



A proudly Canadian company

Level 3 AAMI Isolation Gown

PP & PE Material

AATCC 42 \leq 1.0 g, AATCC 127 \geq 50cm

Redacted Version







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Proprietary Name: [Redacted]

Classification Name: NON-SURGICAL ISOLATION GOWN

Product Code: [OEA](#)

Device Class: 1

Regulation Number: [878.4040](#)

Medical Specialty: General & Plastic Surgery



Registered Establishment Name: [Redacted]

Owner/Operator: [Redacted]

Owner/Operator Number: [Redacted]

Establishment Operations: Manufacturer



中国认可
国际互认
检测
CNAS L0599

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The following sample(s) was/were submitted and identified on behalf of the client as:

Sample Description : (A) Disposable gown (Disposable Isolation gown)

Composition : (A) PP, PE
Sample Color : (A) Blue
Manufacturer : [Redacted]

Sample Receiving Date : Jun 28, 2020
Testing Period : Jun 28, 2020 - Jun 29, 2020


Test Result(s) : Unless otherwise stated the results shown in this test report refer only to the sample(s) tested, for further details, please refer to the following page(s).

Test Performed : Selected test(s) as requested by applicant


Signed for and on behalf of
SGS-CSTC Standards Technical Services (Shanghai) Co., Ltd. Testing Center


Sara Guo

Sara Guo (Account Executive)



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Test Result

Liquid Barrier Performance and Classification of Protective Apparel and Drapes Intended for Use in Health Care Facilities
(ANSI/ASHE P197.2)

Section 4.2.1 Water Resistance: Impact Penetration Test
(AATCC 42-011)

As received

Weight of blotter gained (g)	1#	2#	3#	4#	5#
Area A (Critical zone-Front)	0.0	0.0	0.0	0.0	0.0
Area B (Critical zone-Sleeve)	0.0	0.0	0.0	0.0	0.0
Area C (Critical zone-Back)	0.0	0.0	0.0	0.0	0.0
Seam between areas A&B	0.0	0.0	0.0	0.0	0.0
Seam between areas A&C	0.0	0.0	0.0	0.0	0.0
Seam between areas B&C	0.0	0.0	0.0	0.0	0.0

Remark:

- Level 1: all critical zone components shall have a blotter weight gain of no more than 4.5 grams(g)
- Level 2: all critical zone components shall have a blotter weight gain of no more than 1.0 grams(g)
- Level 3: all critical zone components shall have a blotter weight gain of no more than 1.0 grams(g)


Section 4.2.1 Water Resistance: Hydrostatic Pressure Test
(AATCC 127-2018, Hydrostatic Head: Rate of increase of water pressure 60ml/min; temp. of distilled water: 21°C, fabric face side of water)

As received


Water Column (cmH ₂ O)	1#	2#	3#	4#	5#
Area A (Critical zone-Front)	>50.0	>50.0	>50.0	>50.0	>50.0
Area B (Critical zone-Sleeve)	>50.0	>50.0	>50.0	>50.0	>50.0
Area C (Critical zone-Back)	>50.0	>50.0	>50.0	>50.0	>50.0
Seam between areas A&B	>50.0	>50.0	>50.0	>50.0	>50.0
Seam between areas A&C	>50.0	>50.0	>50.0	>50.0	>50.0
Seam between areas B&C	>50.0	>50.0	>50.0	>50.0	>50.0


Remark:

- Level 2: all critical zone components shall have a hydrostatic resistance of at least 200mmH₂O
- Level 3: all critical zone components shall have a hydrostatic resistance of at least 500mmH₂O



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Barrier performance of each component and final classification commended


	Impact Penetration Test AATCC 42 (g)	Hydrostatic Pressure Test AATCC 127 (cmH ₂ O)	Resistance to Bacteriophage Phs-X174 ASTM F 1671	Level	Final classification
Area A (Critical zone-Front)	0.0	>50.0	/	Level 3	Level 3
Area B (Critical zone-Sleeve)	0.0	>50.0	/	Level 3	
Area C (Critical zone-Back)	0.0	>50.0	/	Level 3	
Seam between areas A&B	0.0	>50.0	/	Level 3	
Seam between areas A&C	0.0	>50.0	/	Level 3	
Seam between areas B&C	0.0	>50.0	/	Level 3	


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: 54.5g
- Level 2: Impact Penetration Test-AATCC 42: 51.0g; Hydrostatic Pressure Test-AATCC 127: 320mmH₂O
- Level 3: Impact Penetration Test-AATCC 42: 51.0g; Hydrostatic Pressure Test-AATCC 127: 500mmH₂O
- Level 4: Resistance to Bacteriophage Phs-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.



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Sample Photo


Face Back

The statement of conformity in this test report is only based on measured values by the laboratory and does not take their uncertainties into consideration.

End of Report



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