



**CENTRALBIDDING**  
FROM CENTRAL AUCTION HOUSE

**5000134120 ONE TIME PURCHASE OF NITRILE EXAM GLOVES FOR THE  
PUBLIC WORKS WEST BANK WAREHOUSE**  
Jefferson Parish Government

Project documents obtained from [www.CentralBidding.com](http://www.CentralBidding.com)  
11-Apr-2021 08:43:44 PM



**BID 50-134120**  
**ONE TIME PURCHASE OF NITRILE EXAM GLOVES FOR**  
**THE PUBLIC WORKS WEST BANK WAREHOUSE**

**April 12, 2021 @ 11:00 A.M.**

**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](http://www.jeffparishbids.net), by the bid due date and time.**

**Please Email Questions to:**  
**Mark Buttery**  
**[MButtery@jeffparish.net](mailto:MButtery@jeffparish.net)**  
**504-364-2810**



# JEFFERSON PARISH

## DEPARTMENT OF PURCHASING

CYNTHIA LEE SHENG  
PARISH PRESIDENT

RENNY SIMNO  
DIRECTOR

September 2020

### **Changes to Jefferson Parish Bidding Information**

The Jefferson Parish Purchasing Department would like to make vendors aware of the following changes:

**Total Bid Price Must Include the Cost of Naming Jefferson Parish as Additional Insured:**

Bidder acknowledges that Bidder recovered the cost of any required insurance in the contract price as required by La.R.S. 9:2780.1 and that Bidder recovered any such cost for the purposes of insuring an obligation to indemnify Jefferson Parish, defend Jefferson Parish, or hold Jefferson Parish harmless and that Bidder's indemnity liability is limited to the amount of the proceeds that are payable under the insurance policy or policies that Bidder has obtained.

**Electronic Procurement:** Beginning November 1, 2020, Jefferson Parish will no longer accept manual bid submissions; and will only accept bid submissions electronically via our e-Procurement system, Central Bidding. Central Bidding can be accessed by visiting either [www.centralbidding.com](http://www.centralbidding.com) or [www.jeffparishbids.net](http://www.jeffparishbids.net). All bidders will be required to register with Central Bidding. Jefferson Parish vendors are able to register for free by accessing the following link:  
<https://www.centrauctionhouse.com/registration.php>.

**Probable Construction Cost:** Per Jefferson Parish Administrative Policy, the probable construction cost is not revealed in the Jefferson Parish Bidding Documents. Jefferson Parish Administrative Policy has changed and a range of the probable construction cost will be stated in the Jefferson Parish bidding document, entitled Important Notice to All Bidders – Bid Requirements. Per Louisiana Public Bid Law, the probable construction cost will be read at the bid opening.

**Insurance Requirement:** All bidders must provide proof of valid insurance in the required amounts as stated in the Standard Insurance Requirements for bidding purposes. Failure to provide the proof of valid insurance in all of the required coverage amounts will result in bid rejection.

GENERAL GOVERNMENT BLDG. – 200 DERBIGNY ST., SUITE 4400, GRETNA, LA 70053  
OFFICE 504.364.2678

JOSEPH S. YENNI BLDG. – 1221 ELMWOOD PARK BLVD., SUITE 404, JEFFERSON, LA 70123  
OFFICE 504.364.2678

EMAIL: [PURCHASING@JEFFPARISH.NET](mailto:PURCHASING@JEFFPARISH.NET) WEBSITE: [WWW.JEFFPARISH.NET](http://WWW.JEFFPARISH.NET)

DATE: 4/07/2021

INVITATION TO BID  
THIS IS NOT AN ORDER

Page: 1

BID NO.: 50-00134120

**JEFFERSON PARISH**  
PURCHASING DEPARTMENT  
P.O. BOX 9  
GRETN, LA. 70054-0009  
504-364-2678

VENDOR:

BUYER: MBUTTERY@jeffparish.net

**Bids will be received until 11:00 AM, 4/12/2021 via online at [www.jeffparishbids.net](http://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](http://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 A117.1-1961).

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](http://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.

## INSTRUCTIONS FOR BIDDERS AND GENERAL CONDITIONS

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: 4/07/2021

INVITATION TO BID  
THIS IS NOT AN ORDER

Page: 5

BID NO.: 50-00134120

**JEFFERSON PARISH**

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

VENDOR:

BUYER: MBUTTERY

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**

3-7 Business Days  
once confirmed  
PO

INDICATE DELIVERY DATE ON EQUIPMENT AND SUPPLIES

INDICATE STARTING TIME (IN DAYS) FOR CONSTRUCTION WORK

N/A

INDICATE COMPLETION TIME (IN DAYS) FOR CONSTRUCTION WORK

N/A

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:

Buttonwood Inc.

SIGNATURE:

(Must be signed here)



TITLE:

Business Development Manager

PRINT OR TYPE NAME:

Daniel P. Black

ADDRESS:

7683 S.E 27th St #112

CITY, STATE:

Mercer Island, WA

ZIP:

98040

TELEPHONE:

(361)946-3078

FAX:

( )

EMAIL ADDRESS:

Daniel.Black@bttnusa.com

TOTAL PRICE OF ALL BID ITEMS: \$ 17,000.00



## INVITATION TO BID FROM JEFFERSON PARISH - continued

BID NO.: 50-00134120

SEALED BID

ITEM NUMBER	QUANTITY	U/M	DESCRIPTION OF ARTICLES	UNIT PRICE QUOTED	TOTALS
1	1,000.00	BX	ONE TIME PURCHASE OF NITRILE EXAM GLOVES FOR THE PUBLIC WORKS WEST BANK WAREHOUSE  0010 - GLOVES, BLUE NITRILE, DISPOSABLE, AMBIDEXTROUS, TEXTURED, LARGE, 6 MIL, 9-1/2 IN LENGTH, POWDER FREE, 100 GLOVES PER DISPENSER BOX, MAGID #T9338L OR EQUAL SK# 00-058038M	\$17.00/box	\$17,000.00



# STOP C-19 NITRILE GLOVES

CONTACT YOUR LOCAL REP

DECEMBER

# STOP C-19 NITRILE GLOVES



Carton Of 1000 Nitril Gloves - One Hundred Gloves Per Box




STOP C-19 : Open Box of Nitrile Exam Gloves



STOP C-19 : Nitrile Exam Glove Stretch



# NITRILE GLOVE TESTING

 DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room - WO66-0609  
Silver Spring, MD 20993-0002

Better Care Plastic Technology CP., Limited  
C/O Ms. Jie Liu  
Surprotect, Incorporated  
3973 Schaefer Avenue  
Chino, California 91710

AUG 06 2010

Re: K101595  
Trade/Device Name: Powder Free Nitrile Patient Examination Gloves, Blue  
Regulation Number: 21 CFR 880.6250  
Regulation Name: Patient Examination Glove  
Regulatory Class: 1  
Product Code: LZA  
Dated: July 19, 2010  
Received: July 21, 2010

Dear Ms. Liu:

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.

FDA 510K

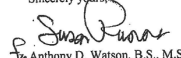
Page 2- Ms. Liu

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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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/ReportProblem/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,

  
Anthony D. Watson, B.S., M.S., M.B.A.  
Director  
Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

FDA 510K

FDA 510K Details:

- Regulation Number: 21 CFR 880.6250
- Regulation Name: Patient Examination Glove
- Regulatory Class: 1
- Product Code: LZA



# NITRILE GLOVE PERFORMANCE TESTING

## Performance Testing

The Standards used for production of Powder Free Nitrile Patient Examination Gloves (Blue) are mainly based on ASTM D6319-19. In accordance with physical requirements established by the ASTM standard, the following are the physical requirements and dimensional testing results:

Technological Characteristics	Standard/Test/FDA Minimum Guidance	Inspection Level and AQL	Results Summary	Conclusion
Length (mm)	220mm for size XS-S 230mm for size M-XL	S-2, AQL 4.0	XS: 230-238mm	Pass
			S: 234-242mm	
			M: 230-242mm	
			L: 238-244mm	
			XL: 232-241mm	
Width (mm)	XS: 70±10	S-2, AQL 4.0	77-78mm	Pass
	S: 80±10		86-88mm	
	M: 95±10		96-98mm	
	L: 110±10		108-110mm	
	XL: 120±10		116-117mm	
Palm Thickness (mm)	0.05mm minimum	S-2, AQL 4.0	0.085-0.095mm	Pass
Finger Thickness (mm)	0.05mm minimum	S-2, AQL 4.0	0.09-0.105mm	Pass
Tensile Strength (Mpa)				
Before aging	14Mpa minimum	S-2, AQL 4.0	15.7-19Mpa	Pass
After aging	14Mpa minimum	S-2, AQL 4.0	15.2-18.6Mpa	Pass
Ultimate Elongation (%)				
Before aging	500% minimum	S-2, AQL 4.0	500-550%	Pass
After aging	400% minimum	S-2, AQL 4.0	430-530%	Pass
Freedom from Holes	AQL 2.5	G-I, AQL 2.5	0/125, meets AQL 2.5 requirements	Pass
Residual Powder	Not more than 2mg per Glove	N=5	0.5mg	Pass

ASTM D6319-19

ASTM. D6319-19, ASTM 0515 I -19 and FDA 1000ml Water Leak Test (21 CFR 800.20).



# NITRILE GLOVE PERFORMANCE TESTING

ASTM D5151-19 and FDA  
1000ml Water Leak Test  
(21 CFR 800.20).

Testing Criteria						Testing Result	Conclusion
Lot Size	Round	Sample Size	Cumulative Sample Size	Accepted Rejection Criteria		125 gloves sampled, zero (0) pcs. leak	Pass
				Accept	Reject		
35,000 and above	1 <sup>st</sup>	125	125	1	7		
	2 <sup>nd</sup>	125	250	4	10		
	3 <sup>rd</sup>	125	375	8	13		
	4 <sup>th</sup>	125	500	12	17		
	5 <sup>th</sup>	125	625	17	20		
	6 <sup>th</sup>	125	750	21	23		
	7 <sup>th</sup>	125	875	25	26		

## Test Method:

As specified in ASTM D6124-06 (2017) Standard Test Method for Residual Powder content on Medical Gloves:

## Testing results:

Size	XS	S	M	L	XL
Sample Quantity	5	5	5	5	5
Average Content (mg/glove)	0.55	0.56	0.59	0.60	0.61
Powder Content Criteria: Not to exceed more than 2mg/glove for Powder Free Nitrile Examination Gloves.					

ASTM D6124-06  
(2017) Standard Test  
Method for Residual  
Powder content on  
Medical Gloves

# NITRILE GLOVE PERFORMANCE TESTING

EN455-1 : 2000 Medical Gloves For  
Single Use

Part 1 : Requirements & Testing For  
Physical Holes

EN455-2:2015 Medical Gloves For  
Single Use

Part 2 : Requirements & Testing For  
Physical Properties

EN455-3 2015 Medical Gloves For  
Single Use

Part 3 : Requirements & Testing For  
Biological Evaluation Clause 4.4 & 4.6

Test Report Number(s):

SHHL1602007536MD-01

The image shows a verification certificate from SGS. At the top right is the SGS logo, which includes a blue bird icon and the letters 'SGS'. The title of the certificate is 'VERIFICATION OF EN 455 CONDITIONAL COMPLIANCE'. The background features a world map. The certificate contains the following information:

- No.:** SHHL1602007536MD-01C
- Product Name:** DISPOSABLE NITRILE GLOVE
- Style No:** XS, S, M, L, XL, XXL
- Applicant:** SHIJIAZHUANG HONGRAY GROUP CO., LTD  
SOUTH TONGDA RD., EAST DIST. JINZHOU CITY, HEBEI,  
052260, CHINA
- Manufacturer:** SHIJIAZHUANG HONGRAY GROUP CO., LTD  
SOUTH TONGDA RD., EAST DIST. JINZHOU CITY, HEBEI,  
052260, CHINA
- Test Standard:** EN455-1:2000 MEDICAL GLOVES FOR SINGLE USE-  
PART 1: REQUIREMENTS AND TESTING FOR FREEDOM FROM  
HOLES  
EN455-2:2015 MEDICAL GLOVES FOR SINGLE USE-  
PART 2: REQUIREMENTS AND TESTING FOR PHYSICAL  
PROPERTIES  
EN455-3:2015 MEDICAL GLOVES FOR SINGLE USE-  
PART 3: REQUIREMENTS AND TESTING FOR BIOLOGICAL  
EVALUATION CLAUSE 4.4 & 4.6
- as shown in the Test Report Number(s):** SHHL1602007536MD-01

A statement at the bottom reads: 'This verification is only valid for the equipment and configuration described, and in conjunction with the test data detailed. It contains the result of the single examination of the subject being in hand and does not represent any universally valid decision concerning the quality of any subject of the current production.'

On the left, there is a signature and the text: 'Dorra Gu', 'GRS-Handline SBU Section Head', 'SGS-CSTC Standards Technical Services Co., Ltd.'.

On the right, the date 'Apr 12, 2016' is printed.

Below the signature, it states: 'Copyright of this verification is owned by SGS-CSTC Standards Technical Services Co., Ltd. and may not be reproduced other than in full and with the prior approval of the General Manager. This verification is subjected to the governance of the General Conditions of Services, printed overleaf.'

Below that, it says: 'Member of SGS Group (Société Générale de Surveillance)'.

At the bottom left, there is a small disclaimer: 'This document is issued on the Client's behalf, by the Company under its General Conditions of Service printed overleaf. The Client's attention is drawn to the limitation of liability, indemnification and jurisdiction issues defined therein.'

At the bottom right, it says 'SGSPAPER' and '16598818' next to a barcode.



# STOP C-19 NITRILE GLOVES

CONTACT YOUR LOCAL REP

DECEMBER





## btn: Executive Summary