



LEVEL 1, 2 & 3 ISOLATION GOWN



- Material: 2 mil thick polyethylene (PE)
- Certification: ANSI/AAMI PB70, AATCC 42 & 127 certified to Level 3
- Feature: Dust proof, water proof and anti oil absorbent
- Color: Clear or light blue (based on availability)
- Style: Over the head design with waist ties and thumbhooks in sleeves
- Coverage: Open back
- Size: One size fits most
- Case Quantity: 100 gowns
- Packaging: Individually in poly bags
- Case Dimensions: 18in x 12in x 13in
- Case Weight: 18 lbs
- Production Origin: California
- Non-sterilized
- Disposable
- FDA registration number 3016870095
- Sample available upon request



WARNING: This product contains chemicals known to the State of California to cause cancer and birth defects or other reproductive harm.

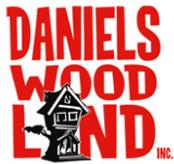


2125 Ardmore Road, Paso Robles, CA 93446

P: 800-441-3468 F: 805-226-8738 www.danielswoodland.com

DWL
STUDIOS





The following number must appear on all related correspondence, shipping papers, and invoices.

SALES ORDER

Purchaser Issues PO# [PO Number]

Purchased By:

Ship To:

[Name]

[Name]

[Company]

[Company]

[Street Address]

[Street Address]

[City/State/Zip]

[City/State/Zip]

[Phone Number]

[Phone Number]

DATE	PURCHASER	SHIPPED VIA		TERMS	
		Ship	Pick Up	Credit Card	Net 15

QTY	UNIT	DESCRIPTION	UNIT PRICE	TOTAL
	Case	Level 1, 2 & 3 Isolation Gown (Qty 100 gowns per case)	\$550.00	

*CA sales tax and shipping & handling costs applied upon invoicing

Declarations:

1. Each shipment will be invoiced separately
2. Sales order valid for all portions of order shipped within 30 days
3. Back orders accepted
4. Credit card or net 15 payment terms (approval required)
5. If paying via credit card DWL agent will contact buyer for card information

Sign Name / Title

Date

This product has been developed to fill an emergency need and shortage of PPE. Purchaser will indemnify, defend and hold DWL, its agents and employees, harmless from and against all claims, damages, losses and expenses, including attorneys' fees, arising out of or resulting from any alleged damages including emotional harm, bodily injury or death. This Agreement will be interpreted and construed in accordance with the laws of the State of California. Any controversy or claim arising out of or relating to this Agreement will be settled by arbitration in accordance with the Commercial Arbitration Rules of the American Arbitration Association.

Please email order form back to andy@danielswoodland.com

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705 Front Street
Toledo, OH 43605
Phone: 419-693-5307
Fax: 419-691-0418
www.lexamed.net

FI Global
Box 891
Petaluma, CA 94953
Attn: Peter Solimene

AAMI PB70 Liquid Barrier Performance and Classification

Test Article: 2ML Non-Surgical Isolation Gown LDPE Daniels Woodland USA

A total of thirty-two (32) specimens were tested from thirty-two (32) test articles. Specimens were chosen from the critical zones as described in AAMI PB70 for an isolation gown. Test specimens were subjected to the following tests:

AATCC 42 Water Resistance: Impact Penetration Test
AATCC 127 Water Resistance: Hydrostatic Pressure Test.

Based on the results of the testing as summarized in the attached reports, numbers 2003917 and 2003918, the product listed above was classified as **AAMI PB70 Level 3**.

Record Storage: All raw data pertaining to this study will be maintained in the LexaMed archives for a minimum of 5 years.

Approved by

Date

5-22-20



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705 Front Street
 Toledo, OH 43605
 Phone: 419-693-5307
 Fax: 419-691-0418
 www.lexamed.net

FI Global
 Box 891
 Petaluma, CA 94953
 ATTN: Peter Solimene

Lab # 2003917
 PO # 20-229AMS

Test Article: 2ML Non-Surgical Isolation Gown LDPE Daniels Woodland USA
 Part # N/A Lot # N/A Batch # N/A

AATCC 42 Water Resistance: Impact Penetration Test

Test article received: 5/19/2020
 Test start date: 5/21/2020
 Test termination date: 5/22/2020
 SOP No. (current version): LEXLP-074

Procedure: Thirty-two (32) sections each measuring 178 x 330 mm were cut from 32 products from areas representing the critical zones as described in AAMI PB 70 for an isolation gown. The test specimens and one (1) blotter sheet for each were preconditioned at 65±2% rh and 21±1°C for a minimum of 4 hours. Test samples were then clamped to the incline stand of an Impact Tester. Blotter paper was weighed and inserted beneath the test sample. Deionized Water (DIW) heated to 27± 1°C was poured into the funnel and the water sprayed onto the test article. The blotter paper was removed and re-weighed.

The post-weight for each specimen was used to determine the AAMI PB70 Level met based on the following criteria:

Post -Weight Gain Acceptance Criteria		
Level 1	Level 2	Level 3
≤ 4.5 gm	≤ 1.0 gm	≤ 1.0 gm

Results: A total of 32 / 32 specimens had a weight gain of ≤ 1.0 gm.

Conclusion: Based on the results of the test and an AQL of 4% / RQL of 20% the test article was classified as PB70 Level 3.

Record Storage: All raw data pertaining to this study will be maintained in the LexaMed archives for a minimum of 5 years.

Approved by *Andrew M. Glahn* Tech: AP/GP Date 5/22/20



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Fax: 419-691-0418
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FI Global
Box 891
Petaluma, CA 94953
ATTN: Peter Solimene

Lab # 2003918
PO # 20-229AMS

Test Article: 2ML Non-Surgical Isolation Gown LDPE Daniels Woodland USA
Part # N/A Lot # N/A Batch # N/A

AATCC 127 Water Resistance: Hydrostatic Pressure Test

Test article received: 5/19/2020
Test start date: 5/21/2020
Test termination date: 5/22/2020

Procedure: Thirty-two (32) sections each measuring 200 mm x 200 mm were cut from 32 products from areas representing the critical zones as described in AAMI PB 70 for an isolation gown. The test specimens were preconditioned at 65±2% rh and 21±1°C for a minimum of 4 hours. Individual specimens were clamped into the Hydrostatic Tester and analyzed.

The hydrostatic pressure required for water penetration for each specimen was used to determine the AAMI PB70 Level met based on the following criteria:

Hydrostatic Pressure Acceptance Criteria	
Level 2	Level 3
≥ 20 cmH ₂ O	≥ 50 cmH ₂ O

Results: A total of 32 / 32 specimens had a hydrostatic pressure for water penetration of ≥ 50 cmH₂O.

Conclusion: Based on the results of the test and an AQL of 4% / RQL of 20% the test article was classified as PB70 Level 3.

Record Storage: All raw data pertaining to this study will be maintained in the LexaMed archives for a minimum of 5 years.

Approved by *Peter Solimene* Tech: AP/GP Date 5/22/20



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2020

CERTIFICATE OF REGISTRATION

This certifies that:

DANIELS WOOD LAND, INC.
2125 Ardmore Road
Paso Robles , CA 93446

is registered with the U.S. Food and Drug Administration for FY 2020 pursuant to Title 21, 807 et seq. of the United States Code of Federal Regulations:

Establishment Owner/Operator Number:
Device Classification Name:

10073817
NON-SURGICAL ISOLATION
GOWN

Product Code:
Regulation Number:
Official Correspondent:

OEA
878.4040
Registrar Corp
144 Research Drive, Hampton, Virginia,
23666, USA
Telephone: +1-757-224-0177 • Fax:
+1-757-224-0179

Registrar Corp will confirm that such registration remains effective upon request and presentation of this certificate until the end of the year stated above, unless said registration is terminated after issuance of this certificate. Registrar Corp makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. Registrar Corp assumes no liability to any person or entity in connection with the foregoing.

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144 Research Drive, Hampton, Virginia, 23666, USA
Telephone: +1-757-224-0177 • Fax: +1-757-224-0179
info@registrarcorp.com • www.registrarcorp.com

David Lennarz
Executive Director

Registrar Corp

Dated: May 19, 2020

5/14/2020

FDA | U.S. Food and Drug Administration



Registration Confirmation

Facility: DANIELS WOOD LAND, INC., Paso Robles, California,

You have successfully entered your facility registration and device listing information. You should print a copy of this page for your records. Listing numbers appear below for the products manufactured, developed, or processed at this facility.

As a manufacturer, specification developer, or single-use device reprocessor, you are required to pay an annual fee for medical device facility registration.

You will receive another e-mail providing you with your registration number in approximately 30 to 90 days. Until your registration number is assigned, reference your Owner/Operator number in any correspondence with the Center for Devices and Radiological Health.

Your registration will be valid through Dec 31, 2020. An e-mail will be sent to the Owner/Operator and the Official Correspondent 90 days before the facility is required to re-register for Fiscal Year 2020 with instructions on how and when to re-register.

Note: 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 reglist@cdrh.fda.gov (<mailto:reglist@cdrh.fda.gov>).

The Owner/Operator Number for this Registration is: 10073817

Facility Information

Initial Importer:	N
Facility Name:	DANIELS WOOD LAND, INC.
Address:	2125 Ardmore Road Paso Robles, California, 93446,
Foreign Trade Zone:	N
Facility URL:	https://danielswoodland.com

Owner/Operator Information

Owner/Operator Number: 10073817
Contact Name: Andy Dauterman
Company: DANIELS WOOD LAND, INC.
Address: 2125 Ardmore Road
 Paso Robles, CALIFORNIA, 93446, UNITED STATES
Telephone: 1 - 805 - 2392832
Fax: 1 - 805 - 2268738
E-mail: andy@danielswoodland.com

Official Correspondent Information

Contact Name: David Lennarz
Company: Registrar Corp
Address: 144 Research Drive
 Hampton, VIRGINIA, 23666, UNITED STATES
Telephone: 1 - 757 - 2240177
Fax: 1 - 757 - 2240179
E-mail: david.lennarz@registrarcorp.com
DUNS Number: 139242874

Device Listings

Listing Number	Premarket Submission Number/Type	Product Code(s)	Device Name(s)	Activities
D402243	Exempt	OEA	Non-surgical isolation gown	Manufacturer

Date of Initial Registration: Thu May 14 13:44:11 EDT 2020