



**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)  
07-Apr-2021 02:08:12 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)

INVITATION TO BID  
THIS IS NOT AN ORDER

Page: 1

DATE: 4/07/2021

BID NO.: 50-00134120

**JEFFERSON PARISH**  
PURCHASING DEPARTMENT  
P.O. BOX 9  
GRETNA, 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 A1 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](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: Performance Safety Group

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.

<b>DELIVERY: FOB JEFFERSON PARISH</b>	
INDICATE DELIVERY DATE ON EQUIPMENT AND SUPPLIES	7 Days from Receipt of PO
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) \_\_\_\_\_

<b>*** ALL BIDDERS MUST COMPLETE SECTION BELOW ***</b>	
FIRM NAME: Performance Safety Group	
SIGNATURE: (Must be signed here)	TITLE: Gov't Contracts Manager
PRINT OR TYPE NAME: Drew Allrich	
ADDRESS: 781A Rudder Road	
CITY, STATE: St. Louis, MO	ZIP: 63026
TELEPHONE: (636) 326-4688	FAX: (877)774-1329
EMAIL ADDRESS: GOVT@PSGgear.com	

TOTAL PRICE OF ALL BID ITEMS: \$ 24,990.00

## 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	<p data-bbox="542 342 1089 390">ONE TIME PURCHASE OF NITRILE EXAM GLOVES FOR THE PUBLIC WORKS WEST BANK WAREHOUSE</p> <p data-bbox="542 436 1062 554">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</p> <p data-bbox="553 600 1045 636">*Pricing based on 100/box Quantities*</p>	<p data-bbox="1166 436 1252 464">\$24.99</p>	<p data-bbox="1349 436 1490 464">\$24,990.00</p>



**PSG**<sup>TM</sup>

PERFORMANCE SAFETY GROUP

SAFE SAVINGS. SMART SOURCING.

ADVANCING PERFORMANCE IN HEALTHCARE

**SINGLE-USE**  
**EXAM GLOVES**

MEDICAL GRADE

# COBALT FIT NITRILE

## POWDER-FREE EXAMINATION GLOVES



# COBALT FIT NITRILE

by PERFORMANCE SAFETY GROUP

## MEDICAL GRADE EXAMINATION GLOVES

Affordable, Worry-Free Protection for Healthcare Professionals



A New Level of Comfort, Protection & Value

### FEATURES & BENEFITS

#### Facility-Wide Solution

Standardize ONE exam glove for virtually ALL your needs

#### Natural Rubber Latex-Free

Prevents Type I allergy & reduces the potential of Type IV hypersensitivity

#### Excellent Strength

Ultra-soft, thin & lightweight, yet highly elastic & strong

#### Superior Barrier Protection

Defends against viruses, pathogens, chemicals, & chemotherapy drugs

#### Finger-Textured

Exceptional grip on instruments in wet or dry environments

#### Environmentally Responsible Packaging

300-count boxes maximize space, reduce waste, & minimize cost

### CHEMOTHERAPY DRUGS PERMEATION TEST

ASTM D6978-05 (2013)

Cytarabine	Methotrexate	
Cisplatin	Mitomycin C	
*Cyclophosphamide (Cytoxan)	Mitoxantrone	No Breakthrough after 240 minutes
*Doxorubicin HCl	*Paclitaxel (Taxol)	
Dacarbazine (DTIC)	Vincristine Sulfate	
*Etoposide		
*Fluorouracil		
Ifosfamide		
*Thiotepa		30 minutes
*Carmustine		10 minutes

\* denotes mandatory chemotherapy drugs

### RESISTANCE to PERMEATION by CHEMICALS

(EN 374:2003 Part 3)	Level
10% Acetic Acid	3
4% Chlorhexidine Digluconate	6
5% Ethidium Bromide	6
36% Formaldehyde	3
50% Glutaraldehyde	6
4% Gluter aldehyde	6
3% Hydrogen Peroxide	6
1.5% Methanol in Water	6
0.1% Phenol	6
40% Sodium Hydroxide	6
10-13% Sodium Hypochlorite	6
50% Sulphuric Acid	6

with measured breakthrough time of minimum 480 minutes for level 6 & minimum 60 minutes for level 3

### PACKAGING INFORMATION

Case Dimension (mm) : 430 x 265 x 255

Box Dimension (mm) : 240 x 128 x 98

300 pcs per box, 10 boxes per case

### PRODUCT CODES

X-Small: CF3-50000	Large: CF3-50015
Small: CF3-50005	X-Large: CF3-50020
Medium: CF3-50010	2X-Large: CF3-50025

### SPECIFICATIONS & TYPICAL PERFORMANCE (ASTM D6319 & EN 455)

	SPEC	TYPICAL
<b>Thickness (mm)</b>		
Cuff	Min. 0.04	0.04 - 0.05
Palm	Min. 0.05	0.07 - 0.08
Finger	Min. 0.06	0.09 - 0.10
<b>Dimension (mm)</b>		
Length	Min. 240	245 - 248
<b>Physical Properties - Unaged</b>		
Tensile Strength (MPa)	Min. 14	30 - 41
Elongation (%)	Min. 500	500 - 560
Force at Break (N)	Min. 6.0	6.0 - 7.0
<b>Physical Properties - Aged</b>		
Tensile Strength (MPa)	Min. 14	30 - 37
Elongation (%)	Min. 400	480 - 520
Force at Break (N)	Min. 6.0	6.1 - 7.0

### CERTIFICATIONS

Comply to International Standard (ASTM D6319 & EN455)  
FDA 510(k) Pre-market Notification

#### Biological Evaluation

Primary Skin Irritation Test  
Dermal Sensitization Assay  
Cytotoxicity Test

#### Additional Test

Viral Penetration (ASTM F1671-13)  
Chemotherapy Drugs (ASTM D6978)  
Chemical Residue

#### Food Handling

US FDA 21 CFR 177.2600  
(EU) No. 10/2011 (EN 1186)

#### MDD Compliance

MDD 93/42/EEC

#### PPE Compliance

PPE 89/686/EEC, CAT III

### PRODUCT ATTRIBUTES

Powder-Free - Latex-Free - Finger Textured - AQL 1.5  
Standard Cuff - Beaded - Ambidextrous - Chlorinated



### RECOMMENDED APPLICATIONS





**U.S. FOOD & DRUG**  
ADMINISTRATION

Dear Performance Safety Group:

This e-mail provides confirmation that the annual registration for the following medical device establishment has been successfully completed for 2020:

**Registration Number: 3009305903**  
**Owner Operator Number: 10041459**  
**PERFORMANCE SAFETY GROUP, INC.**  
**781A Rudder Rd.**  
**Fenton, MO 63026**  
**UNITED STATES**

If you do not see a registration number assigned to the establishment and your establishment previously had one, please send an email to [reglist@cdrh.fda.gov](mailto:reglist@cdrh.fda.gov) and include the registration number you believe is assigned to your establishment. We will review and determine if a duplicate registration has been created for your establishment.

Your registration is valid until December 31, 2018. Registration for 2019 will be conducted between October 1 and December 31, 2018.

Please note that registering your device facility and listing your devices does not, in any way, constitute FDA approval of your facility or your devices.

Should you have any questions, please send an e-mail to the CDRH Registration and Listing Helpdesk at [reglist@cdrh.fda.gov](mailto:reglist@cdrh.fda.gov).

CDRH Registration and Listing Helpdesk  
Office of Compliance  
Center for Devices and Radiological Health  
U.S. Food and Drug Administration  
Email: [reglist@cdrh.fda.gov](mailto:reglist@cdrh.fda.gov)



**U.S. FOOD & DRUG**  
ADMINISTRATION

Licence Number

**13017**

Numéro de la licence

**Medical Device  
Establishment Licence**

**Licence d'établissement  
pour les instruments médicaux**

**PERFORMANCE SAFETY GROUP I, LP**

PERFORMANCE SAFETY GROUP  
781A RUDDER ROAD  
ST. LOUIS, MISSOURI  
UNITED STATES  
63026

This licence is issued in accordance with the Medical Devices Regulations of the Food and Drugs Act for the following activities:

Cette licence est délivrée conformément à la Loi sur les aliments et drogues, règlement sur les instruments médicaux pour les activités qui suivent:

	Distributor / Distributeur	Importer / Importateur	Manufacture Devices for Distribution / Fabricant d'instruments médicaux pour distribution
Class I / Classe I	Yes / Oui	No / Non	Yes / Oui
Class II / Classe II	Yes / Oui	No / Non	.....
Class III / Classe III	No / Non	No / Non	.....
Class IV / Classe IV	No / Non	No / Non	.....

**Attestation made :**

**Attestations faites :**

<p>The establishment has documented procedures in place in respect of:</p> <ul style="list-style-type: none"> <li>• distribution records</li> <li>• complaint handling</li> <li>• recalls</li> <li>• mandatory problem reporting</li> <li>• handling, storage, delivery</li> <li>• installation</li> <li>• corrective action</li> <li>• servicing</li> </ul>	<p>[ Y ]</p> <p>[ Y ]</p> <p>[ Y ]</p> <p>[ N ]</p> <p>[ Y ]</p> <p>[ N ]</p> <p>[ N ]</p> <p>[ N ]</p>	<p>L'établissement a mis en oeuvre une procédure écrite concernant:</p> <ul style="list-style-type: none"> <li>• les registres de distribution</li> <li>• les plaintes</li> <li>• les rappels</li> <li>• rapports d'incident obligatoires</li> <li>• la manutention, le stockage, la livraison</li> <li>• l'installation,</li> <li>• les mesures correctives</li> <li>• l'entretien</li> </ul>
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Site listing begins on the back of this page

Liste des sites commence au verso de cette page

Issue Date, date de délivrance: 2020-08-07

<p>Minister of Health Ministre de la santé</p>	<p>Countersigned: Director, Medical Devices Compliance Program or delegated authority Contresigné par: Directeur, Programme de la conformité des matériels médicaux ou autorité déléguée</p> <div style="text-align: center;">               Chad Sheehy         </div>
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Cette licence appartient au Programme de la conformité des matériels médicaux et doit être retournée sur demande.

*Thank You*

to those risking their lives to save ours:  
Our Healthcare Workers  
and First Responders.  
Thank You, Healthcare Heroes

*We Appreciate You*

