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# Level 1 AAMI Isolation Gown

PP & PE Material

AATCC 42  $\leq$  4.5 g, AATCC 127  $\geq$

N/A

*Redacted Version*



## Level 1 AAMI Isolation Gown | PP & PE Material



## Packaging Options

### Full Case Count

80 units/ case

12 cases/ skid




### Full Case Dimensions

20 x 14 x 21 inches



# Level 1 AAMI Isolation Gown | PP & PE Material

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**ANALYSIS REPORT**  
SCC Accreditation No.: 40;

Mr. Adam Karamath      Date: June 18, 2020  
Safe Direct Medical Supplies      Report:


**IDENTIFICATION:** Single Use Medical Gown, Light Blue with White Collar, Style: ISO-25-N; Fabric (CTT #4), Straight Seam (CTT #4), Cross Seam (CTT #4), Point of Attachment (CTT #4)  
Received: June 1, 2020


**STANDARD:** Table 1: Classification of Barrier Performance of Surgical Gowns, ANSI/AAMI PB70:2012  
Isolation Gowns, Other Protective Apparel, Surgical Drapes and Drapes Accessories

**TEST:** Water Resistance: Impact Penetration      AATCC TM42-2017c

**TEST CONDITIONS:** Conditioning atmosphere: 21°C, 65% R.H.; Apparatus: Impact Penetration Tester (Type I); Water temperature: 27 ± 1°C; Date of test: June 17, 2020

RESULTS:	Individual Data	Avg.	S.D.	% CV
<b>Fabric (CTT #4)</b>				
Increase in mass of the blotter (g):	0.0   0.0   0.0	0.0	0.0	0.0
Sample level:	See p.3			
<b>Straight Seam (CTT #4)</b>				
Increase in mass of the blotter (g):	0.0   1.4   2.8	1.4	1.4	100.0
Sample level:	1			
<b>Cross Seam (CTT #4)</b>				
Increase in mass of the blotter (g):	>5.0			
Sample level:	N/A			
<b>Point of Attachment (CTT #4)</b>				
Increase in mass of the blotter (g):	1.9   0.3   1.2	1.1	0.8	70.8
Sample level:	1			

Prepared by:   
Nora Boudjoudi  
Technician

Approved by:   
Marion Zech  
Project Leader




Date: June 18, 2020

**\*\*For any information concerning this report, please contact Marion Zech.\*\***

The reports are identified by an alphanumeric code, the letter preceding "cc" refers to the revision number, control in ascending order. The electronic copy sent by CTT Group is the official report. The report identification is based on what was observed on the material sample and on information provided by the customer. The sample in relation to this report are retained for a period of 30 days following transmission of the report. The above reported results refer exclusively to the sample submitted for evaluation. This analysis report cannot be partly used or reproduced, unless in whole, without CTT Group prior written consent. © The ISO/IEC 17025 Scope of Accreditation of CTT Group is available at [www.gtg.com](http://www.gtg.com). In this report, the test which number is followed by the symbol 1 are not covered by this accreditation. For customer's complete address, please refer to the email.

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**ANALYSIS REPORT**  
SCC Accreditation No.: 40;

Mr. Adam Karamath      Date: June 18, 2020  
Safe Direct Medical Supplies      Report:

**REQUIREMENTS:** The Sample level classification is based on the lowest specimens' level.  
Level 1 : AATCC 42 : ≤ 4.5g  
Level 2 : AATCC 42 : ≤ 1.0g and AATCC 127 : ≥ 20 cm  
Level 3 : AATCC 42 : ≤ 1.0g and AATCC 127 : ≥ 50 cm

AQL Requirement (Alpha = .05): 4%  
RQL Requirement (Beta = 0.10): 20%

Prepared by:   
Nora Boudjoudi  
Technician

Approved by:   
Marion Zech  
Project Leader




Date: June 18, 2020

**\*\*For any information concerning this report, please contact Marion Zech.\*\***

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**ANALYSIS REPORT**  
SCC Accreditation No.: 40;

Mr. Adam Karamath      Date: June 18, 2020  
Safe Direct Medical Supplies      Report:

**IDENTIFICATION:** Single Use Medical Gown, Light Blue with White Collar, Style: ISO-25-N; Fabric (CTT #4)  
Received: June 1, 2020

**STANDARD:** Table 1: Classification of Barrier Performance of Surgical Gowns, ANSI/AAMI PB70:2012  
Isolation Gowns, Other Protective Apparel, Surgical Drapes and Drapes Accessories


**TEST:** Water Resistance: Hydrostatic Pressure - Option 2: Hydrostatic Head Tester      AATCC TM127-2017:2018c


**TEST CONDITIONS:** Conditioning atmosphere: 21°C, 65% R.H.; Apparatus used: Textest Hydrostatic Head Tester, Model FX 3000; Water pressure applied from below the test specimen; Rate of increasing water pressure: 40 cm/minute; Water temperature (°C): 21±2  
Type of water: Deionized  
Side of fabric in contact with water: Face side  
Area tested (cm²): 100  
Specimens tested as received, Date of test: June 17, 2020

RESULTS:	Individual Data	Avg.	S.D.	% CV
Pressure (cm):	>100*   77   >100*			
Sample level:	3			

**REQUIREMENTS:** The Sample level classification is based on the lowest specimens' level.  
Level 1 : AATCC 42 : ≤ 4.5g  
Level 2 : AATCC 42 : ≤ 1.0g and AATCC 127 : ≥ 20 cm  
Level 3 : AATCC 42 : ≤ 1.0g and AATCC 127 : ≥ 50 cm  
AQL Requirement (Alpha = .05): 4%  
RQL Requirement (Beta = 0.10): 20%

**REMARKS:** \* The test was stopped at 100 cm H2O because it meets the maximum requirement of the standard for Level 3 (≥ 50 cm).

Prepared by:   
Julie Gagnon  
Technician

Approved by:   
Marion Zech  
Project Leader

Date: June 18, 2020


**\*\*For any information concerning this report, please contact Marion Zech.\*\***


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ANALYSIS REPORT

ICC Accreditation No. 482

Mr. Adnan Karanath  
Sub Director Medical Supplies

Date: June 19, 2020

Project:

Single Use Medical Goods, Light Blue with White Color, Style: ISO-25-3-N (C-17) P41

Received June 1, 2020


STANDARDS

TEST	Testing Method of Nonwoven Fabrics by the Tensile Properties	ASTM D5731-99f
TEST CONDITIONS	Conditioning atmosphere: 23°C, 65% R.H. Apparatus used: Force-measuring with a Constant Rate of Extension (CRE) Type of calibration used: Maximum stretch Date of test: June 19, 2020	


RESULTS

	Individual Data					Avg.	S.D.	% CV
<b>3-Direction Direction</b>								
1-Testing Method (MD)	15.3	16.0	22.6	17.0	16.1	17.4	3.8	17.8
2-Testing Method (MD)	5.4	3.6	5.1	5.8	3.6	3.9	0.7	17.6
<b>3-Direction Direction</b>								
1-Testing Method (MD)	26.1	23.8	19.4	24.1	26.1	24.3	3.2	13.1
2-Testing Method (MD)	6.3	5.8	4.4	5.4	5.4	5.5	0.7	12.8

Prepared by:

  
 Lead Designer,  
Technician


Approved by:

  
 Mr. Zuh  
 Medical Sales  
 Project Leader

Date: June 19, 2020

\*\*For any information concerning this report please contact Mr. Zuh\*\*

The reports are identified by an alphanumeric code, the first representing "year" also in the previous number specified in ascending order. The alphanumeric code used by CTT Group in the collected reports is as follows: 19200601. The first two digits represent the year in which the report was prepared. The third and fourth digits represent the month in which the report was prepared. The last four digits represent the sequence number of the report. The first three reported data sets mentioned in the report are indicated for verification. This statistic report aims to provide data to support claims in a claim, unless CTT Group and/or other parties receive specific requests. The ISO 25-3-N (C-17) group is available in two variations. In this report, the data for the standard is followed by the symbol (a) accompanied by the number (1) in parentheses.



ICC, Intertek Inc. 3600 Riverchase Boulevard (Dallas) DALLAS, TX 75246, USA

Tel: +1 972 786-8375 Fax: +1 972 786-8371 E-mail: info@iccsolutions.com

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 150011113064			中国合格评定 国家认可中心 TESTING CNAS L1184
<h1>检 验 报 告</h1> <h2>TEST REPORT</h2>			
NO: <span style="background-color: #cccccc; padding: 0 20px;"></span>			
产品名称： 一次性隔离衣			
Sample name: Single-use isolation gown _____			
青岛丝诺纺织制品有限公司			
委托单位： Applicant <span style="background-color: #cccccc; padding: 0 50px;"></span> _____			
生产单位： Manufacturer / _____			
检验类别： 委托检验			
Test type Test Entrust _____			
 <b>国家生态纺织品质量监督检验中心</b> National Ecological Textiles Quality Supervision and Inspection Center			

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## **Contact Information**

### **Phone Number**

**+1 (647)-588-2250**

### **Email**

**[alex@safedirectms.com](mailto:alex@safedirectms.com)**

### **Office Address**

**1100 - 33 Yonge Street  
Toronto, ON  
M5E 0A9**