

Level 3 Isolation Gown Tri-Layer SMS

| | |
|---------------|--|
| SKU | PE-003E |
| Description | Tri-Layer SMS with full back & tie neck. Heavy weight, 45G, tape & stitch seams. Blue, non-sterile, Sizes L/XL |
| AAMI Level | 3 |
| Material | SMS |
| Back Style | Full |
| Wrist Style | Elastic |
| Neck Style | Tie |
| Closure Style | Back Tie |
| Colors | Blue |
| Sizes | L/XL one size Universal |
| Seams | Tape & Stitch |
| Weight | Heavy Weight, 45g |
| Origin | Cambodia |
| Non-Sterile | Non-Sterile |



AAMI Level 3 gowns

AAMI Level 3 isolation gown (tape seam)

· Comfort and reliable medium weight SMS fabric

- » Made from SMS material
- » Neck tie styles with back ties
- » Elastic Cuffs



tape



tape seam



Neck ties



Back ties



Elastic cuffs

AAMI Level 3

AAMI Level 3 gowns

Multi-angle View

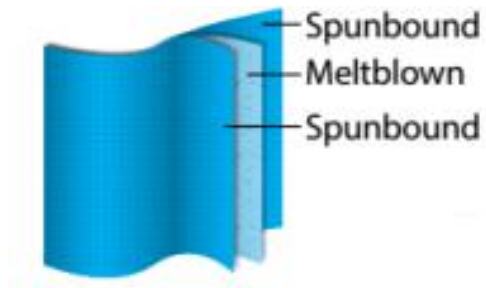


AAMI Level 3 gowns

Material & Measurement

AAMI Level 3 isolation gown (**tape seam**)

- Comfort and reliable medium weight **SMS fabric**
- Fabric Weight 45g/m^2 (+/- 5g/m^2)



THIS REPORT CANCELS AND SUPERSEDES THE TEST REPORT NO.SL52035274711501TX DATE: 2020-

**08-03 ISSUED BY SGS (SHANGHAI)
UPDATED SAMPLE INFORMATION.**

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

Sample Description : (A)Isolation gowns

Sample Color : (A)blue

Composition : (A)SMS 45g/m2

Style No. : PSG17231 Level 3

Manufacturer :

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

Sample Receiving Date : Jul 24, 2020

Testing Period : Jul 31, 2020 - Aug 03, 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).

| |
|---------------------------|
| Revised Reason |
| Amended the Manufacturer, |



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Comment:

| | |
|---|---------|
| Standard Specification for Isolation Gowns Intended for Use in Healthcare Facilities (ASTM F3352-19) | (A) |
| Section 7.1 Liquid Barrier Performance and Classification of Protective apparel and Drapes Intended for Use in Health Care Facilities (ANSI/AAMI PB70-2012) | Level 3 |
| Section 7.1 Tensile Strength | M |
| Section 7.1 Tear Strength | M |
| Section 7.1 Seam Strength | M |
| Flammability | M# |

Remark: M=Meet ASTM F3352-19 requirement

M#= Meet Clients' requirement(This test is not required in ASTM F3352-19)

Level 3= the provided sample does meet ANSI/AAMI PB70-2012 Level 3.

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



Sara Guo (Account Executive)

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Test Result

Standard Specification for Isolation Gowns Intended for Use in Healthcare Facilities
(ASTM F3352-19)

Section 7.1 Liquid Barrier Performance and Classification of Protective apparel and Drapes Intended for Use in Health Care Facilities*
(ANSI/AAMI PB70:2012)

ANSI/AAMI PB70-2012 Section 4.2.1 Water Resistance: Impact Penetration Test
(AATCC 42-2017)

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 4.5grams(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)

ANSI/AAMI PB70-2012 Section 4.2.1 Water Resistance: Hydrostatic Pressure Test

(AATCC 127-2018; Hydrostatic Head; Rate of increase of water pressure:60mbar/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 20cmH₂O
- Level 3: all critical zone components shall have a hydrostatic resistance of at least 50cmH₂O



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 Phi-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 | |
| <p>Remark:</p> <ul style="list-style-type: none"> ● 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. | | | | | |

Section 7.1 Tensile Strength

(ASTM D5034-09(Reapproved 2017))

| | | <u>Requirement</u> |
|------------|-------|--------------------|
| Length (N) | 135.0 | ≥30N |
| Width (N) | 95.5 | ≥30N |

Section 7.1 Tear Strength

(ASTM D5733-1999, Trapezoid Procedure)

| | | <u>Requirement</u> |
|-------------------------------|------|--------------------|
| Lengthwise direction torn (N) | 73.5 | ≥10N |
| Widthwise direction torn (N) | 41.0 | ≥10N |



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Section 7.1 Seam Strength

(ASTM D 1683/D1683M-17(2018), Procedure A)

| | | <u>Requirement</u> |
|-------------------|-------------|--------------------|
| Sleeve seam (N) | 93.0(F.R.) | ≥30N |
| Armhole seam (N) | 92.0(F.R.) | ≥30N |
| Shoulder seam (N) | 123.5(F.R.) | ≥30N |

Remarks: F.R. = Fabric Rupture;

Flammability

(16 CFR Part 1610 - 2008)

Sample : (A)
 Fabric Surface : Smooth without coating
 Test Specimen Direction : Length (face)

As Received

Burn Code

- (1) IBE
- (2) IBE
- (3) IBE
- (4) IBE
- (5) IBE

Flammability Classification : Class 1

Requirement: Class 1

Conclusion: Pass

Remarks

Class 1 Normal Flammability
 Class 1 textiles exhibit normal flammability and are acceptable for use in clothing.

Burn Code Description:

IBE = Ignited, but extinguished

*THE TEST RESULTS ARE COPIED FROM REPORT NO. SL52035274042001TX DATE: JUL 30, 2020



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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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