

Level 4 AAMI PB70 Isolation Gown

Sino Film + PP+PE Material

ASTM F1671
ASTM F1670

Tested to Level 3 Barrier Protection
Tested to Level 4 Blood and Viral Penetration

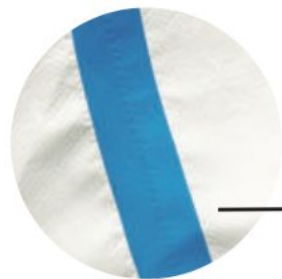
Sterile & Non-Sterile Available

Redacted Version

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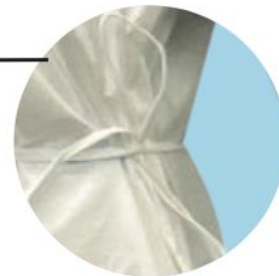
Taped Seams



Knitted Cuffs




Neck Tie



Side Belt

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Establishment Registration & Device Listing

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Proprietary Name:

Classification Name: NON-SURGICAL ISOLATION GOWN

Product Code: [OEA](#)

Device Class: 1

Regulation Number: [878.4040](#)

Medical Specialty: General & Plastic Surgery

Registered Establishment Name:

Owner/Operator:

Owner/Operator Number:

Establishment Operations: Manufacturer

The screenshot shows the FDA's public database for establishment registrations. The header includes the FDA logo and navigation links for various product categories. The main content area displays details for a specific establishment, including its name, address, registration number, and contact information for the official correspondent and US agent.

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Establishment:
TORONTO YACHT CORPORATION
Business Trade Name:
Safe Direct Medical Supplies

1100-33 Yonge St
Toronto Ontario, CA M5E 0A9
Registration Number: 3017181008
FEI Number*: 3017181008
Status: Active
Date Of Registration Status: 2020

Owner/Operator:
[Toronto Yacht Corporation](#)
1100-33 Yonge St
Toronto, Ontario CA M5E 0A9
Owner/Operator Number: [10076319](#)

Official Correspondent:
David Lennarz
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Email: David.Lennarz@Registrarcorp.Com

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

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July 29, 2020

Safe Direct Medical Supplies
33 Yonge Street Suite 1100
Toronto, ON, M5E 1G4
CA

Reference: 1101897513 4789569240

Subject: Commercial Testing Services - Testing of Isolation Gowns – New Model

Dear Safe Direct Medical Supplies,

Per your request, project 4789569240 was opened, in accordance with your requested test protocol for the evaluation of your Isolation Gown SINO-IsoGown-L4-70M4 per AAMI PB70 Level 4 Requirements. Testing was completed on the critical zone per AAMI PB70-2012 requirements in section 4.2.3.1. The critical zone of this garment was determined as the structural seam located on the sleeves.

UL Commercial Test Services did not select the samples, determine whether the samples were representative of production samples, witness the production of the test samples, or were we provided with information relative to the formulation or identification of component materials used in the test samples. The test results apply only to the actual samples tested.

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This letter will serve to report that all tests on the subject product have been completed.

Thank you for the opportunity to provide your company with these services. Please do not hesitate to contact us if you should have any questions or comments.

Sincerely,

Olivia Weiers
Olivia Weiers
Engineering Project Handler
Personal Protective Equipment

Reviewed by:

Amanda Newsom
Amanda Newsom
Principal Engineer
Personal Protective Equipment



VIRAL PENETRATION RESISTANCE TEST ASTM F1671

Item Type	Barrier Material
Description	SINO-IsoGown-L4-70M4 Isolation Gown
Exposure Side	Blue Tape Side
DO SPECIMENS COMPLY WITH THE REQUIREMENTS OF THE STANDARD [YES/NO]	
YES	

Specimen	Pre-challenge Concentration (PFU/mL)	Post-challenge Concentration (PFU/mL)	Assay Titer (PFU/mL)	Visual Penetration	Test Result [Pass/Fail]
1	3.60 x 10 ⁶	3.76 x 10 ⁶	< 1*	None Seen	Pass
2	3.60 x 10 ⁶	3.76 x 10 ⁶	< 1*	None Seen	Pass
3	3.60 x 10 ⁶	3.76 x 10 ⁶	< 1*	None Seen	Pass
Requirement				None Seen	Pass

Values of <1 PFU/mL is reported for assay plates showing no plaques.
PFU = Plaque Forming Units




SYNTHETIC BLOOD PENETRATION RESISTANCE TEST ASTM F1670

Item Type	Barrier Material
Description	SINO-IsoGown-L4-70M4 Isolation Gown
Exposure Side	Blue Tape Side
DO SPECIMENS COMPLY WITH THE REQUIREMENTS OF THE STANDARD [YES/NO]	
YES	

Specimen	Visual Penetration	Test Result [Pass/Fail]
1	None Seen	Pass
2	None Seen	Pass
3	None Seen	Pass
Requirement		None Seen
		Pass

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ANALYSIS REPORT
S.C.C. Accreditation No.: 401

Mr. Adam Karamall Date: July 27, 2020
 Safe Direct Medical Supplies Report: 5826-0017-374-en

IDENTIFICATION: White disposable gown, SINO-ISOLGOWN-L3-SMS-10044-7; Fabric: (CTT #15), Straight seam (CTT # 15)
Received July 22, 2020

STANDARD: Table 1: Classification of Barrier Performance of Surgical Gowns, Isolation Gowns, Other Protective Apparel, Surgical Drapes and Drape Accessories. ANSI/AAMI PB70:2012

TEST: Water Resistance: Spray Protection AATCC TM42:2012(1)

TEST CONDITIONS: Contaminating agent: TTC (SIN-8-01)
Apparatus: Impact Protection Tester (Type 1)
Water temperature: 21 °C
Note: The actual value of the increase in the mass of the fabric is entered in the report even if the result is $\leq 10\%$.
Date of test: July 27, 2020

RESULTS: Individual Data

Fabric (CTT #15)
Increase in mass of the fabric (g): 0.0 0.0 0.0

Straight seam (CTT #15)
Increase in mass of the fabric (g): 0.0 0.0

Cross seam (CTT #15)
Increase in mass of the fabric (g): 0.0 0.0

Sample level: See p.3




Prepared by: *Marianne Deslauriers* Approved by: *Lois Thibault*
 Marie Deslauriers, Project Leader / Laboratory
 Technicienne Date: July 27, 2020

For any information concerning this report, please contact ELSA Desjardins

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ANALYSIS REPORT
S.C.C. Accreditation No.: 401

Mr. Adam Karamall Date: July 27, 2020
 Safe Direct Medical Supplies Report: 5826-0017-374-en

REQUIREMENTS: The sample level classification is based on the lowest specimen's level.
Level 1: AATCC 42: $\leq 4.5\%$

Level 2: AATCC 42: $\leq 1.0\%$ and AATCC 127: ≤ 20 mm
Level 3: AATCC 42: $\leq 1.0\%$ and AATCC 127: ≤ 20 mm

AQL Requirement (Alpha): $\leq 0.1\%$
POK Requirement (Beta): $\leq 10.0\%$ POK

REMARKS: Two specimens tested for straight seam and cross seam due to insufficient fabric.




Prepared by: *Marianne Deslauriers* Approved by: *Lois Thibault*
 Marie Deslauriers, Project Leader / Laboratory
 Technicienne Date: July 27, 2020

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Mr. Adam Karamall Date: July 27, 2020
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IDENTIFICATION: White disposable gown, SINO-ISOLGOWN-L3-SMS-10044-7; Fabric: (CTT #15), Straight seam (CTT # 15)
Received July 22, 2020

STANDARD: Table 1: Classification of Barrier Performance of Surgical Gowns, Isolation Gowns, Other Protective Apparel, Surgical Drapes and Drape Accessories. ANSI/AAMI PB70:2012

TEST: Water Resistance: Hydraulic Pressure - Option 2: Hydrostatic Head Tests AATCC TM127:2012(1)(a)

TEST CONDITIONS: Contaminating agent: TTC (SIN-8-01)
Water pressure applied from below the test specimen.
Rate of increasing water pressure: 80 mm/min.
Apparatus used: Tissue Hydrostatic Head Tester, Model HF 3000 V
Apparatus used: Tissue Hydrostatic Head Tester, Model HF 3000 V
Water temperature: 21, 21.2
Type of water: Distilled
Soak fabric in contact with water: Face side
Area tested (cm²): 100
Specimens tested as received.
Date of test: July 27, 2020

RESULTS: Individual Data

	Individual Data	Avg.	S.D.	%CC
Fabric (CTT #15)				
Pressure (cm):	>100* >100* >100*			
Sample level:	3			
Straight seam (CTT #15)				
Pressure (cm):	>100* >100* >100*			
Sample level:	3			
Cross seam (CTT #15)				
Pressure (cm):	>100* >100*			
Sample level:	3			




Prepared by: *Julie Lamoureux* Approved by: *Lois Thibault*
 Julie Lamoureux, Project Leader / Laboratory
 Technicienne Date: July 27, 2020

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Level 1: AATCC 42: $\leq 4.5\%$

Level 2: AATCC 42: $\leq 1.0\%$ and AATCC 127: ≤ 20 mm
Level 3: AATCC 42: $\leq 1.0\%$ and AATCC 127: ≤ 20 mm

AQL Requirement (Alpha): $\leq 0.1\%$
POK Requirement (Beta): $\leq 10.0\%$ POK

REMARKS: Two specimens tested for cross seam due to insufficient fabric.
* The test was stopped at 100 cm H₂O because it reaches the maximum requirement of the standard for Level 3 (over 50 mm).

Prepared by: *Julie Lamoureux* Approved by: *Lois Thibault*
 Julie Lamoureux, Project Leader / Laboratory
 Technicienne Date: July 27, 2020

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