

# LAMINATED SURGICAL GOWN

SMS non woven fabric of 35gr. It is composed of SPUNBOND - MELTBLOWN - SPUNBOND - LAMINATED made of 100% polypropylene



## Measurements

- Width: 67.5
- Length: 108 - 110 cm

## Weight

- 125 gr approx

- **Round neck with 2 adjustment strips**
- **4 waist adjustment strips 2 inboard and 2 external**
- **Fabric dressing cardigan 50% cotton 50% polyester**
- **Non sterile**

## Observations

- Disposable, NON-STERILE
- Antiallergic, hygienic and comfortable.
- Microbial barrier, capable of blocking pathogenic germs from the blood.
- Blood permeable and fluids
- Antistatic
- Long sleeve with spring cuff and waist and neck support.
- Color: white, baby blue.

### AAMI PB70 Liquid Barrier Performance and Classification

Test Article: Blue Plastic Touacan

A total of thirty-two (32) specimens were tested from ten (10) test articles. Specimens were chosen from the critical zones as described in AAMI PB70 for an isolation gown. Test specimens were subjected to the following tests:

**AATCC 42 Water Resistance: Impact Penetration Test**  
**AATCC 127 Water Resistance: Hydrostatic Pressure Test.**

Based on the results of the testing as summarized in the attached reports, numbers 2004287 and 2004288, the product listed above was classified as **AAMI PB70 Level 3**.

**Record Storage:** All raw data pertaining to this study will be maintained in the LexaMed archives for a minimum of 5 years.

Approved by  Date 6-12-20

Test Article: Blue Plastic Touacan  
Part # N/A Lot # N/A Batch # N/A

### AATCC 42 Water Resistance: Impact Penetration Test

Test article received: 6/4/2020  
Test start date: 6/8/2020  
Test termination date: 6/9/2020  
SOP No. (current version): LEXLP-074

**Procedure:** Thirty-two (32) sections each measuring 178 x 330 mm were cut from 30 products from areas representing the critical zones as described in AAMI PB 70 for an isolation gown. The test specimens and one (1) blotter sheet for each were preconditioned at  $65 \pm 2\%$  rh and  $21 \pm 1^\circ\text{C}$  for a minimum of 4 hours. Test samples were then clamped to the incline stand of an Impact Tester. Blotter paper was weighed and inserted beneath the test sample. Deionized Water (DIW) heated to  $27 \pm 1^\circ\text{C}$  was poured into the funnel and the water sprayed onto the test article. The blotter paper was removed and re-weighed.

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
$\leq 4.5$ gm	$\leq 1.0$ gm	$\leq 1.0$ gm

**Results:** A total of 32 / 32 specimens had a weight gain of  $\leq 1.0$  gm.

**Conclusion:** Based on the results of the test and an AQL of 4% / RQL of 20% the test article was classified as PB70 Level 3.

**Record Storage:** All raw data pertaining to this study will be maintained in the LexaMed archives for a minimum of 5 years.

Approved by  Tech: AP/GP Date 6/11/20

Test Article: Blue Plastic Touacan  
 Part # N/A Lot # N/A Batch # N/A

**AATCC 127 Water Resistance: Hydrostatic Pressure Test**

Test article received: 6/4/2020  
 Test start date: 6/8/2020  
 Test termination date: 6/9/2020

**Procedure:** Thirty-two (32) sections each measuring 200 mm x 200 mm were cut from 30 products from areas representing the critical zones as described in AAMI PB 70 for an isolation gown. The test specimens were preconditioned at 65±2% rh and 21±1°C for a minimum of 4 hours. Individual specimens were clamped into the Hydrostatic Tester and analyzed.

The hydrostatic pressure required for water penetration for each specimen was used to determine the AAMI PB70 Level met based on the following criteria:

Hydrostatic Pressure Acceptance Criteria	
Level 2	Level 3
≥ 20 cmH <sub>2</sub> O	≥ 50 cmH <sub>2</sub> O

**Results:** A total of 32 / 32 specimens had a hydrostatic pressure for water penetration of ≥ 50 cmH<sub>2</sub>O.

**Conclusion:** Based on the results of the test and an AQL of 4% / RQL of 20% the test article was classified as PB70 Level 3.

**Record Storage:** All raw data pertaining to this study will be maintained in the LexaMed archives for a minimum of 5 years.

Approved by *Rebecca M. Skala* Tech: AP/GP Date 6-11-20



All reports are submitted as confidential communications. Reports may not be reproduced except in their entirety pending LexaMed approval.