

Public Sector
200 Schulz Drive
Red Bank, N.J. 07701
(800) 232-1309
(732) 219-5127 Fax
www.lifestyles.com/sexualhealth

May 18, 2012

State of West Virginia
Dept of Administration
Purchasing Division
Attn Roberta Wagner
2019 Washington Street East
Charleston WV 25311

2012 MAY 18 AM 9: 44

WV PURCHASING
DIVISION

Dear Ms. Wagner:

Enclosed is Ansell's response to your Invitation to RFQ MCH12157. We will be bidding on our LifeStyles condoms.

All latex condoms manufactured by Ansell meet or exceed the requirements set down by the latest revision of the American Society for Testing and Materials standards (ASTM), the Federal guidelines. We are in compliance with Good Manufacturing Practices regulations promulgated by the Food and Drug Administration.

With regards to Technical Documentation, enclosed please find the following:

- 1. Statement of Product Information
- 2. Sample of Certificate of Conformance
- 3. Certification Statement
- 4. Statement of Compliance/Conformance
- Certificate of Registration

Ansell's condoms are the same LifeStyles condoms sold in commercial marketplace. We would supply a well-known condom brand to you. LifeStyles are available at the following retailers: CVS, Walgreens, Rite Aid, Kroger and Wal-Mart.

In order for a brand to have a retail presence, consumer acceptance and demand must be high. You can assume the product has a strong reputable company with experience supporting its product line. Our LifeStyles brand is a name people recognize.

Further, for questions or problems, we are the manufacturer with our headquarters office located in New Jersey.

Ansell's terms are Net 30 days. All orders are shipped F.O.B destination.

Thank you for the opportunity to participate in this offering. We hope our bid will be successful. Please do not hesitate to contact me if you have any problems or questions.

Sincerely,

Christine Murphy

Manager

Public Sector



Request for Quotation

RFO NUMBER
MCH12157

PAGE 1

ADDRESS CORRESPONDENCE TO ATTENTION OF

ROBERTA WAGNER 304-558-0067

*709024704 800-232-1309 ANSELL HEALTHCARE PRODUCTS INC ATTN PUBLIC SECTOR 200 SCHULZ DR RED BANK NJ 07701

HEALTH AND HUMAN RESOURCES
BPH - OMCFH
MATERIALS MANAGEMENT
900 BULLITT STREET
CHARLESTON, WV
25301 304-558-3417

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GENERAL TERMS & CONDITIONS REQUEST FOR QUOTATION (RFQ) AND REQUEST FOR PROPOSAL (RFP)

- 1. Awards will be made in the best interest of the State of West Virginia.
- 2. The State may accept or reject in part, or in whole, any bid.
- 3. Prior to any award, the apparent successful vendor must be properly registered with the Purchasing Division and have paid the required \$125 fee.
- 4. All services performed or goods delivered under State Purchase Order/Contracts are to be continued for the term of the Purchase Order/Contracts, contingent upon funds being appropriated by the Legislature or otherwise being made available. In the event funds are not appropriated or otherwise available for these services or goods this Purchase Order/Contract becomes void and of no effect after June 30.
- 5. Payment may only be made after the delivery and acceptance of goods or services.
- 6. Interest may be paid for late payment in accordance with the West Virginia Code.
- 7. Vendor preference will be granted upon written request in accordance with the West Virginia Code.
- 8. The State of West Virginia is exempt from federal and state taxes and will not pay or reimburse such taxes.
- 9. The Director of Purchasing may cancel any Purchase Order/Contract upon 30 days written notice to the seller.
- 10. The laws of the State of West Virginia and the Legislative Rules of the Purchasing Division shall govern the purchasing process.
- 11. Any reference to automatic renewal is hereby deleted. The Contract may be renewed only upon mutual written agreement of the parties.
- 12. BANKRUPTCY: In the event the vendor/contractor files for bankruptcy protection, the State may deem this contract null and void, and terminate such contract without further order.
- 13. HIPAA BUSINESS ASSOCIATE ADDENDUM: The West Virginia State Government HIPAA Business Associate Addendum (BAA), approved by the Attorney General, is available online at www.state.wv.us/admin/purchase/vrc/hipaa.html and is hereby made part of the agreement provided that the Agency meets the definition of a Cover Entity (45 CFR §160.103) and will be disclosing Protected Health Information (45 CFR §160.103) to the vendor.
- 14. CONFIDENTIALITY: The vendor agrees that he or she will not disclose to anyone, directly or indirectly, any such personally identifiable information or other confidential information gained from the agency, unless the individual who is the subject of the information consents to the disclosure in writing or the disclosure is made pursuant to the agency's policies, procedures, and rules. Vendor further agrees to comply with the Confidentiality Policies and Information Security Accountability Requirements, set forth in http://www.state.wv.us/admin/purchase/privacy/noticeConfidentiality.pdf.
- 15. LICENSING: Vendors must be licensed and in good standing in accordance with any and all state and local laws and requirements by any state or local agency of West Virginia, including, but not limited to, the West Virginia Secretary of State's Office, the West Virginia Tax Department, and the West Virginia Insurance Commission. The vendor must provide all necessary releases to obtain information to enable the director or spending unit to verify that the vendor is licensed and in good standing with the above entities.
- 16. ANTITRUST: In submitting a bid to any agency for the State of West Virginia, the bidder offers and agrees that if the bid is accepted the bidder will convey, sell, assign or transfer to the State of West Virginia all rights, title and interest in and to all causes of action it may now or hereafter acquire under the antitrust laws of the United States and the State of West Virginia for price fixing and/or unreasonable restraints of trade relating to the particular commodities or services purchased or acquired by the State of West Virginia. Such assignment shall be made and become effective at the time the purchasing agency tenders the initial payment to the bidder.

I certify that this bid is made without prior understanding, agreement, or connection with any corporation, firm, limited liability company, partnership, or person or entity submitting a bid for the same material, supplies, equipment or services and is in all respects fair and without collusion or Fraud. I further certify that I am authorized to sign the certification on behalf of the bidder or this bid.

INSTRUCTIONS TO BIDDERS

- 1. Use the quotation forms provided by the Purchasing Division. Complete all sections of the quotation form.
- 2. Items offered must be in compliance with the specifications. Any deviation from the specifications must be clearly indicated by the bidder. Alternates offered by the bidder as **EQUAL** to the specifications must be clearly defined. A bidder offering an alternate should attach complete specifications and literature to the bid. The Purchasing Division may waive minor deviations to specifications.
- 3. Unit prices shall prevail in case of discrepancy. All quotations are considered F.O.B. destination unless alternate shipping terms are clearly identified in the quotation.
- 4. All quotations must be delivered by the bidder to the office listed below prior to the date and time of the bid opening. Failure of the bidder to deliver the quotations on time will result in bid disqualifications: Department of Administration, Purchasing Division, 2019 Washington Street East, P.O. Box 50130, Charleston, WV 25305-0130

5. Communication during the solicitation, bid, evaluation or award periods, except through the Purchasing Division, is strictly prohibited (W.Va. C.S.R. §148-1-6.6).



Request for Quotation

RFQ NUMBER MCH12157

PAGE 2

ADDRESS CORRESPONDENCE TO ATTENTION OF

ROBERTA WAGNER 304-558-0067

*709024704 800-232-1309 ANSELL HEALTHCARE PRODUCTS INC ATTN PUBLIC SECTOR 200 SCHULZ DR RED BANK NJ 07701

HEALTH AND HUMAN RESOURCES

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Request for Quotation

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PAGE 3

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900 BULLITT STREET

CHARLESTON, WV

25301 304-558-3417

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ATTN PUBLIC SECTOR

State of West Virginia Department of Administration Purchasing Division 2019 Washington Street East Post Office Box 50130 Charleston, WV 25305-0130

ANSELL HEALTHCARE PRODUCTS INC

07701

800-232-1309

Request for Quotation

RFQ NUMBER MCH12157 PAGE 4

ADDRESS CORRESPONDENCE TO ATTENTION OF

ROBERTA WAGNER 304-558-0067

HEALTH AND HUMAN RESOURCES

BPH - OMCFH

MATERIALS MANAGEMENT 900 BULLITT STREET

CHARLESTON, WV

25301

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Request for Quotation

RFQ NUMBER
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PAGE 5

ADDRESS CORRESPONDENCE TO ATTENTION OF

ROBERTA WAGNER 304-558-0067

*709024704 800-232-1309 ANSELL HEALTHCARE PRODUCTS INC ATTN PUBLIC SECTOR 200 SCHULZ DR RED BANK NJ 07701

HEALTH AND HUMAN RESOURCES

BPH - OMCFH

MATERIALS MANAGEMENT

900 BULLITT STREET

CHARLESTON, WV

25301 304-558-3417

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State of West Virginia Department of Administration **Purchasing Division** 2019 Washington Street East Post Office Box 50130 Charleston, WV 25305-0130

Request for Quotation

RFQ NUMBER MCH12157

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ADDRESS CORRESPONDENCE TO ATTENTION OF

ROBERTA WAGNER 304-558-0067

*709024704 800-232-1309 ANSELL HEALTHCARE PRODUCTS INC ATTN PUBLIC SECTOR 200 SCHULZ DR RED BANK NJ 07701

HEALTH AND HUMAN RESOURCES BPH - OMCFH MATERIALS MANAGEMENT 900 BULLITT STREET CHARLESTON, WV 25301 304-558-3417

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Request for Quotation

RFQ NUMBER MCH12157

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SPECIFICATIONS

PURPOSE

The West Virginia Department of Health and Human Resources (DHHR), Bureau for Public Health (BPH), Office of Maternal, Child and Family Health (OMCFH), Family Planning Program (FPP) is seeking vendor quotations for providing lubricated and non-lubricated condoms.

MANDATORY REQUIREMENTS

Vendor will supply lubricated and non-lubricated latex condoms that meet the following required specifications for use by the network of FPP participating provider agencies:

Lubricated Condom Requirements:

- 1. Condoms will be 100% latex rubber.
- 2. Condoms will have a minimum thickness of eight (8) micro-meters.
- 3. Condoms will be lubricated with 350 mg. to 500 mg. water-based lubricant.
- 4. Condoms will have a minimum of 18 liters at 1.0 kilopascals pressure air-burst volume before and after oven conditioning.
- 5. Condoms will have a maximum leakage of 0.25 acceptable quality level (AQL).
- 6. Condoms will be individually packaged in impermeable flexible aluminum foil to avoid deterioration while being stored.
- 7. Condoms provided in strips will be separated by perforations that allow the packages to be separated by hand without interfering with seals.
- 8. Each condom will have a minimum expiration date of five (5) years at the time it is shipped.
- 9. Each condom package will be labeled with Lot #, manufacturer name and expiration date.
- 10. Condoms will be packaged in cases of a minimum of 1,000 and maximum of 1,044 per case. Each case will be labeled with manufacturer name, manufacture date, Lot #, and expiration date.

Non-Lubricated Condom Requirements:

- 1. Condoms will be 100% latex rubber.
- 2. Condoms will have a minimum thickness of eight (8) micro-meters.
- 3. Condoms will have a minimum of 18 liters at 1.0 kilopascals pressure air-burst volume before and after oven conditioning.
- 4. Condoms will have a maximum leakage of 0.25 acceptable quality level (AQL).
- 5. Condoms will be individually packaged in impermeable flexible aluminum foil to avoid deterioration while being stored.
- 6. Condoms provided in strips will be separated by perforations that allow the packages to be separated by hand without interfering with seals.
- 7. Each condom will have a minimum expiration date of five (5) years at the time it is shipped.

8. Each condom package will be labeled with Lot #, manufacturer name and

expiration date.

9. Condoms will be packaged in cases of a minimum of 1,000 and maximum of 1,044 per case. Each case will be labeled with manufacturer name, manufacture date, Lot #, and expiration date.

Vendor Requirements:

 Vendor will inform the FPP within 48 hours when condoms purchased by FPP are recalled and will provide instructions for returning recalled condoms. Vendor will pay all shipping costs for recalled products. Vendor will replace recalled products or refund FPP's cost.

2. Vendor will ship condom orders within seven (7) days (excluding holidays) after

receipt of each order.

3. Vendor will ship condom orders to WVDHHR Materials Management Warehouse located at 900 Bullitt Street Charleston, West Virginia 25301.

4. Vendor will ship condom orders prepaid by vendor.

5. Vendor will include an itemized invoice with each shipment.

Bid Requirements

Vendor will meet the following requirements for submitting a bid:

- 1. Vendor will provide independent laboratory tests results for dimensions, air-burst volume before and after oven conditioning, package integrity and leakage for its lubricated and non-lubricated condoms.
- 2. Vendor will provide confirmation that its lubricated and non-lubricated condoms meet the British Standard Kitemark or BS EN 600 standard.
- Vendor will complete, sign, and date the Bid Price Sheet provided with the understanding that the vendor submitting the lowest total unit cost bid price that substantiates the requirements under these specifications will be awarded this contract.

METHOD OF BID EVALUATION

FPP will use the Total Bid Price from the Bid Price Sheet to determine the low-bid vendor and will award an open end contract to the lowest bidder meeting the requirements of these specifications.

LIFE OF CONTRACT

This contract becomes effective on the date of award and will extend for a period of one (1) year. Contract may be renewed for two (2) additional one (1) year periods upon the mutual written consent of FPP and the vendor in accordance with the terms and conditions of the original contract.

BID PRICE SHEET - MCH12157

Item	Estimated Annual Quantity ¹	Description	Unit Bid Price ²	Total Bid Price				
1	1,500 cases	Requirements: - 100% latex - minimum thickness of 8 micro-meters - lubricated with a minimum of 350 mg and maximum of 500 mg water-based lubricant - minimum of 18 liters at 1.0 kilopascals pressure air-burst volume before and after oven conditioning - maximum leakage of 0.25 acceptable quality level - individually packaged in impermeable flexible aluminum foil - separated by perforations if provided in strips - minimum expiration date of five (5) years at time of shipment - condom package labeled with Lot #, manufacturer name, and expiration date - minimum of 1,000 and maximum of 1,044 condoms per case - case labeled with manufacturer name, manufacture date, Lot #, and expiration date.	59-	88,500				
2	50 cases	NON-LUBRICATED CONDOM Requirements: - 100% latex - minimum thickness of 8 micro-meters - minimum of 18 liters at 1.0 kilopascals pressure air-burst volume before and after oven conditioning - maximum leakage of 0.25 acceptable quality level - individually packaged in impermeable flexible aluminum foil - separated by perforations if provided in strips - minimum expiration date of five (5) years at time of shipment - condom package labeled with Lot #, manufacturer name, and expiration date - minimum of 1,000 and maximum of 1,044 condoms per case - case labeled with manufacturer name, manufacture date, Lot #, and expiration date.	60 -	3,000				
Lot #, and expiration date. TOTAL BID PRICE:								

¹ Estimated Annual Quantity: Estimate of the number of cases (1,000 – 1,044 condoms per case) of condoms FPP will order annually. Quantities are based on prior years' orders.

CONTROLLER WITE THE STATE OF TH
Vendor Name: apsell Healthcare Products LLC
201 62/11 12/10
Address: 200 Scholz Vrive
Red Bank NJ 07701
Fax#: 732 219 5127

² Unit Bid Price: Cost vendor will charge for each case (1,000 – 1,044 condoms per case) of lubricated and non-lubricated condoms for the entire term of the contract regardless of quantities ordered annually.

Phone #: 800 232 1309 x 5338 02 732 345 6338	0011
E-mail Address: Cmurphy Pa ansell- Com	
Remit to address: Ansell HealthCare froducts Dept CH 17373 Palatine IL 60055	
Signature: Date:	

Basis for Award: FPP will use the Total Bid Price from the Bid Price Sheet to determine the low-bid vendor and will award an open end contract to the lowest bidder meeting the requirements of these specifications.

State of West Virginia NA to Ansell VENDOR PREFERENCE CERTIFICATE HEALTHCARE

Certification and application* is hereby made for Preference in accordance with West Virginia Code, §5A-3-37. (Does not apply to construction contracts). West Virginia Code, §5A-3-37, provides an opportunity for qualifying vendors to request (at the time of bid) preference for their residency status. Such preference is an evaluation method only and will be applied only to the cost bid in accordance with the West Virginia Code. This certificate for application is to be used to request such preference. The Purchasing

Division v	will make the determination of the Resident Vendor Preference, if applicable.
	Application is made for 2.5% resident vendor preference for the reason checked: Bidder is an individual resident vendor and has resided continuously in West Virginia for four (4) years immediately preceding the date of this certification; or, Bidder is a partnership, association or corporation resident vendor and has maintained its headquarters or principal place of business continuously in West Virginia for four (4) years immediately preceding the date of this certification; or 80% of the ownership interest of Bidder is held by another individual, partnership, association or corporation resident vendor who has maintained its headquarters or principal place of business continuously in West Virginia for four (4) years immediately preceding the date of this certification; or, Bidder is a nonresident vendor which has an affiliate or subsidiary which employs a minimum of one hundred state residents and which has maintained its headquarters or principal place of business within West Virginia continuously for the four (4) years immediately preceding the date of this certification; or,
[Application is made for 2.5% resident vendor preference for the reason checked: Bidder is a resident vendor who certifies that, during the life of the contract, on average at least 75% of the employees working on the project being bid are residents of West Virginia who have resided in the state continuously for the two years immediately preceding submission of this bid; or,
	Application is made for 2.5% resident vendor preference for the reason checked: Bidder is a nonresident vendor employing a minimum of one hundred state residents or is a nonresident vendor with an affiliate or subsidiary which maintains its headquarters or principal place of business within West Virginia employing a minimum of one hundred state residents who certifies that, during the life of the contract, on average at least 75% of the employees or Bidder's affiliate's or subsidiary's employees are residents of West Virginia who have resided in the state continuously for the two years immediately preceding submission of this bid; or,
	Application is made for 5% resident vendor preference for the reason checked: Bidder meets either the requirement of both subdivisions (1) and (2) or subdivision (1) and (3) as stated above; or,
	Application is made for 3.5% resident vendor preference who is a veteran for the reason checked: Bidder is an individual resident vendor who is a veteran of the United States armed forces, the reserves or the National Guard and has resided in West Virginia continuously for the four years immediately preceding the date on which the bid is submitted; or,
	Application is made for 3.5% resident vendor preference who is a veteran for the reason checked: Bidder is a resident vendor who is a veteran of the United States armed forces, the reserves or the National Guard, if, for purposes of producing or distributing the commodities or completing the project which is the subject of the vendor's bid and continuously over the entire term of the project, on average at least seventy-five percent of the vendor's employees are residents of West Virginia who have resided in the state continuously for the two immediately preceding years.
requirem against s	nderstands if the Secretary of Revenue determines that a Bidder receiving preference has failed to continue to meet the nents for such preference, the Secretary may order the Director of Purchasing to: (a) reject the bid; or (b) assess a penalty such Bidder in an amount not to exceed 5% of the bid amount and that such penalty will be paid to the contracting agency sted from any unpaid balance on the contract or purchase order.
authorize the requi	nission of this certificate, Bidder agrees to disclose any reasonably requested information to the Purchasing Division and he set the Department of Revenue to disclose to the Director of Purchasing appropriate information verifying that Bidder has paid fired business taxes, provided that such information does not contain the amounts of taxes paid nor any other information by the Tax Commissioner to be confidential.
and acc	enalty of law for false swearing (West Virginia Code, §61-5-3), Bidder hereby certifies that this certificate is true urate in all respects; and that if a contract is issued to Bidder and if anything contained within this certificate s during the term of the contract, Bidder will notify the Purchasing Division in writing immediately.

Title:

Signed:

^{*}Check any combination of preference consideration(s) indicated above, which you are entitled to receive.

RFQ No. MCH 12157

STATE OF WEST VIRGINIA Purchasing Division

PURCHASING AFFIDAVIT

West Virginia Code §5A-3-10a states: 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 the debt owed is an amount greater than one thousand dollars in the aggregate.

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.

"Debtor" means any individual, corporation, partnership, association, limited liability company or any other form or business association owing a debt to the state or any of its political subdivisions. "Political subdivision" means any county commission; municipality; county board of education; any instrumentality established by a county or municipality; any separate corporation or instrumentality established by one or more counties or municipalities, as permitted by law; or any public body charged by law with the performance of a government function or whose jurisdiction is coextensive with one or more counties or municipalities. "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.

EXCEPTION: The prohibition of this section does not apply where a vendor has contested any tax administered pursuant to chapter eleven of this 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.

Under penalty of law for false swearing (West Virginia Code §61-5-3), it is hereby certified that the vendor affirms and acknowledges the information in this affidavit and is in compliance with the requirements as stated.

WITNESS THE FOLLOWING SIGNATURE	
Vendor's Name: Ansell Healthcare Freducts 26C	
Authorized Signature: Date: 5-17-12	
State of New Jersey	
County of Monmouth, to-wit:	
Taken, subscribed, and sworn to before me this 11 day of	
My Commission expires A Notary Public of New Jersey PATRICIA L. LAURIELLO	
AFFIX SEAL HERE My Commission Expires July 28, 2012 NOTARY PUBLIC Attrice NOTARY PUBLIC	



STATEMENT OF PRODUCT INFORMATION

Device Information

<u>Description</u>	<u>510(k) Number</u>	
LifeStyles Lubricated	K983320	
Lifestyles Non-Lubricated	K081886	

Device Quality

The products listed above are manufactured to meet the requirements of ASTM D3492 Standard Specification for Rubber contraceptives (Male Condoms). The product quality conforms to the Quality Inspection Requirements of ASTM D3492 as given below:

Characteristics	Inspection Level	<u>AQL (%)</u>
Dimensions	S-2	4.0
Air Burst Properties	1	1.5
Leakage	1	0.25
Package Integrity	S-3	2.5

ANSELL HEALTHCARE INC.

Tammy McGriff

Quality Assurance Manager



ANSELL HEALTHCARE CERTIFICATE OF CONFORMANCE TO ASTM D3492

Ansell certifies that the product manufactured and packaged for this lot number was produced to current standard operating procedures and process specifications and will comply with the requirements of the standard for rubber contraceptives (condoms) for ASTM - D3492.

PRODUCT: S53 THIN

PRODUCT CODE: 610055 / ORACLE NO.: 101423

MFG. DATE: 12/2011

LOT NUMBER: 11120458DT LOT SIZE: 595 GROSS

EXP. DATE: 11/2016

SECT	ION	DESCRIPTION	STANDARD	RESULT
3.	Material		Natural Latex	Conforms
4.2	4.2.1.2	Length of Condom Length of Condom Length of Condom (Large) Width of Condom Width of Condom (Large) Wall Thickness of Condom	(min) 160mm (min) 180mm (max) 54mm (max) 58mm (min) .03mm	Conforms Conforms Conforms Conforms
4.4	Bursting V 4.4.1 4.4.2	Volume and Pressure Pressure Volume — 49mm Volume — 50/51mm Volume — 52mm Volume — 53/54mm Volume — 55mm Volume — 56mm	(min) 1.0 KPa (min) 14.0 Liters (min) 15.0 Liters (min) 16.0 Liters (min) 17.0 Liters (min) 18.0 Liters (min) 19.0 Liters	Conforms Conforms Conforms Conforms Conforms Conforms Conforms
4.5	Water Leakage		No Leakage	Conforms
5.	Packaging 5.1 5.2	Packaging Packaging Integrity	As Required By Std. 50.8 KPa	Conforms Conforms
6.0	Labelling		As Required By Std.	Conforms
7.0	Storage		As Required By Std.	Conforms
*Exceptions declared in FDA 510(K) Date: April 3, 2012 Form #0478-1/5			For and on behalf of Ansell Healthcare Quality Control Department	

Ansell Healthcare Products LLC 1635 Industrial Road Dothan, Alabama 36303 Telephone (334) 794-4231 FAX (334) 615-2568



ANSELL HEALTHCARE CERTIFICATE OF CONFORMANCE TO ASTM D3492-08

Ansell certifies that the product manufactured and packaged for this lot number was produced to current standard operating procedures and process specifications and will comply with the requirements of the standard for rubber contraceptives (condoms) for ASTM - D3492-08.

PRODUCT: S52 CLEAR

PRODUCT CODE: 610056 / ORACLE NO.: 101424

MFG. DATE: 03/2012

LOT NUMBER: 1203040322 LOT SIZE: 1078 GROSS EXP. DATE: 02/2017

<u>SECTION</u>		DESCRIPTION	STANDARD	RESULT
3.	Material		Natural Latex	Conforms
4.2	Dimension 4.2.1.1	Nominal Length of Condom *Length of Condom (Large) Nominal Width of Condom	(min) 170mm (max) 210mm (min) 180mm (min) 47mm	Conforms Conforms Conforms
	4.2.1.3	*Width of Condom (Large) Wall Thickness of Condom	(max) 57mm (max) 58mm (min) .03mm	Conforms Conforms Conforms
4.4	Bursting V 4.4.1 4.4.2	Volume and Pressure Pressure Volume – 49mm Volume – 50/51mm Volume – 52mm Volume – 53/54mm Volume – 55mm Volume – 55mm Volume – 56mm	(min) 1.0 KPa (min) 14.0 Liters (min) 15.0 Liters (min) 16.0 Liters (min) 17.0 Liters (min) 18.0 Liters (min) 19.0 Liters	Conforms Conforms Conforms Conforms Conforms Conforms Conforms
4.5	Water Leakage		No Leakage	Conforms
5.	Packaging 5.1 5.2	Packaging Packaging Integrity	As Required By Std. 50,8 KPa	Conforms Conforms
6.0	Labelling		As Required By Std.	Conforms
7.0	Storage		As Required By Std.	Conforms
*Exceptions declared in FDA 510(K) For and on behalf of Ansell Healthcare			hcare	
Date: <u>May 4, 2012</u> Form #0478-2			Quality Control Department	



CERTIFICATION STATEMENT

Ansell Healthcare Products LLC is a manufacturer/distributor of male latex condoms which are medical devices. As a manufacturer/distributor of medical devices, Ansell is regulated by the United States Food and Drug Administration. Ansell's manufacturing facilities undergo FDA inspections to assure compliance with the QS requirements, Quality System Regulation (QS)/Good Manufacturing Practices (GMP) - 21 CFR Part 820.

Condoms manufactured and distributed by Ansell meet or exceed requirements established by the American Society for Testing and Materials Standards D3492, International Standard Organization (ISO) 4074, and European Standard EN600.

Ansell Healthcare Products LLC maintains establishment registration as required by 21 CFR 807. Ansell's FDA Establishment Registration Number is 1019632.

Cynthia A. Ingram

Regulatory Affairs Manager, Americas

May 3, 2012



STATEMENT OF COMPLIANCE / CONFORMANCE

Products manufactured by Ansell Healthcare Products LLC for distribution under the provisions of this contract conform to the requirements of ASTM D3492, Standard Specification for Rubber Contraceptives (Male Condoms), and meet or exceed the minimum specifications therein.

Packaged condoms, including dressing materials and compounding ingredients, are manufactured in compliance with the applicable FDA regulations in force at the time of manufacture.

Cynthia a. Ingram
Cynthia A. Ingram

Regulatory Affairs Manager, Americas

May 3, 2012



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485: 2003

This is to certify that:

Ansell Healthcare Products LLC 1635 Industrial Road Dothan Alabama 36303 USA

Holds Certificate No: FM 76779

and test operates a Quality Management System which complies with the requirements of ISO 13485: 2003 for the following scope:

The packaging & distribution of latex condoms. For the legal manufacture of condoms, medical gloves & liquid personal lubricants for distribution into Canada.

For and on behalf of BSI:

President, BSI America, Inc.

Originally Registered: 10/17/2003

Effective Date: 10/29/2010

Expiry Date: 10/28/2013



CMDCAS Recognized Registrar



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