



West Virginia Purchasing Division

2019 Washington Street, East
Charleston, WV 25305
Telephone: 304-558-2306
General Fax: 304-558-6026
Bid Fax: 304-558-3970

The following documentation is an electronically-submitted vendor response to an advertised solicitation from the *West Virginia Purchasing Bulletin* within the Vendor Self-Service portal at ***wvOASIS.gov***. As part of the State of West Virginia's procurement process, and to maintain the transparency of the bid-opening process, this documentation submitted online is publicly posted by the West Virginia Purchasing Division at ***WVPurchasing.gov*** with any other vendor responses to this solicitation submitted to the Purchasing Division in hard copy format.

Header @ 4

List View

General Information | Contact | Default Values | Discount | Document Information

Procurement Folder: 237804

SO Doc Code: CRFQ

Procurement Type: Central Master Agreement

SO Dept: 0506

Vendor ID: 000000186296

SO Doc ID: BPH1700000002

Legal Name: GLOBAL PROTECTION CORPORATION

Published Date: 9/26/16

Alias/DBA:

Close Date: 10/25/16

Total Bid: \$292,749.23

Close Time: 13:30

Response Date: 10/25/2016

Status: Closed

Response Time: 8:37

Solicitation Description: Lubricated, non-lubricated, latex free condoms and colored

Total of Header Attachments: 4

Total of All Attachments: 4



Purchasing Division
 2019 Washington Street East
 Post Office Box 50130
 Charleston, WV 25305-0130

**State of West Virginia
 Solicitation Response**

Proc Folder : 237804

Solicitation Description : Lubricated, non-lubricated, latex free condoms and colored

Proc Type : Central Master Agreement

Date issued	Solicitation Closes	Solicitation Response	Version
	2016-10-25 13:30:00	SR 0506 ESR10251600000001826	1

VENDOR
000000186296 GLOBAL PROTECTION CORPORATION

Solicitation Number: CRFQ 0506 BPH1700000002

Total Bid : \$292,749.23 **Response Date:** 2016-10-25 **Response Time:** 08:37:43

Comments:

FOR INFORMATION CONTACT THE BUYER
 April Battle
 (304) 558-0067
 april.e.battle@wv.gov

Signature on File	FEIN #	DATE
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All offers subject to all terms and conditions contained in this solicitation

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
1	Lubricated condoms	2001600.00000	EA	\$0.046000	\$92,073.60

Comm Code	Manufacturer	Specification	Model #
53131622			

Extended Description : 3.1.1 Contract item #1 - Lifestyles Brand Lubricated Latex Condom, Part #5800 or equal.

Comments: Substitute
Atlas Ultra Lubricated

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
2	Non-Lubricated condoms	252250.00000	EA	\$0.046500	\$11,729.63

Comm Code	Manufacturer	Specification	Model #
53131622			

Extended Description : 3.1.2 Contract Item #2 - Lifestyles Brand Non-Lubricated Latex Condom, Part #5700 or equal.

Comments: Substitute
Atlas Non Lubricated Condoms

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
3	Latex Free Lubricated condoms	252250.00000	EA	\$0.360000	\$90,810.00

Comm Code	Manufacturer	Specification	Model #
53131622			

Extended Description : 3.1.3 Contract item #3 - Lifestyles Brand NON-Latex Lubricated Condom, Part #7800 or equal.

Comments: NO SUBSTITUTION

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Ln Total Or Contract Amount
4	Colored Condoms	2088000.00000	EA	\$0.047000	\$98,136.00

Comm Code	Manufacturer	Specification	Model #
53131622			

Extended Description : 3.1.4 Contract item #4 - Lifestyles Brand Assorted ColorCondom, Part #5300 or equal.

Comments: Substitution
Atlas Assorted Colors



Purchasing Division
 2019 Washington Street East
 Post Office Box 50130
 Charleston, WV 25305-0130

State of West Virginia
 Request for Quotation
 26 - Medical

Proc Folder: 237804

Doc Description: Lubricated, non-lubricated, latex free condoms and colored

Proc Type: Central Master Agreement

Date Issued	Solicitation Closes	Solicitation No	Version
2016-09-26	2016-10-25 13:30:00	CRFQ 0506 BPH1700000002	1

BID RECEIVING LOCATION

BID CLERK
 DEPARTMENT OF ADMINISTRATION
 PURCHASING DIVISION
 2019 WASHINGTON ST E
 CHARLESTON WV 25305
 US

VENDOR

Vendor Name, Address and Telephone Number:

*Global Protection Corp
 12 Channel St
 Boston MA 02210
 617-946-2800 x724*

FOR INFORMATION CONTACT THE BUYER

April Battle
 (304) 558-0067
 april.e.battle@wv.gov

Signature X *David L. Roddy* FEIN # *043043077* DATE *10/24/16*
 All offers subject to all terms and conditions contained in this solicitation

ADDITIONAL INFORMATION:

The West Virginia Purchasing Division is soliciting bids on behalf of the West Virginia Department of Health and Human Resources, Bureau for Public Health to establish an open-end contract for Lubricated, Non-Lubricate, Latex-Free Condoms and Assorted Colored Condoms.

INVOICE TO		SHIP TO	
ALL STATE AGENCIES VARIOUS LOCATIONS AS INDICATED BY ORDER		STATE OF WEST VIRGINIA VARIOUS LOCATIONS AS INDICATED BY ORDER	
No City	WV99999	No City	WV 99999
US		US	

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Total Price
1	Lubricated condoms	2001600.00000	EA	46.00	92,092.00

Comm Code	Manufacturer	Specification	Model #
53131622	Global Protection	ATLAS LUBRICATED	10000C

Extended Description :

3.1.1 Contract item #1 - Lifestyles Brand Lubricated Latex Condom, Part #5800 or equal.

INVOICE TO		SHIP TO	
ALL STATE AGENCIES VARIOUS LOCATIONS AS INDICATED BY ORDER		STATE OF WEST VIRGINIA VARIOUS LOCATIONS AS INDICATED BY ORDER	
No City	WV99999	No City	WV 99999
US		US	

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Total Price
2	Non-Lubricated condoms	252250.00000	EA	46.50	11,764.50

Comm Code	Manufacturer	Specification	Model #
53131622	Global Protection Corp	ATLAS NONLUBRICATED	10600C

Extended Description :

3.1.2 Contract Item #2 - Lifestyles Brand Non-Lubricated Latex Condom, Part #5700 or equal.

INVOICE TO		SHIP TO	
ALL STATE AGENCIES VARIOUS LOCATIONS AS INDICATED BY ORDER		STATE OF WEST VIRGINIA VARIOUS LOCATIONS AS INDICATED BY ORDER	
No City	WV99999	No City	WV 99999
US		US	

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Total Price
3	Latex Free Lubricated condoms	252250.00000	EA	360	91,080.00

Comm Code	Manufacturer	Specification	Model #
53131622	Lifestyles	Lifestyles NonLatex	A78000

Extended Description :

3.1.3 Contract item #3 - Lifestyles Brand NON-Latex Lubricated Condom, Part #7800 or equal.

INVOICE TO		SHIP TO	
ALL STATE AGENCIES VARIOUS LOCATIONS AS INDICATED BY ORDER		STATE OF WEST VIRGINIA VARIOUS LOCATIONS AS INDICATED BY ORDER	
No City	WV99999	No City	WV 99999
US		US	

Line	Comm Ln Desc	Qty	Unit Issue	Unit Price	Total Price
4	Colored Condoms	2088000.00000	EA	46.00	96,600.-

Comm Code	Manufacturer	Specification	Model #
53131622	Global Protection Corp	Atlas Colored	10100C

Extended Description :

3.1.4 Contract item #4 - Lifestyles Brand Assorted ColorCondom, Part #5300 or equal.

SCHEDULE OF EVENTS

Line	Event	Event Date
1	Questions Due	2016-10-11

BPH170000002	Document Phase Final	Document Description Lubricated, non-lubricated, latex free condoms and colored	Page 4 of 4
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ADDITIONAL TERMS AND CONDITIONS

See attached document(s) for additional Terms and Conditions

REQUEST FOR QUOTATION
CRFQ 0506 BPH1700000002
Lubricated, Non-Lubricated and Latex Free Condoms

- 8.3 Reports:** Vendor shall provide quarterly reports and annual summaries to the Agency showing the Agency's items purchased, quantities of items purchased, and total dollar value of the items purchased. Vendor shall also provide reports, upon request, showing the items purchased during the term of this Contract, the quantity purchased for each of those items, and the total value of purchases for each of those items. Failure to supply such reports may be grounds for cancellation of this Contract.
- 8.4 Contract Manager:** During its performance of this Contract, Vendor must designate and maintain a primary contract manager responsible for overseeing Vendor's responsibilities under this Contract. The Contract manager must be available during normal business hours to address any customer service or other issues related to this Contract. Vendor should list its Contract manager and his or her contact information below.

Contract Manager: David Roddy
Telephone Number: 617-946-2800 x24
Fax Number: 617-946-3246
Email Address: david@globalprotection.com

DESIGNATED CONTACT: Vendor appoints the individual identified in this Section as the Contract Administrator and the initial point of contact for matters relating to this Contract.

David Roddy Account Manager
(Name, Title)

David Roddy Account Manager
(Printed Name and Title)

12 Channel St 4th Floor Boston MA 02210
(Address)

617-946-2800 x124(P) 617-946-3246(F)
(Phone Number) / (Fax Number)

david@globalprotection.com
(email address)

CERTIFICATION AND SIGNATURE: By signing below, or submitting documentation through wvOASIS, I certify that I have reviewed this Solicitation in its entirety; that I understand the requirements, terms and conditions, and other information contained herein; that this bid, offer or proposal constitutes an offer to the State that cannot be unilaterally withdrawn; that the product or service proposed meets the mandatory requirements contained in the Solicitation for that product or service, unless otherwise stated herein; that the Vendor accepts the terms and conditions contained in the Solicitation, unless otherwise stated herein; that I am submitting this bid, offer or proposal for review and consideration; that I am authorized by the vendor to execute and submit this bid, offer, or proposal, or any documents related thereto on vendor's behalf; that I am authorized to bind the vendor in a contractual relationship; and that to the best of my knowledge, the vendor has properly registered with any State agency that may require registration.

Global Protection Corp
(Company)

David L Roddy Account Manager
(Authorized Signature) (Representative Name, Title)

David Roddy Account Manager
(Printed Name and Title of Authorized Representative)

10/24/16
(Date)

617-946-2800 x124 617-946-3246
(Phone Number) (Fax Number)

ADDENDUM ACKNOWLEDGEMENT FORM
SOLICITATION NO.: CRFQ 0506 BPH170000002

Instructions: Please acknowledge receipt of all addenda issued with this solicitation by completing this addendum acknowledgment form. Check the box next to each addendum received and sign below. Failure to acknowledge addenda may result in bid disqualification.

Acknowledgment: I hereby acknowledge receipt of the following addenda and have made the necessary revisions to my proposal, plans and/or specification, etc.

Addendum Numbers Received:

(Check the box next to each addendum received)

- | | |
|---|--|
| <input type="checkbox"/> Addendum No. 1 | <input type="checkbox"/> Addendum No. 6 |
| <input type="checkbox"/> Addendum No. 2 | <input type="checkbox"/> Addendum No. 7 |
| <input type="checkbox"/> Addendum No. 3 | <input type="checkbox"/> Addendum No. 8 |
| <input type="checkbox"/> Addendum No. 4 | <input type="checkbox"/> Addendum No. 9 |
| <input type="checkbox"/> Addendum No. 5 | <input type="checkbox"/> Addendum No. 10 |

I understand that failure to confirm the receipt of addenda may be cause for rejection of this bid. I further understand that any verbal representation made or assumed to be made during any oral discussion held between Vendor's representatives and any state personnel is not binding. Only the information issued in writing and added to the specifications by an official addendum is binding.

Global Protection Corp
Company

Daniel J. Roddy
Authorized Signature

10/24/16
Date

NOTE: This addendum acknowledgment should be submitted with the bid to expedite document processing.

STATE OF WEST VIRGINIA
Purchasing Division

PURCHASING AFFIDAVIT

MANDATE: Under W. Va. Code §5A-3-10a, no contract or renewal of any contract may be awarded by the state or any of its political subdivisions to any vendor or prospective vendor when the vendor or prospective vendor or a related party to the vendor or prospective vendor is a debtor and: (1) the debt owed is an amount greater than one thousand dollars in the aggregate; or (2) the debtor is in employer default.

EXCEPTION: The prohibition listed above does not apply where a vendor has contested any tax administered pursuant to chapter eleven of the W. Va. Code, workers' compensation premium, permit fee or environmental fee or assessment and the matter has not become final or where the vendor has entered into a payment plan or agreement and the vendor is not in default of any of the provisions of such plan or agreement.

DEFINITIONS:

"Debt" means any assessment, premium, penalty, fine, tax or other amount of money owed to the state or any of its political subdivisions because of a judgment, fine, permit violation, license assessment, defaulted workers' compensation premium, penalty or other assessment presently delinquent or due and required to be paid to the state or any of its political subdivisions, including any interest or additional penalties accrued thereon.

"Employer default" means having an outstanding balance or liability to the old fund or to the uninsured employers' fund or being in policy default, as defined in W. Va. Code § 23-2c-2, failure to maintain mandatory workers' compensation coverage, or failure to fully meet its obligations as a workers' compensation self-insured employer. An employer is not in employer default if it has entered into a repayment agreement with the Insurance Commissioner and remains in compliance with the obligations under the repayment agreement.

"Related party" means a party, whether an individual, corporation, partnership, association, limited liability company or any other form or business association or other entity whatsoever, related to any vendor by blood, marriage, ownership or contract through which the party has a relationship of ownership or other interest with the vendor so that the party will actually or by effect receive or control a portion of the benefit, profit or other consideration from performance of a vendor contract with the party receiving an amount that meets or exceed five percent of the total contract amount.

AFFIRMATION: By signing this form, the vendor's authorized signer affirms and acknowledges under penalty of law for false swearing (*W. Va. Code §61-5-3*) that neither vendor nor any related party owe a debt as defined above and that neither vendor nor any related party are in employer default as defined above, unless the debt or employer default is permitted under the exception above.

WITNESS THE FOLLOWING SIGNATURE:

Vendor's Name: Global Protection Coop

Authorized Signature: David L Roddy Date: 10/24/16

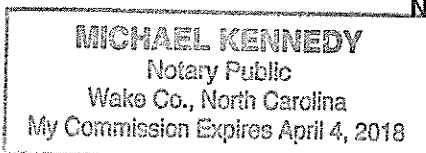
State of North Carolina

County of Wake, to-wit:

Taken, subscribed, and sworn to before me this 24 day of October, 2016.

My Commission expires April 4, 2018.

AFFIX SEAL HERE



NOTARY PUBLIC

Michael Kennedy
Purchasing Affidavit (Revised 08/01/2015)

**BID PRICE SHEET –
CRFM BPH1700000002**

Item	Estimated Annual Quantity ¹	Description	Unit Bid Price	Total Bid Price
1	2,001,600 Condoms	3.1.1 Contract Item #1 – Lifestyles Brand Lubricated Latex Condom, Part #5800 or equal.	46.00	92,092.00
2	252,250 Condoms	3.1.2 Contract Item #2 – Lifestyles Brand Non-Lubricated Latex Condom, Part #5700 or equal.	46.50	11,764.50
3	252,250 condoms	3.1.3 Contract item #3 – Lifestyles Brand NON-Latex Lubricated Condom, Part #7800 or equal.	360.00	91,080.00
4	2,088,000 condoms	3.1.4 Contract item #4- Lifestyles Brand Assorted Colored Condom Part #5300 or equal.	46.00	96,600.00
Grand Total Price				291,536.50

Estimated Quantity: Estimate of the number of condoms. Agency will order annually. Quantities are based on prior years' orders.

Unit Bid Price: Cost vendor will charge per condom of lubricated and non-lubricated, Non latex condoms for the entire term of the contract regardless of quantities ordered.

**Quantities are listed for bid evaluation purposes only.

Global Protection Corp
Vendor Name

David Roddy
Vendor Authorized Representative (print name)

David Roddy
Vendor Authorized Representative Signature

11/24/16
Date

12 Channel St Boston MA 02210
Vendor Address/Fax and Phone number

617-946-3246 F

617-946-2800 xt 24 Phone



GLOBALPROTECTIONCORP.
 12 Channel St.
 4th Floor
 Boston MA 02210
 USA

Pro-Forma Order

Order #: **4378**
 Sales Rep.: **David Roddy**

Order Date: **10/24/16**
 Terms: **PRE - PRE**

Bill To: L63606
WVDHHR/BPH/Central Finance
 350 Capitol St
 Room 203
 Charleston, WV 25301
 United States

Ship To:
WVDHHR/BPH/Central Finance
 350 Capitol Street
 Room 206
 Charleston, WV 25301-3715
 USA

Phone: **304-256-4117** Fax: **304-558-8005**

Customer PO #:
 F.O.B.:

Ship Via: **UPS Ground Trac**

Line #	Item	Description	Site	Qty Ordered, UOM	Price, UOM	Extended Price
1	10000C	Atlas® Ultra-Lubed, Case of 1000	WHS	2,002.0000 CS	46.0000 CS	92,092.0000
2	10600C	Atlas® Non-Lubricated, Case of 1000	WHS	253.0000 CS	46.5000 CS	11,764.5000
3	A7800C	Lifestyles NON Latex, Case of 1000	WHS	253.0000 CS	360.0000 CS	91,080.0000
4	10100C	Atlas® Colors, Case of 1000	WHS	2,100.0000 CS	46.0000 CS	96,600.0000

Order Comments:

Sub-Total: **291,536.5000**
 Misc. Charges: **0.0000**
 Estimated Freight: **0.0000**
 Tax: **0.0000**
 Total: **291,536.5000**

510(k) Numbers by Product

Condom:	Product Type	FDA 510(k) Number:	510(k) Owner:	OEM / CM
Atlas® Ultra-Lubed	Straight Wall / Natural Color / Lubricated	K081886	Karex Industries	Karex Industries
ONE® Classic Select™				
ONE® True Fit™				
Sir Richard's™ Ultra Thin				
PlayGirl®				
Impulse Lubricated				
Chrome™ Slippery When Wet				
Atlas® True Fit	Contoured / Natural Color / Lubricated			
ONE® Pleasure Dome™	Flared / Natural Color / Lubricated	K081886	Karex Industries	Karex Industries
Atlas® Ultra Thin	Straight Wall - Thin / Natural Color / Lubricated	K081886	Karex Industries	Karex Industries
ONE® Super Sensitive™				
Chrome™ Clear Coat				
ONE® Vanish™ ONE® Hyperthin™	Smooth – Super Thin / Natural Color / Lubricated	K141059	Karex Industries	Karex Industries
ONE® ZeroThin™	Flared - Thin / Natural Color / Lubricated	K024324	Global Protection Corp.	Fuji
Atlas® Studded	Straight Wall / Textured - Studded / Natural Color / Lubricated	K081886	Karex Industries	Karex Industries
ONE® 576 Sensations™				
ONE® Super Studs™				
Sir Richard's™ Pleasure Dots				
Chrome™ Road Warrior				
Adam & Eve® Hard Rider				
Sir Richard's™ Classic Ribbed	Straight Wall / Textured - Ribbed / Natural Color / Lubricated			
Chrome™ Rumble Strips				
Atlas® Extra Large	XL - Straight Wall / Natural Color / Lubricated	K113061 K012964	Karex Industries Innolates	Karex Industries Innolates
Sir Richard's™ Extra Large				
Monster® Energy Drink				
ICON Large Thin Condoms				
Chrome™ Big Rig				
Impulse XL				
ONE® The Legend™ Straight Walled				
ONE® The Legend™	XL - Flared / Natural Color / Lubricated	K113061 K012964	Karex Industries Innolates	Karex Industries Innolates
Atlas® Colors	Straight Wall / Assorted Colors / Lubricated	K024324	Global Protection Corp.	Karex Industries
ONE® Color Sensations™				
Global Colors				
Adam & Eve® Lightly Lubricated				
Chrome™ Paint Job				
Atlas® Black Jack				
ONE® FlavorWaves™	Straight Wall / Assorted Colors / Flavor-Scented Lubricated			
ONE® Tantric Pleasures™	Flared / Textured - Ribbed / Black Color / Lubricated			
Atlas® Non-Lubricated	Straight Wall / Natural Color / Non-Lubricated	K081886	Karex Industries	Karex Industries
Night Light®	Straight Wall / Glow / Lubricated	K960552	Global Protection Corp.	Karex Industries
ONE® Glowing Pleasures™				
Pleasure Plus®	Pouch / Natural Color / Lubricated	K902772	Global Protection Corp.	Karex Industries



GLOBALPROTECTIONCORP.

COPY

DOC. No.: DMR_2

DEVICE MASTER RECORD

DOC. TITLE: ATLAS® DEVICE DRAWING: ATLAS® ULTRA LUBED

REVISION No.:

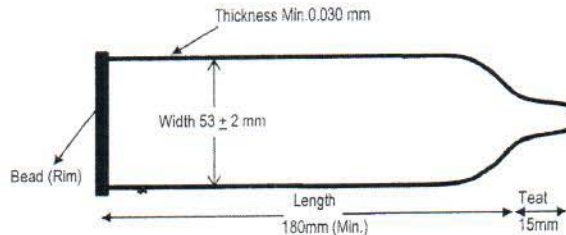
EFFECTIVE DATE: MAY 23 2011

DOC. LEVEL:

APPROVALS:

NAME: Davin Wedel TITLE: President
SIGNATURE: [Signature] DATE: 05/16/11
NAME: Sharon Pietila TITLE: Regulatory/Quality Man
SIGNATURE: [Signature] DATE: 23-MAY-2011

SECTION 22.1-1 ATLAS® DEVICE DRAWING: ATLAS® ULTRA LUBED



General Description : This male latex Condom is a device made of prevulcanised natural rubber latex. The surface of the condom shall be smooth throughout and it is packed in a rolled-up form, lubricated with silicone oil.

Design : The open end of the condom shall have a thickened ring of latex, called a bead. The condom shall have straight and parallel sides with a visible shoulder leading to a reservoir pouch at the tip.

Specification :
Colour : Natural
Shape : Parallel - Sided
Texture : Smooth
Lubricant : Silicone Oil DM 350 EP (400mg)
Length : Min. 180 mm
Width : 53 ± 2 mm
Thickness : Min. 0.030 mm

Raw Materials
a. Natural Rubber Latex
b. Aqueous Ammonia
c. Corn Starch & Magnesium Carbonate - Dusting powder
d. Silicone Oil - lubricant



GLOBAL PROTECTION CORP.

COPY

DOC. No.: DMR_22

DEVICE MASTER RECORD

DOC. TITLE: ATLAS® DEVICE DRAWING: ATLAS® COLORS

REVISION No.:

EFFECTIVE DATE:

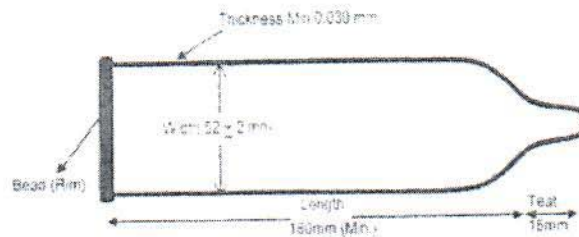
MAY 23 2011

DOC. LEVEL:

APPROVALS:

NAME: Davin Wedel TITLE: President
SIGNATURE: [Signature] DATE: 05/16/11
NAME: Sharon Pietila TITLE: Regulatory/Quality Manager
SIGNATURE: [Signature] DATE: 23-MAY-2011

SECTION 22.1-6 ATLAS® DEVICE DRAWING: ATLAS® COLORS



General Description : This male latex Condom is a device made of prevulcanised natural rubber latex. The surface of the condom shall be smooth throughout and it is packed in a rolled-up form lubricated with silicone oil.

Design : The open end of the condom shall have a thickened ring of latex, called a bead. The condom shall have straight and parallel sides with a visible shoulder leading to a reservoir pouch at the tip.

Specification :
Colour : Yellow, Purple, Green, Orange, Blue, Red
Shape : Parallel - Sided
Texture : Smooth
Lubricant : Silicone Oil DM 350 EP (400mg)
Length : Min 180 mm
Width : 52 ± 2 mm
Thickness : Min 0.030 mm

Raw Materials

- a. Natural Rubber Latex
b. Aqueous Ammonia
c. Corn Starch & Magnesium Carbonate - Dusting powder
d. Silicone Oil - Lubricant
e. Pigment : Yellow - Flexonyl Yellow DGR - LA
Purple - Colanyl Violet RL130
Green - Colanyl Green GG131
Orange - Flexonyl Orange G100
Blue - Colanyl Blue A2R 131
Red - Colanyl Carmine LTX100 - 1D



GLOBAL PROTECTION CORP.

DOC. No.: DMR_22

DEVICE MASTER RECORD

DOC. TITLE: ATLAS® DEVICE DRAWING:
ATLAS® EXTRA LARGE

REVISION No.:

EFFECTIVE DATE:

JUL 16 2012

DOC. LEVEL:

APPROVALS:

NAME: Davin Wedel

TITLE: President

SIGNATURE: *Davin Wedel*

DATE: 07/16/12

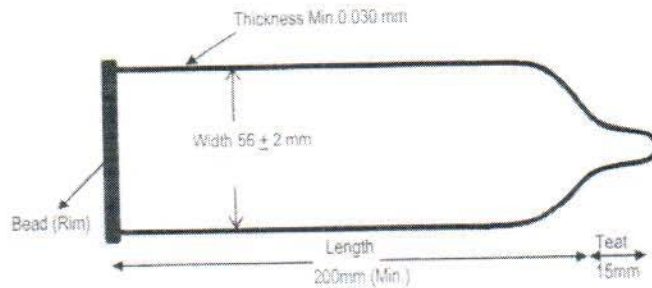
NAME: Sharon Pietila

TITLE: Regulatory/Quality Manager

SIGNATURE: *Sharon A. Pietila*

DATE: 16-JUL-2012

SECTION 22.1-5 ATLAS® DEVICE DRAWING: ATLAS® EXTRA LARGE



General Description

: This male latex Condom is a device made of prevulcanised natural rubber latex. The surface of the condom shall be smooth throughout and it is packed in a rolled-up form, lubricated with silicone oil.

Design

: The open end of the condom shall have a thickened ring of latex, called a bead. The condom shall have straight and parallel sides with a visible shoulder leading to a reservoir pouch at the tip.

Specification :

- Colour : Natural
- Shape : Parallel - Sided
- Texture : Smooth
- Lubricant : Silicone Oil DM 350 EP (400mg)
- Length : 200 mm (Min.)
- Width : 56 ± 2 mm
- Thickness : Min. 0.030mm

Raw Materials

- a. Natural Rubber Latex
- b. Aqueous Ammonia
- c. Corn Starch & Magnesium Carbonate - Dusting powder
- d. Silicone Oil - lubricant

510(k) Numbers by Product

Condom:	Product Type	FDA 510(k) Number:	510(k) Owner:	OEM / CM
Atlas® Ultra-Lubed	Straight Wall / Natural Color / Lubricated	K081886	Karex Industries	Karex Industries
ONE® Classic Select™				
ONE® True Fit™				
Sir Richard's™ Ultra Thin				
PlayGirl®				
Impulse Lubricated				
Chrome™ Slippery When Wet				
Atlas® True Fit	Contoured / Natural Color / Lubricated			
ONE® Pleasure Dome™	Flared / Natural Color / Lubricated	K081886	Karex Industries	Karex Industries
Atlas® Ultra Thin	Straight Wall - Thin / Natural Color / Lubricated	K081886	Karex Industries	Karex Industries
ONE® Super Sensitive™				
Chrome™ Clear Coat				
ONE® Vanish™ ONE® Hyperthin™	Smooth – Super Thin / Natural Color / Lubricated	K141059	Karex Industries	Karex Industries
ONE® ZeroThin™	Flared - Thin / Natural Color / Lubricated	K024324	Global Protection Corp.	Fuji
Atlas® Studded	Straight Wall / Textured - Studded / Natural Color / Lubricated	K081886	Karex Industries	Karex Industries
ONE® 576 Sensations™				
ONE® Super Studs™				
Sir Richard's™ Pleasure Dots				
Chrome™ Road Warrior				
Adam & Eve® Hard Rider				
Sir Richard's™ Classic Ribbed	Straight Wall / Textured - Ribbed / Natural Color / Lubricated			
Chrome™ Rumble Strips				
Atlas® Extra Large	XL - Straight Wall / Natural Color / Lubricated	K113061 K012964	Karex Industries Innolates	Karex Industries Innolates
Sir Richard's™ Extra Large				
Monster® Energy Drink				
ICON Large Thin Condoms				
Chrome™ Big Rig				
Impulse XL				
ONE® The Legend™ Straight Walled				
ONE® The Legend™	XL - Flared / Natural Color / Lubricated	K113061 K012964	Karex Industries Innolates	Karex Industries Innolates
Atlas® Colors	Straight Wall / Assorted Colors / Lubricated	K024324	Global Protection Corp.	Karex Industries
ONE® Color Sensations™				
Global Colors				
Adam & Eve® Lightly Lubricated				
Chrome™ Paint Job				
Atlas® Black Jack				
ONE® FlavorWaves™	Straight Wall / Assorted Colors / Flavor-Scented Lubricated			
ONE® Tantric Pleasures™	Flared / Textured - Ribbed / Black Color / Lubricated			
Atlas® Non-Lubricated	Straight Wall / Natural Color / Non-Lubricated	K081886	Karex Industries	Karex Industries
Night Light®	Straight Wall / Glow / Lubricated	K960552	Global Protection Corp.	Karex Industries
ONE® Glowing Pleasures™				
Pleasure Plus®	Pouch / Natural Color / Lubricated	K902772	Global Protection Corp.	Karex Industries