



**Three
Zones**



USA MADE PE & SMS LEVEL 3 ISOLATION GOWNS



Three Zones LLC
1441 E 16th St Los Angeles, CA 90021
800-710-7353



2021

CERTIFICATE OF REGISTRATION

This certifies that:

THREE ZONES, LLC
1441 E 16th St
Los Angeles , CA 90021

is registered with the U.S. Food and Drug Administration for FY 2021 pursuant to Title 21, 807 et seq. of the United States Code of Federal Regulations:

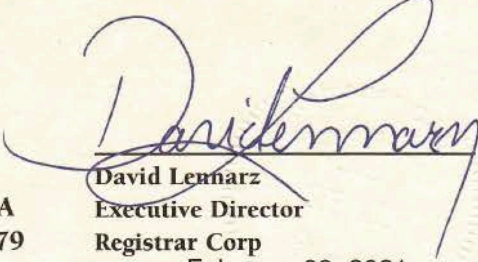
Establishment Owner/Operator Number: **10080442**
Device Classification Name: **NON-SURGICAL ISOLATION GOWN**
Product Code: **OEA**
Regulation Number: **878.4040**
Official Correspondent: **Registrar Corp**
144 Research Drive, Hampton, Virginia, 23666, USA
Telephone: +1-757-224-0177 • Fax: +1-757-224-0179

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David Lennarz
Executive Director
Registrar Corp
Dated: February 08, 2021



Three Zones



PE Isolation Gowns

ANSI/AAMI PB70, AATCC 42 & 127 certified for use up to Level 3

Features:

- Disposable
- Made of polyethylene (PE)
- Non-sterile
- Closed back
- Neck and waist ties
- Thumb hooks in sleeves
- Light blue color
- Large or X-large sizes available

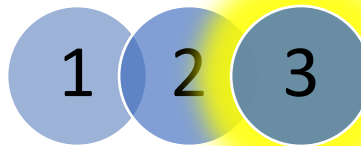
Packaging:

- Packaged individually
- 100 gowns per case

Produced and sold under 510k FDA mandate exemption

AAMI Levels

Minimal Protection	Low Protection	Moderate Protection
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Three Zones LLC
 1441 E 16th St Los Angeles, CA 90021
 800-710-7353

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



IPS TESTING

Test Report
February 5, 2021
Page 1 of 6
SGS-IPS 00249-21

Report to: Samantha Paltac
Three Zones
1441 E 16th St.
Los Angeles, CA 90021

Sample Description: **One Gown Sample**

Date Received: February 2, 2021

Test(s) Requested: Water Resistance: Impact Penetration (AATCC 42), Water Resistance: Hydrostatic Pressure

PO Number: Credit Card

Analysis of One Gown Sample

SGS-IPS Testing completed the testing listed above on one gown sample provided by Three Zones. Testing was conducted on five client specified gown locations. A sixth location "Gown - Necktie" cannot be tested due to the dimensional restraints of its size. The results are listed in Tables 1 and 2 on the following pages of this report. SGS-IPS Testing is an ISO 9001 certified lab issued by ABS Quality Evaluations, with additional ISO 17025 accreditation in the field of testing issued by ANAB which applies to Water Resistance: Impact Penetration (AATCC 42) and Water Resistance: Hydrostatic Pressure.

If you have any questions, please contact us.



Authorized by

Jennifer Goggans
Laboratory Manager

Signed

Tyler F. Hetherington
Senior Lab Technician
Physical Testing
920-749-3040

Table 1. Water Resistance: Impact Penetration (AATCC 42)

	PE Isolation Gown-Seam	PE Isolation Gown-Front	PE Isolation Gown-Back	PE Isolation Gown-Sleeve
  AT-1659				
Water Penetration (g)				
1	0.0	0.0	0.0	0.0
2	0.0	0.0	0.0	0.0
3	0.0	0.0	0.0	0.0
Average	0.0	0.0	0.0	0.0
Std. Dev.	0.01	0.00	0.01	0.01
Maximum	0.0	0.0	0.0	0.0
Minimum	0.0	0.0	0.0	0.0
n=	3	3	3	3
Test Parameters				
Temperature (°C)	27.1	27.1	27.1	27.1
Test Side: Outside				
Blotter Lot: 114123				

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

Table 2. Water Resistance: Hydrostatic Pressure (AATCC 127)

Orientation	PE Isolation Gown-Seam		PE Isolation Gown-Front		PE Isolation Gown-Back		PE Isolation Gown-Sleeve	
	Outside	SdB	Outside	SdB	Outside	SdB	Outside	SdB



AT-1659

Hydrohead (mbar)

1	178	NA	174	NA	180	NA	172	NA
2	207	NA	154	NA	168	NA	208	NA
3	153	NA	144	NA	159	NA	187	NA
Average	179	NA	157	NA	169	NA	189	NA
Std. Dev.	27.0	NA	15.3	NA	10.5	NA	18.1	NA
Maximum	207	NA	174	NA	180	NA	208	NA
Minimum	153	NA	144	NA	159	NA	172	NA
n=	3	NA	3	NA	3	NA	3	NA

Hydrohead (cm of H2O) 183 NA 160 NA 172 NA 193 NA

Test Parameters

Temperature (°C) 22.4 NA 21.6 NA 22.0 NA 22.2 NA

Test Pressure Limit (mbar) 1000 NA 1000 NA 1000 NA 1000 NA

Failure Type Burst NA Burst NA Burst NA Burst NA

Gradient: 60 mbar/min
Water Type: Deionized Water

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

Table 1. Water Resistance: Impact Penetration (AATCC 42) (contd.)

PE Isolation
 Gown-Waist Tie



AT-1659

Water Penetration (g)

1	0.0
2	0.0
3	0.0
Average	0.0
Std. Dev.	0.01
Maximum	0.0
Minimum	0.0
n=	3

Test Parameters

Temperature (°C) 27.1

Test Side: Outside
 Blotter Lot: 114123

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

Table 2. Water Resistance: Hydrostatic Pressure (AATCC 127) (contd.)

Orientation	PE Isolation Gown-Waist Tie	
	Outside	SdB



AT-1659

Hydrohead (mbar)

1	218	NA
2	197	NA
3	169	NA
Average	195	NA
Std. Dev.	24.6	NA
Maximum	218	NA
Minimum	169	NA
n=	3	NA

Hydrohead (cm of H₂O) 199 NA

Test Parameters

Temperature (°C) 21.7 NA

Test Pressure Limit (mbar) 1000 NA

Failure Type Burst NA

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

Gradient: 60 mbar/min
Water Type: Deionized Water

Method(s) and Notes:

All valid results are included in the statistical analyses.
Revisions of SGS-IPS methods when used are current at the time of testing.
Samples tested and conditioned in TAPPI standard conditions unless requested otherwise by customer or otherwise specified.
Samples were not preconditioned.

AATCC 42-2017 Water Resistance: Impact Penetration Test

Type II Impact Penetration Tester was used for this testing.
Samples conditioned in TAPPI standard conditions unless requested otherwise by customer.

The estimated k=2 uncertainty for AATCC 42 is calculated and available on request.

Spray head has a hole in the center, funnel is plastic instead of glass.

Blotter papers used: Ahlstrom Grade 989.

AATCC Test Method 127-2017 Water Resistance: Hydrostatic Pressure Test

Option 2, Hydrostatic Head Tester.
Samples conditioned in TAPPI standard conditions unless requested otherwise by customer.

Analyzed by: TFH
Quality review by: TY
Date(s) of testing: February 4, 2021

Room Conditions

	Relative Humidity (%)	Temperature (°F)
Conditioning Environment	50.0	73.4
Maximum during testing	51.9	73.4
Minimum during testing	50.0	72.5

Note: See the method(s) cited above for available estimates of measurement uncertainty. Unless otherwise noted, sampling was performed by customer.

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Three Zones



SMS Isolation Gowns

ANSI/AAMI PB70, AATCC 42 & 127 certified Level 3

Features:

- Disposable
- Strong & breathable 45gsm SMS Level 3
- Non-sterile
- Closed back
- Neck and waist ties
- Thumb hooks in sleeves
- Large or X-large sizes available

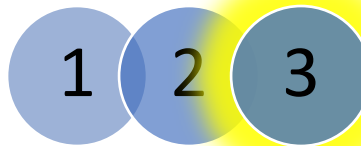
Packaging:

- Packaged individually
- 100 gowns per case

Produced and sold under 510k FDA mandate exemption

AAMI Levels

Minimal Protection Low Protection Moderate Protection



Three Zones LLC
1441 E 16th St Los Angeles, CA 90021
800-710-7353



IPS TESTING

Test Report
February 17, 2021
Page 1 of 6
SGS-IPS 00320-21

Report to: Ofer Kahana
Three Zones LLC
1441 E 16th St
Los Angeles, CA 90021

Sample Description: **One Gown Sample**

Date Received: February 12, 2021

Test(s) Requested: Water Resistance: Impact Penetration (AATCC 42), Water Resistance:
Hydrostatic Pressure (AATCC 127)


PO Number: Credit Card

Analysis of One Gown Sample

SGS-IPS Testing performed the testing listed above on one gown sample provided by Three Zones. The results are summarized in Tables 1 and 2 on the following pages.

If you have any questions, please contact us.

Authorized by


Jennifer Goggans
Laboratory Manager

Signed





Trevor Yokom
Lab Technician
Physical Testing
920-749-3040

Table 1. Water Resistance: Impact Penetration (AATCC 42)

	SMS 45gsm Gown-Front	SMS 45gsm Gown-Back	SMS 45gsm Gown-Sleeve	SMS 45gsm Gown-Waist Tie
  AT-1659				
In Scope of ISO 17025 Accreditation (Y/N)	Y	Y	Y	Y
Water Penetration (g)				
1	0.1	0.1	0.1	0.1
2	0.1	0.1	0.1	0.1
3	0.1	0.1	0.1	0.1
Average	0.1	0.1	0.1	0.1
Std. Dev.	0.02	0.01	0.01	0.01
Maximum	0.1	0.1	0.1	0.1
Minimum	0.1	0.1	0.1	0.1
n=	3	3	3	3
Test Parameters				
Temperature (°C)	27.0	26.7	27.0	27.0
Test Side: Outside				
Blotter Lot: 114123				

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

Table 2. Water Resistance: Hydrostatic Pressure (AATCC 127)

Orientation	SMS 45gsm Gown-Front		SMS 45gsm Gown-Back		SMS 45gsm Gown-Sleeve		SMS 45gsm Gown-Waist Tie	
	Outside	SdB	Outside	SdB	Outside	SdB	Outside	SdB
In Scope of ISO 17025 Accreditation (Y/N)	Y	NA	Y	NA	Y	NA	Y	NA
Hydrohead (mbar)								
1	60.5	NA	69.9	NA	68.6	NA	53.2	NA
2	60.5	NA	63.6	NA	59.8	NA	61.3	NA
3	62.3	NA	70.5	NA	78.8	NA	56.6	NA
Average	61.1	NA	68.0	NA	69.1	NA	57.0	NA
Std. Dev.	1.04	NA	3.82	NA	9.51	NA	4.07	NA
Maximum	62.3	NA	70.5	NA	78.8	NA	61.3	NA
Minimum	60.5	NA	63.6	NA	59.8	NA	53.2	NA
n=	3	NA	3	NA	3	NA	3	NA
Hydrohead (cm of H2O)	62.3	NA	69.4	NA	70.4	NA	58.2	NA
Test Parameters								
Temperature (°C)	22.6	NA	22.6	NA	22.6	NA	22.6	NA
Test Pressure Limit (mbar)	1000	NA	1000	NA	1000	NA	1000	NA
Failure Type	3 Drops	NA	3 Drops	NA	3 Drops	NA	3 Drops	NA

Gradient: 60 mbar/min
 Water Type: Deionized Water

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

Table 1. Water Resistance: Impact Penetration (AATCC 42) (contd.)

SMS 45gsm
 Gown-Seam



AT-1659

In Scope of ISO 17025 Accreditation (Y/N)	Y
Water Penetration (g)	
1	0.1
2	0.0
3	0.0
Average	0.0
Std. Dev.	0.04
Maximum	0.1
Minimum	0.0
n=	3

Test Parameters

Temperature (°C) 27.1

Test Side: Outside
 Blotter Lot: 114123

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

Table 2. Water Resistance: Hydrostatic Pressure (AATCC 127) (contd.)

Orientation	SMS 45gsm Gown-Seam	
	Outside	SdB



AT-1659

In Scope of ISO 17025 Accreditation (Y/N)	Y	NA
Hydrohead (mbar)		

2	63.3	NA
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Hydrostatic Pressure Acceptance Criteria	
Level 2 ≥ 20 cmH ₂ O	Level 3 ≥ 50 cmH ₂ O

Hydrohead (cm of H ₂ O)	34.0	NA
Test Parameters		
Temperature (°C)	22.6	NA
Test Pressure Limit (mbar)	1000	NA
Failure Type	3 Drops	NA

Gradient: 60 mbar/min
 Water Type: Deionized Water

Method(s) and Notes:

All valid results are included in the statistical analyses.
 Revisions of SGS-IPS methods when used are current at the time of testing.
 Samples tested and conditioned in TAPPI standard conditions unless requested otherwise by customer or otherwise specified.
 Samples were not preconditioned.
 AATCC 42-2017 Water Resistance: Impact Penetration Test
 Type II Impact Penetration Tester was used for this testing.
 Samples conditioned in TAPPI standard conditions unless requested otherwise by customer.
 The estimated k=2 uncertainty for AATCC 42 is calculated and available on request.

Spray head has a hole in the center, funnel is plastic instead of glass.
Blotter papers used: Ahlstrom Grade 989.
AATCC Test Method 127-2017 Water Resistance: Hydrostatic Pressure Test
Option 2, Hydrostatic Head Tester.
Samples conditioned in TAPPI standard conditions unless requested otherwise by customer.
Nothing unusual observed during testing. For sample SMS 45gsm Gown-Seam, replicates 1 and 3 failed at the seam, replicate 2 did not fail at the seam.

Analyzed by: TY, SW
Quality review by: EB
Date(s) of testing: February 15-16, 2021

Room Conditions

	Relative Humidity (%)	Temperature (°F)
Conditioning Environment	51.2	73.4
Maximum during testing	51.7	75.0
Minimum during testing	51.2	73.4

Note: See the method(s) cited above for available estimates of measurement uncertainty. Unless otherwise noted, sampling was performed by customer.

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February 1, 2021

Ref: Berry Compliance

Three Zones, LLC hereby certifies that all of our Isolation Gowns (components and end product) produced in our USA manufacturing facilities are fully compliant with 10 U.S.C. § 2533(a), which requires that items be grown, reprocessed, reused, produced domestically in the United States, and is commonly referred to as “the Berry Amendment,” and, particularly, the clause at DFAR 252.225- 7012, “Preference for Certain Domestic Commodities (JAN 2007).”

Furthermore, that all manufacturing, packaging, inspection and shipping operations were completed or performed in the United States.

We certify, fully read and understand the Berry Amendment and the applicability to this purchase order and contract, and we certify full compliance.

