and incubated for 30 minutes for color to develop. The OD of the sample is then determined by reading at 700 nm. The OD values from the alkaline tartrate plate are subtracted from the copper tartrate plate. The resulting values are used to generate the Standard Curve. Protein values for the test items are determined by interpolation from this standard curve. The LOD for the ASTM D5712 assay determined in the laboratory is 2.2 pg/ml and the LOQ is 11.0 pg/gm. An aqueous soluble protein content limit of 200 pg/dm^2 for gloves has been established. (See ASTM D3577 & ASTM D3578.)

ASTM D6499 ELISA Inhibition Assay. The standard and test samples are serially diluted in a 96 well plate, after which an equal volume of diluted rabbit anti-latex polyclonal antibody is added and the plate incubated for 2h at 37°C. One hundred microliters of sample from each well is transferred to the corresponding well of a plate coated with Hevea NRL and blocked with non-fat dry milk and incubated for 2h at 37°C. The plates are then washed and a 100 pi solution of Goat anti-Rabbit IgG conjugated with the enzyme HorseRadish Peroxidase (HRP) is added and incubated for 1h at 37°C. Plates are washed and a 100-pl solution of the substrate OPD is added to each well and color allowed to develop. The reaction is stopped by the addition of 50 pi of 4N H_2SO_4. The plate is then read at 490 nm. Protein values are determined by interpolation from a standard curve.

RESULTS: The sample identified as Prince (TM) Premium+ Nitrile Examination Chemo Tested Powder Free Non-Sterile Ambidextrous Single Use Only Blue Size Large Lot# 411128359 tested below the detection limit of the D5712 and D6499 assays.

April 26, 2021
Douglas Stein
PPE Advantage

ASTM D5712 Test Certificate

Sample Description	Weight (gm)	Area (dm^2)	Extract Vol. (ml)	Assay Cone. (pg/ml)	Antigenic Protein (pg/gm)		Antigenic Protein (pg/dm^2)	
Prince (TM) Premium+ Nitrile Examination Chemo Tested Powder Free Non-Sterile Ambidextrous Single Use Only Blue Size Large Lot# 411128359	5.2	10.1	26.0	b.d.	<	0.2	<	0.1

Where b.d.= below detection, (2.2 fjg/ml)
**Note: The ASTM D5712 standard defines a "Sample" as three items. In the cases where less than three items are provided the Test Certificate is labeled as "Modified".*

ASTM D6499 Test Certificate

Sample Description	Weight (gm)	Area (dm^2)	Extract Vol. (ml)	Assay Cone (MQ/ml)	Total Protein (pg/gm)		Total Protein (Mg/dm^2)	
Prince (TM) Premium+ Nitrile Examination Chemo Tested Powder Free Non-Sterile Ambidextrous Single Use Only Blue Size Large Lot# 411128359	5.2	10.1	26.0	b.d.	<	**11**	<	5
	4.9	10.1	24.5	b.d.				
	4.9	10.1	24.5	b.d.				

Where b.d.= below detection, (0.03 pg/ml)
**Note: The results given in this report relate only to the items tested. This report cannot be reproduced except in full without the written consent ofARDL*

TESTING RESULTS: ASTM D3578 & ASTM D5151

ARDL
AKRON RUBBER DEVELOPMENT LABORATORY, INC.

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April 26, 2021
Douglas Stein
PPE Advantage

SUBJECT: Physical Testing on material submitted by the above company.

RECEIVED: Seven (7) boxes of gloves identified as Prince™ Premium+ Nitrile Examination Chemo Tested Powder Free Non-Sterile Ambidextrous Single Use Only Blue Size Large Lot 411128359

DECISION RULE: Rule #1

DIMENSIONS, ASTM D 3578
13 gloves tested

	LENGTH, mm	WIDTH, mm	FINGER, mm	PALM, mm
	235	107	0.109	0.096
	232	108	0.109	0.107
	242	107	0.104	0.096
	235	107	0.116	0.102
	237	108	0.122	0.096
	237	104	**0.111**	0.091
	230	106	0.118	0.105
	235	105	0.130	0.092
	240	107	0.130	0.097
	240	105	0.132	0.092
	240	104	0.132	0.105
	240	105	0.108	**0.101**
	235	104	0.129	0.118
Requirements	230 min.	111 ± 10	0.08 min	0.08 min.
Pass/Fail	Pass	Pass	Pass	Pass

WATER LEAKAGE, ASTM D 5151
Gloves were filled with 1000 mil. of tap water, then observed for two minutes for evidence of leakage.
500 gloves tested
AQL 2.5

	RESULTS	REQUIREMENTS	PASS/FAIL
Number of Failures	16	accept 21/ reject 22	Pass

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NOTE: Non-ISO 17025 accredited test methods are designated with the [A] symbol to differentiate from ISO 17025 accredited methods in the body of the test report"

April 26, 2021
Douglas Stein
PPE Advantage

Decision Rules

Rule 1. This is the way test results have traditionally been reported by ARDL. If ARDL runs a test for you that has pass/fail requirements, ARDL will report the values observed and then state "Pass" or "Fail", based on those values only. By default, ARDL will apply this rule to all Category I tests and those tests which are not on ARDL's Scope of Accreditation.

Rule 2. This rule takes into account the calculated measurement uncertainty of test results generated. Every test and piece of test equipment has an inherent amount of measurement uncertainty associated with it. Rule 2 establishes "Guard Bands" where the measurement uncertainty value is added to the Minimum Passing requirement and is subtracted from the Maximum Passing requirement. The Pass/Fail requirements thus become tighter and customers may be more "Certain" of their Pass/Fail result.

Rule 3. This rule also takes into account measurement uncertainty but does not set up guard bands. Rule 3 may be used when values are reported, but there is no Pass/Fail requirement called out in the test specification. Rule 3 simply states that the measurement uncertainty is reported to the customer, along with the testing result generated, and the customer decides if the results are suitable for their purposes.

Report Revision Log

Date	Report Revision	Description
4-26-21	New	

Prepared By: Sandy Jones-Hamrick
Project Technician

Approved By: Melissa Marlin
Physical Testing Manager

SC

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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

PRODUCT CERTIFICATION **ASTM D6319**

JOB REF NO. : 2020-10-30-014
DATE RECEIVED : OCTOBER 30, 2020
DATE REPORTED: NOVEMBER 04, 2020

Test Report No. : CRSSA/201149326-CA50324

TEST REPORT

Sample Description	:	Nitrile Examination Glove Powder Free
Brand Name	:	Prince Premium +
Style	:	S
Colour	:	Blue
Country of Origin	:	Malaysia
Size	:	S
Quantity Tested	:	200 pieces
Test Conducted	:	Freedom from holes
Test Method	:	ASTM D6319-10 (Reapproved 2015) & ASTM D5151-06 (Reapproved 2015)
Testing Period	:	30 October 2020 – 04 November 2020

Based on submitted samples, the following results obtained :-

Acceptable Quality Limit (AQL) : 2.5 Accept : 10 Found : 0

Result : Within AQL

SIGNED FOR AND ON BEHALF OF
SGS (MALAYSIA) SDN BHD

.....
CHEE TUCK CHOON
SECTION HEAD
IKM No. M/3983/6401/12/14

PRODUCT CERTIFICATION **ASTM D6319**

SGS

JOB REF NO. : 2020-09-18-007
DATE RECEIVED : SEPTEMBER 18, 2020
DATE REPORTED: OCTOBER 01, 2020

Test Report No. : CRSSA/201047450-CA47109

TEST REPORT

Sample Description	:	Nitrile Examination Powder Free Gloves
Brand Name	:	Prince Premium +
Style	:	L
Colour	:	Blue
Country of Origin	:	Malaysia
Size	:	L
Quantity Tested	:	13 pieces
Test Conducted	:	Dimensions
Test Method	:	ASTM D6319-10 (Reapproved 2015)
Testing Period	:	18 September 2020 – 01 October 2020

Based on submitted samples, the following results obtained :-

Size	L	L	L	L	L	L	L	L	L	L	L	L	L
Width 110 ± 10mm	112	109	111	110	110	111	109	110	108	112	105	111	109
Length Min. 230mm	242	242	245	242	237	237	246	240	247	245	236	243	241
Thickness at palm Min. 0.05mm	0.07	0.07	0.08	0.08	0.08	0.08	0.07	0.08	0.08	0.08	0.08	0.08	0.08
Thickness at finger Min. 0.05mm	0.11	0.10	0.11	0.11	0.11	0.10	0.10	0.10	0.10	0.10	0.11	0.10	0.10

Acceptable Quality Limit (AQL) : 4.0 Accept : 1 Found : 0

SIGNED FOR AND ON BEHALF OF
SGS (MALAYSIA) SDN BHD

CHEE TUCK CHOON
SECTION HEAD
IKM No. M/3983/6401/12/14

PRODUCT CERTIFICATION **ASTM D6319**

Test Report No. : CRSSA/201047450-CA47109

TEST REPORT

Sample Description	:	Nitrile Examination Powder Free Gloves
Brand Name	:	Prince Premium +
Style	:	L
Colour	:	Blue
Country of Origin	:	Malaysia
Size	:	L
Sample Quantity	:	13 pieces per each
Test Conducted	:	Tensile Strength & Elongation (Before Ageing & After Ageing)
Test Method	:	ASTM D6319-10 (Reapproved 2015)
Ageing	:	70 ± 2 Deg C for 168 hrs
Testing Period	:	18 September 2020 – 01 October 2020

Size	Sample No.	BEFORE AGEING		AFTER AGEING	
		Tensile Strength (MPa)	Ultimate Elongation (%)	Tensile Strength (MPa)	Ultimate Elongation (%)
L	1	32.8	520	39.6	540
	2	33.6	520	43.7	560
	3	29.5	500	27.1	500
	4	24.8	500	31.9	500
	5	43.6	560	35.0	520
	6	26.8	500	27.6	500
	7	39.0	540	35.5	540
	8	30.0	500	37.3	560
	9	33.2	520	37.8	560
	10	25.5	500	32.0	500
	11	27.2	500	37.8	560
	12	22.4	480	28.0	500
	13	26.0	500	33.6	520
Requirements:		14 min	500 min	14 min	400 min

SIGNED FOR AND ON BEHALF OF
SGS (MALAYSIA) SDN BHD

CHEE TUCK CHOON
SECTION HEAD
IKM No. M/3983/6401/12/14

PRODUCT CERTIFICATION **ASTM D6319**

Test Report No. : CRSSA/201047450-CA47109

TEST REPORT

Sample Description	:	Nitrile Examination Powder Free Gloves
Brand Name	:	Prince Premium +
Style	:	L
Colour	:	Blue
Country of Origin	:	Malaysia
Size	:	L
Quantity Tested	:	5 pieces
Test Conducted	:	Powder Content
Test Method	:	ASTM D6124-06 (Reapproved 2017)
Testing Period	:	18 September 2020 – 01 October 2020

On testing the samples, the following results were obtained:-

SIZE	Average Powder Mass per Glove
L	0.32 mg

SIGNED FOR AND ON BEHALF OF
SGS (MALAYSIA) SDN BHD

CHEE TUCK CHOON
SECTION HEAD
IKM No. M/3983/6401/12/14

PRODUCT CERTIFICATION **ASTM D6978**

AKRON RUBBER DEVELOPMENT LABORATORY, INC.

Testing. Development. Problem Solving.

January 28, 2021

▪TEST REPORT▪

PN 157544

PHARMACEUTICAL SERVICES

Prepared For:

Douglas Stein
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Prepared By: _____
Tiffany Heller
Manager, Pharmaceutical Services

Approved By: _____
Ana C Barbur, M.S.
Vice President, Analytical & Chemical Services

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AKRON RUBBER DEVELOPMENT LABORATORY, INC.

Testing. Development. Problem Solving.

January 28, 2021

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

RECEIVED: One (1) glove type identified as; Blue Nitrile Gloves Lot# 202001-023, Size Large.

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# 0000098912; Expiration 11/2021
Cisplatin, 1.0 mg/ml (1,000 ppm)	Accord; Lot# P2001296; Expiration 01/2022
Cyclophosphamide (Cytoxan), 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 (Cytoxan), 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

January 28, 2021

TESTING CONDITIONS:

Standard Test Method Used:	ASTM D6978
Analytical Method:	UV/VIS Spectrometry
Testing Temperature:	35.0°C ± 2.0
Collection System:	Closed Loop
Specimen Area Exposed:	5.067 cm^2
Selected Data Points:	25/test
Number of Specimens Tested:	3/test
Location Sampled From:	Cuff

DETECTION METHOD OF CHEMICAL PERMEATION:

UV/VIS ABSORPTION SPECTROMETRY:
Instrument: Perkin Elmer UV/VIS Spectrometer Lambda 25

UV/VIS Absorption Spectrometry was used to measure the absorbance of test chemicals, which permeated through the specimens into the collection medium. The collection medium was circulated in a closed loop through the testing period. Data collection was performed according to the programmed schedule by means of UV Winlab software from the Perkin Elmer Corporation. The list of the characteristic wavelengths is shown below.

Table 3. Characteristic Wavelengths used in UV/VIS Absorption Spectrometry

TESTING DRUG	WAVELENGTH (nm)
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	229
Cisplatin, 1.0 mg/ml (1,000 ppm)	199
Cyclophosphamide (Cytoxan), 20.0 mg/ml (20,000 ppm)	200
Dacarbazine, 10.0 mg/ml (10,000 ppm)	320
Doxorubicin HCl, 2.0 mg/ml (2,000 ppm)	232
Etoposide, 20.0 mg/ml (20,000 ppm)	205
Fluorouracil, 50.0 mg/ml (50,000 ppm)	269
Paclitaxel, 6.0 mg/ml (6,000 ppm)	232
ThioTepa, 10.0 mg/ml (10,000 ppm)	199

SAMPLE CHARACTERISTICS:
Table 4. Thickness characteristics for the tested: Blue Nitrile Gloves Lot# 202001-023, Size Large.

Testing Drug	Thickness (mm)			Average (mm)
	Sample 1	Sample 2	Sample 3	
Carmustine (BCNU)	0.103	0.096	0.092	0.097
Cisplatin	0.095	0.097	0.097	0.096
Cyclophosphamide (Cytoxan)	0.097	0.096	0.096	0.096
Dacarbazine	0.103	0.097	0.097	0.099
Doxorubicin HCl	0.101	0.088	0.100	0.096
Etoposide	0.096	0.093	0.093	0.094
Fluorouracil	0.095	0.094	0.096	0.095
Paclitaxel	0.092	0.091	0.091	0.091
ThioTepa	0.094	0.098	0.097	0.096
Weight/Unit Area (g/m2)	**80.7**			

January 28, 2021

RESULTS:

Table 5. Permeation Test Results on testing of: Blue Nitrile Gloves Lot# 202001-023, Size Large.

TEST CHEMOTHERAPY DRUGS	AVERAGE BREAKTHROUGH DETECTION TIME (Specimen1/2/3) (Minutes)	AVERAGE STEADY STATE PERM. RATE (Specimen1/2/3) (µg/cm²/minute)	OTHER OBSERVATIONS
Carmustine (BCNU), 3.3 mg/ml (3,300 ppm)	43.7 (45.3,43.7,45.4)	0.5 (0.5,0.5,0.4)	Moderate swelling and no degradation
Cisplatin, 1.0 mg/ml (1,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Cyclophosphamide (Cytoxan), 20.0 mg/ml (20,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Dacarbazine, 10.0 mg/ml (10,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Doxorubicin HCl, 2.0 mg/ml (2,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Etoposide, 20.0 mg/ml (20,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Fluorouracil, 50.0 mg/ml (50,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
Paclitaxel, 6.0 mg/ml (6,000 ppm)	>240 min.	N/A	Slight swelling and no degradation
ThioTepa, 10.0 mg/ml (10,000 ppm)	98.6 (108.4,98.6,109.0)	0.2 (0.2,0.2,0.2)	Slight swelling and no degradation

PRODUCT CERTIFICATION **ASTM D6978**

January 28, 2021

SAMPLES RECEIVED:

Blue Nitrile Gloves Lot# 202001-023, Size Large.

Prepared By: _____
Tiffany Heller
Manager, Pharmaceutical Services

Approved By: _____
Ana C Barbur, M.S.
Vice President, Analytical & Chemical Services

**ARDL is ISO 17025 accredited by A2LA 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.*