

# LEVEL 3 GOWNS



## Test Report

No. 4951926TX

Date: August 27, 2020

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### Sample Picture



Selected tests as requested by applicant against specified requirement / test request form / quotation.

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

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DATE OF ISSUE: 2020-07-17

LAB 4020584

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# ORIGINAL

## Results:

Method: AATCC 100-2004

Test/Parameter	Method	Specification	Result	Status
Pseudomonas	ATCC 1542	Meets requirements	Conform	Pass
E. Coli	ATCC 11229	Meets requirements	Conform	Pass
S. Aureus	ATCC 6538	Meets requirements	Conform	Pass
Salmonella	ATCC 14028	Meets requirements	Conform	Pass
Listeria	ATCC 19115	Meets requirements	Conform	Pass

Test contracted

No. Report: 06A2004289

SGS Sample No.: 06S20009231-01

\*\*\*\*\* END REPORT\*\*\*\*\*

## AIPH

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THE RESULTS OF THESE TESTS ARE VALID ONLY AND EXCLUSIVELY FOR THE SAMPLES TESTED. ANY ALTERATION TO THIS DOCUMENT INVALIDATES IT.

Actual: May 07, 2019

FA.37.58 Rev.00

SGS de México, S.A. de C.V. Industria Eléctrica # 19-PB Fraccionamiento parque industrial Naucalpan, Naucalpan de Juárez, Estado de México C.P. 53489, México, D.F., T (55) 5395 7226 F (55) 5395 7134 [www.sgs.com](http://www.sgs.com)  
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## Test Report

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The following sample was submitted and identified by applicant as:

Testing Stage	:	Finished Product
Use	:	Surgical Isolation Gown, Disposable
Intended Customer	:	Healthcare
Barrier Protection Level	:	Level 3
Buyer Name	:	Texas Medical Center LLC
Style number	:	Disposable Isolation Gown
Lot #	:	Not Provided
Order number / PO	:	Not Provided
Color	:	Blue
Manufacturer	:	Not Provided
Fiber Content	:	SMS
Country of Destination	:	Not Provided
Country of Origin	:	Mexico
Sample Receiving Date	:	August 05, 2020
Test Performance Period	:	August 05 - 27, 2020
Tests Performed	:	Selected test(s) as requested by the applicant.
Test Results	:	Please refer to the following page(s).

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Date: 2020-07-08

## Test Report

No. MX20-002038 Rev. 0

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### 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
- (e) Accreditation in the Mechanical Metal division No. MM-0719-105/16
- (o) COFEPRIIS Authorization TA-80-18

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Date: 2020-07-08

## Test Report

No. MX20-002038 Rev. 0

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### Flammability of Clothing Textiles

Test Method : 16 CFR 1610-2011

	001	Requirements
Surface	Result	
Preliminary Testing	Flat	-
Test sample direction performance	DNI	-
Original Sample burn code 1	Lengthwise(Face)	-
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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Date: 2020-07-08

## Test Report

No. MX20-002038 Rev. 0

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

Test Method : ASTM D5587-15

	001 Result	Requirements
<b>Lengthwise</b>		
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
<b>Widthwise</b>		
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
<b>Conclusion</b>	<b>Pass</b>	

Notes : Contracted test  
Unaccredited test  
Report Number: NL-TX-078089  
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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FA.37.58 Rev.00 Release: 2019-May-07

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June 19, 2020

**RE: Regulatory Status of Level 3 Surgical Isolation Gowns**

Mr. Shafran,

The purpose of this letter is to provide regulatory information as it relates to the Food and Drug Administration's (FDA's) enforcement policy of Level 3 Surgical Isolation Gowns during the Coronavirus Disease (COVID-19) Public Health Emergency<sup>1</sup>, as well as regulation classification information for these types of medical devices once exemptions under the Public Health Emergency have expired.

The FDA considers Level 3 gowns to be "moderate barrier protection" intended for use in health care settings requiring moderate liquid barrier protection levels (e.g., ANSI/AAMI PB70 barrier protection Level 3) and that are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, bodily fluids, and particulate material in moderate-risk situations.

Surgical isolation gowns are classified per FDA regulation 21 CFR 878.4040 under product code FYC<sup>2</sup>. Under this regulation class and product code, all surgical isolation gowns are considered Class II and require premarket notification requirements under section 510(k) of the FD&C Act. At this time, testing required to show safety and effectiveness as part of the 510(k) submission process is underway, as well as compilation of the 510(k) file application documentation.

In parallel to pursuing the 510(k) regulatory pathway for FDA clearance of the device, Texas Medical Center Supply is also meeting the urgent need during the COVID-19 public health emergency for moderate-to-high barrier protection surgical gowns due to increased use and demand which has led to shortages in their availability. To ensure the availability of these types of surgical gowns during the COVID-19 public health emergency, the FDA does not intend to object to the distribution and use of ANSI/AAMI PB70 Level 3 moderate-to-high barrier protection surgical gowns that do not have prior submission of a premarket notification under the 510(k) of the FD&C Act as long as the product:

- Meets liquid barrier protection at Level 3 or higher, consistent with ANSI/AAMI PB70 for the critical zone area
- Meets the Class I or Class II flammability standard per 16 CFR Part 1610
- Labeling includes:
  - Product's sterility status (sterile or non-sterile), including any sterilization method used
  - Barrier protection as Level 3
  - Flammability classification (Class I or Class II)





### **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

A handwritten signature in black ink, appearing to read "David M. Slater", written over a horizontal line.

Date

6-12-20



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Lab # 2004287  
PO # N/A

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
$\leq 4.5 \text{ gm}$	$\leq 1.0 \text{ gm}$	$\leq 1.0 \text{ gm}$

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

**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



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