

Protective Isolation Gowns

Description

Isolation Gown

Size: S / M

Size: L / XL

Specification

Premium isolation gown with elastic cuff
Fluid resistant
Ultrasonic craft

Material:

SMS polypropylene

Certifications Standards

FDA,
ISO13485:2016
AAMI Level I



SMS, SMMS, SMMMS...

Material of Polypropylene of 25 to 50 g/m²

AAMI Level I

GD-3512



Level 1





THIS CERTIFIES THAT:

**DOMTEX, S.A. DE C.V.
POLANCO III SECCIÓN, MIGUEL HIDALGO
OSCAR WILDE #29, CP. 11550**

Has listed the referenced device with the U.S. Food and Drug Administration pursuant to part 207 of Title 21, U.S. Code of Federal Regulations, such listing having been verified as currently effective on the date hereof by Registrar Corp.:

Product Trade Name:	DOMTEX
Labeler:	DOMTEX, S.A. de C.V.
Manufacturer:	DOMTEX, S.A. de C.V.
Telephone:	5202 0574
Owner operator number:	10073832
Listing number:	D402332
Product code:	OEA
Device name:	Non-surgical isolation gown
Owner operator number:	10073832
Listing number:	D402333
Product code:	LYU
Device name:	Accesory, Face Masks

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REGISTRANT:

**DOMTEX, S.A. DE C.V.
POLANCO III SECCIÓN, MIGUEL HIDALGO
OSCAR WILDE #29, CP. 11550**

A handwritten signature in black ink, appearing to read "JMS", is written over a horizontal line.

**JAIME M SANCHEZ
DOMTEX, S.A. DE C.V.**



IPS TESTING

Test Report
June 25, 2020

SGS-IPS 01015-20

Report to: Carlos Abadi
Bassatex LLC
3 East 48th Street, 2nd Floor
NYC, New York 10018

Sample Identification: **Two Gown Samples**

Date Received: June 18, 2020

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

PO Number: Wire

Analysis of Two Gown Samples

SGS-IPS Testing performed the testing listed above on two gown samples provided by Bassatex LLC. The results are listed in Tables 1 and 2 on the following pages.

If you have any questions, please contact us.

Authorized by Mai Pa V. Xiong

MaiPa Xiong
Laboratory Manager

Signed Eric Belter

Eric Belter
Lab Technician
Analytical Services
920-749-3040



	Water Penetration Test AATCC 42(g)	Hydrostatic Pressure Test AATCC 127 (cmH2O)	Resistance to Bacteriophage Phi-X174 ASTM F 1671	Level	Final classification
Sleeve	≤4.5	10.1	n/a	Level 1	Level 1
Base	≤4.5	9.4	n/a	Level 1	
Back	≤4.5	10.4	n/a	Level 1	
<p>Remark: The barrier performance of all critical zone components, including seams and points of attachments, shall be determined. The classification of isolation gown shall be a number denoting the performance of the critical zone component having the lower barrier performance. Level 1: Impact Penetration Test-AATCC 42: ≤4.5g; Level 2: Impact Penetration Test-AATCC 42: ≤1.0g; Hydrostatic Pressure Test-AATCC 127: ≥20cmH2O; Level 3: Impact Penetration Test-AATCC 42: ≤1.0g; Hydrostatic Pressure Test-AATCC 127: ≥50cmH2O; Level 4: Resistance to Bacteriophage Phi-X174-ASTM F 1671: Pass. Only test the barrier performance of the sample. Label request, construction and other classed in ANSI/AAMI PB70-2012 is not checked.</p>					

Test Parameters

Temperature (°C)	22.9	NA	22.9	NA	22.9	NA	22.9	NA
Test Pressure Limit (mbar)	1000	NA	1000	NA	1000	NA	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.

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.

Analyzed by: EB

Quality review by: RJM

Date(s) of testing: June 25, 2020

Room Conditions

	Relative Humidity (%)	Temperature (°F)
Conditioning Environment	50.0	73.8
Maximum during testing	50.3	74.1
Minimum during testing	48.7	73.6

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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