

LEVEL 4

# SURGICAL GOWN

| SMS 50 GRMS TYVEK COVER 15 GRMS BLUE/WHITE

100% FLUID REPELLENT

STERILE

XL

TREATED WITH ANTIMICROBIAL FINISHES



## AAMI Levels

Minimal protection

Low protection

Moderate protection

High protection

1

2

3

4

**Only Level 4 gowns are tested for viral penetration resistance, and therefore only Level 4 garments are considered impermeable to viral penetration.**

## **What is TYVEK?**

Tyvek® is a fully synthetic material made from high-density polyethylene fibers that are held together through a process to obtain a non-woven fabric. Lightweight, durable and breathable, yet resistant to water, abrasion, bacteria penetration, and the passage of time, Tyvek® turns out to be an incredible material that is used to enhance various applications in various industries.

## **STERILE WITH UV LIGHT AND VACUUM SEALED BAG:**

**100% FLUID RESISTANCE**

### **LINT AND ABRASION RESISTANCE**

- Fluid resistance: barrier protection to prevent blood ingress and fluid contamination
- Fire resistance: meets the NFPA industry standard for low flammability.
- Lint and abrasion resistance: reduces the risk of lint contamination in wounds and related postoperative complications.

**Water resistant • Breathability • Barrier protection  
Tensile strength • Recycling capacity • Ease of printing**

### **Used in HIGH risk situation:**

For example, during lengthy fluid intensive procedures, surgery, when resistance to pathogens is needed or infectious diseases (non-airborne) are suspected.

# PRODUCT SPECIFICATION

## Surgical Gown Level 4

### SMS 50GMS

#### PHYSICAL PROPERTIES

Property	Unit	Target	Method	Tolerance
1) Grammage	gr	50.0	IN10BM013 (1)	Min Prom: 42.0 Min Indiv: 38.0
2) Resistance				
a. Machine Direction	kg/in	13.0	IN10BM010 (2)	Min Prom: 8.0 Min Indiv: 6.0
b. Dirección Transversal	kg/in	9.0	IN10BM010 (2)	Min Prom: 5.0 Min Indiv: 3.0
3) Elongation				
a. Machine Direction	%	70.0	IN10BM010 (2)	Prom: 50.0 – 100.0 Indiv: 40.0 – 90.0
b. Dirección Transversal	%	90.0	IN10BM010 (2)	Prom: 70.0 – 120.0 Indiv: 60.0 – 110.0
4) Water Column	mm H2O	300	IN10BM018	Min Prom: 200 Min Indiv: 155
5) Calandrad's Pattern				
6) Training and Color		Calandrado of Rhombs		
		Blue 519 Eco blue. Training according to standard guarded in Berry.		

(1). Based on ASTM D3776-85 Test Method.

(2). Basado en ASTM D5034-95 (Grab Test) Test Method.

#### CUT AND WOUND MEASUREMENTS AND PROPERTIES

Property	Unit	Target	Tolerances / Criteria
1) Width	mm	As indicated in Section I.	/- 3 mm Width evaluated in material under tension.
2) Length	m	3500 350 (1771545)	+/- 200m. +/- 20m. <small>Tag with real footage. Lemity evaluated in material under voltage.</small>
3) To connect	Type	2 in. Red PP Tape	2 in. PP Red Tape Only
4) To splice	#	0	Maximum 1 splice per roll. Only 10% of the op
5) Telescopio	cm	0	Maximum 0.6 cm relative to the shaft.
6) Step	cm	0	Maximum 2 steps per roll 0.6 cm deep.
7) Alignment to the cardboard center	cm	0	+/- 0.5cm
8) Appearance on the edges			

Uniform cutting without fabric strips or metal particles due to poor cutting.

# TEST REPORT



Date: 2020-08-12

Test Report

No. MX20-002256 Rev. 0

Page 1 of 6

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

as: SURGICAL GOWN LEVEL 4

FIBER CONTENT: SMS (SPUNBOND/MELTBLOWN/SPUNBOND)

FABRIC COLOR: BLUE

WEIGHT: 112 gr

END USE: SURGICAL GOWN

SGS Job No. :	4021588
Sample receiving date :	2020-08-05
Test Performing Period :	2020 08-06 to 2020-08-011
Test Requested :	Selected test(s) as requested by client.
Test Method :	Please refer to next page(s).
Test Results :	Please refer to next page(s).

Signed for and on behalf of  
SGS de México, S.A. de



Fabiola Vega Rodríguez  
Technical Expert

12082020183200001962

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Date: 2020-08-12

Test Report

No.MX20-002256Rev.0

Page 2 of 6

Tests Summary :

Test Requested :	Test Method	Evaluation
Standard Test Methods for Mass Per Unit Area (Weight) of Fabric	ASTM D3776/D3776M - 09a (Reapproved 2017)	PASS
Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)	ASTM D5034 - 09 (Reapproved 2017)	PASS
(✓) Flammability of Clothing Textiles	16 CFR 1610-2011	PASS
Standard Test Method for Tearing Strength of Fabrics by Trapezoid Procedure	ASTM D5587-15	PASS

Accredited Tests :

- (\*) Accreditation in the Chemical division No. Q-0871-110/17
- (✓) Accreditation in the Textile and Apparel division No. TV-0144-003/11
- (\*) Accreditation in the Mechanical Metal division No. MM-0719-105/16
- (o) COFEPRIS Authorization TA-80-18

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Date: 2020-08-12

Test Report

No. MX20-002256 Rev.0

Page 3 of 6

Test Results :

Test Part Description

Item No.	SGS Sample ID	Description
1	MX20-002256.001	SURGICAL GOWN LEVEL 4

Standard Test Methods for Mass Per Unit Area (Weight) of Fabric

TestMethod: ASTM D3776/D3776M - 09a (Reapproved2017)

Weight (g/m²)

Conclusion

Method C

Notes: NA

Standard Test Method for Breaking Strength and Elongation of Textile Fabrics (Grab Test)

TestMethod: ASTM D5034 - 09 (Reapproved2017)

Lengthwise (newton)

Lengthwise elongation (%)

Widthwise (newton)

Widthwise elongation (%)

Conclusion

Jaw Faces: 25x25 mm and 25 x 50 mm Testindry.

Type of testing machine used: CRE Pretension 2newtons

Notes: NA

001

Result

57

Pass

Requirements

50 g/m² minimum

001

Result

56.1

183.4

58.8

392.6

Pass

Requirements

≥ 30 newton

\*\*

≥ 30 newton

\*\*

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Test Report

No. MX20-002256 Rev.0

Page 4 of 6

Flammability of Clothing Textiles

Test Method: 16 CFR 1610-2011

	001	Requirements
Surface	Flat	-
Preliminary Testing	DNI	-
Test sample direction performance	Lengthwise(Face)	-
Original Sample burn code 1	DNI	-
Original Sample burn code 2	DNI	-
Original Sample burn code 3	DNI	-
Original Sample burn code 4	DNI	-
Original Sample burn code 5	DNI	-
Average	DNI	-
Flammability	Class 1	Class 2
Conclusion	Pass	

Notes : DNI: Did Not Ignite  
 Requirements for Plain Surface Textiles:  
 Class 1 Normal Flammability – 3.5 seconds or > (Pass)  
 Class 2 N/A (for raised-fiber surface textiles only)  
 Class 3 Rapid and Intense Burning - < 3.5 seconds (Fail)

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Test Report

No. MX20-002256 Rev.0

Page 5 of 6

Standard Test Method for Tearing Strength of Fabrics by Trapezoid Procedure Test

Method: ASTM D5587-15

	001	Requirements
	Result	
Lengthwise		
Lengthwise M1 (newton)	21.9	-
Lengthwise M2 (newton)	23.8	-
Lengthwise M3 (newton)	22.0	-
Lengthwise M4 (newton)	21.7	-
Lengthwise M5 (newton)	20.9	-
Average lengthwise (newton)	22.1	≥ 10 newton
Widthwise		
Widthwise M1 (newton)	19.4	-
Widthwise M2 (newton)	17.4	-
Widthwise M3 (newton)	17.2	-
Widthwise M4 (newton)	18.4	-
Widthwise M5 (newton)	16.3	-
Average widthwise (newton)	17.7	≥ 10 newton
Conclusion	Pass	

Notes : Contracted test  
 Unaccredited test  
 Report Number: NL-TX-072301  
 Laboratory with accreditation No. TV-0072-001/11  
 Condition: dry  
 Speed: 300 mm/ min  
 The material supplied is plastic, so the reported values are approximate.

Remarks :  
 (1) MQL = Method Quantification Limit (4) "-" = Not Analyzed  
 (2) ND = Not Detected (< MQL) (5) "--" = Analysis in Process  
 (3) NA = Not Applicable

Comments :  
 The results of these tests are valid only and exclusively for the samples tested. Any alteration to this document invalidates it. To request verification or clarification of this report must do so within 10 business days after the date of issue.  
 Test conditions: 21°C ± 2°C / 65% ± 5% HR. According to the standard ASTM D1776 / D1776M - 20

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Sample Photo :



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Photo :



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\*\*\* End of Report \*\*\*

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