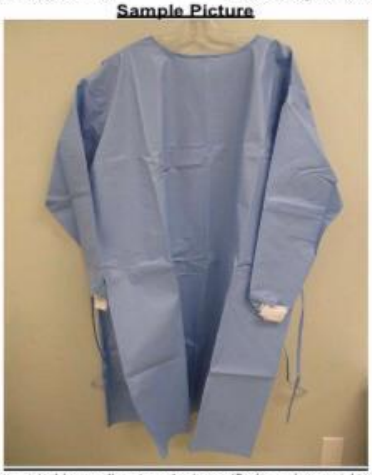
LEVEL 3 GOWNS

Sample Picture



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

*** End of Report ***

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
Lioteria	ATCC 19115	Meets requirements	Conform	Pass

Test contracted
No. Report: 06A2004289
SGS Sample No.: 06S20009231-01

***** END REPORT******

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 Juarez, Estado de México C.P. 53489, México, D.F., T (55) 5395 7226 F (55) 5395 7134 www.sgs.com
Member of the SGS Group (SGS S.A.)

The following sample was submitted and identified by applicantas:

Testing Stage	:	Finished Product
Use	:	Surgical Isolation Gown, Disposable
Intended Customer	:	Healthcare
Barrier Protection Level	:	Level 3
Buyer Name	:	Texas Medical CenterLLC
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).

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

Flammability of Clothing Textiles

Test Method : 16 CFR 1610-2011

	001	Requirements
	Result	
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)

Standard Test Method for Tearing Strength of Fabrics by Trapezoid Procedure

Test Method : ASTM D5587-15

	001 Result	Requirements
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-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

SGS de México, S.A. de C.V.

Industria Eléctrica # 19-PB Fraccionamiento parque industrial Naucalpan, Naucalpan de Juarez, Estado de México C.P. 53489, México., T (55) 5395 7225 F (55) 5395 7134 - www.sgs.com

CYA MEDICAL DEVICE CONSULTING

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[1], 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[2]. 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)

LEXAMED

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 6-12-2

ANAB ACCREDITED TESTING LABORATORY

Certified WBENC Women's Business Enterprise

LEXAMED

Lab # 2004287
PO # N/A

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

AATCC 42 Water Resistance: Imp ıct 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 ₄ 330 mm were cut from 30 products from areas representing the critical zones as described ₙ AAMI PB 70 for an isolation gown. The test specimens and one (1) blotter sheet for eə ₄h were preconditioned at 65±2% rh and 21±1°C for a minimum of 4 hours. Test samples were f ₄en clamped to the incline stand of an Impact Tester. Blotter paper was weighed and inserted ' ₄eneath the test sample. Deionized Water (DIW) heated to 27± 1°C was poured into the funnel a ₙd the water sprayed onto the test article. The blotter paper was removed and re-weighed.

The post-weight for each specimen wa: used to determine the AAMI PB70 Level met based on the following criteria:

Post -Weight Ga	n Acceptance Criteria	
Level 1	evel 2	Level 3
≤ 4.5 gm	≤ 1.0 gm	≤ 1.0 gm

Results: A total of 32 / 32 specimens had a weight gain of ≤ 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

ANAB ACCREDITED TESTING LABORATORY

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