CH-1983WST-SURG

CARTER-HEALTH™
DISPOSABLES

MADE IN TURKEY | MEDICAL APPARELS

STERILE | EO

SURGICAL GOWN - LEVEL 4

DATA SHEET

FDA REGISTERED

CE 2163

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TS EN 13795-1 - EN ISO 9001 - EN ISO 13485 - ISO 14001 - ISO 22716

Single Use

LATEX Free

Surgical Gown

Level 4

Latex Free

Single Use

STERILE - EO

HIGH LIQUID PROTECTION

ANTI-STATIC & BREATHABLE

CE 2163 FDA REGISTERED ISO 9001:2015

About

The level 4 sterile surgical gown is a single-use disposable garment featuring a high-liquid barrier protection and breathable fabric. The ultrasonic seams and elastic cuffs ensure the safety of the health personnel and their patients. The level 4 sterile surgical gowns are used during long and invasive surgeries.

Specifications

Material: ASTM F2407 / ISO EN 13795-1:2019, SMMS + PE, Non-woven, and Spun-bound

Color: Blue

Sterilization: Ethylene Oxide (EN 550)

Construction: Ultrasonic Seams

FDA Classification: Surgical Gown (FYA - Class 2)

Compatibility: Meets Class 1 Flammability Requirements

Features

- Knit Cuffs & Medical Fold
- Full Coverage Protection
- Velcro Back Neck Closure
- Breathable Fabric
- European Quality Controls

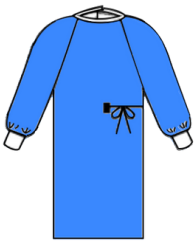
Available Sizes

CH1983WST-SURG-M	MEDIUM	60 Pc / Case
CH-1983WST-SURG-L	LARGE	60 Pc / Case
CH-1983WST-SURG-XL	X-LARGE	60 Pc / Case
CH-1983WST-SURG-XXL	2X-LARGE	60 Pc / Case

www.carter-health.com

info@chdisposables.com

407.296.6689



Surgical Gown Level 4

Test Reports

AB-0583-T
20048098-ing
12-20

EKOTEKS LABORATORY & EXAMINATION SERVICES A.S.

Required Tests	Result	Comments
PHYSICAL PROPERTIES		
Tensile Strength / **Dry**	**P**	
Tensile Strength / **Wet**	**P**	
Bursting Strength / **Dry**	**P**	
Bursting Strength / **Wet**	**P**	
Water Permeability	**P**	
Lint and Other Particles Generation From Non-woven	**P**	
MICROBIOLOGICAL TESTS		
Microbial Cleanliness (Bioburden)	**P**	
Wet-Bacterial Penetration	**P**	
Dry-Bacterial Penetration	**P**	

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20048098-ing
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P: Pass
F: Fail
R: Refer to retailer technologist

Test results were evaluated according to EN 13795-1:2019 Standard Properties Critical Sample Group limit values

TEST RESULT

Latex Free

Single Use

TENSILE STRENGHT; EN 29073-3:1996
Instron 5969 (Load: 50 kN), Strip Method.
Speed: 100 mm/min ± 10, Gauge length 200mm.
Pre-load was not applied. Without wetting samples.
The average results are given for weft and warp direction of five samples.
Performed in the conditioned room (20±2°C-65%±4).

Wet;

	RESULT	REQUIREMENT
Weft	44,2 N	⩾ 20N (Dry)
Warp	100,3 N	⩾ 20N (Dry)

TENSILE STRENGHT; EN 29073-3:1996
Instron 5969 (Load: 50 kN), Strip Method.
Speed: 100 mm/min ± 10, Gauge length 200mm.
Pre-load was not applied. Without wetting samples.
The average results are given for weft and warp direction of five samples.
Performed in the conditioned room (20±2°C-65%±4).

Wet;

	RESULT	REQUIREMENT
Weft	44,2 N	⩾ 20N (Wet)
Warp	100,3 N	⩾ 20N (Wet)

BURSTING STRENGHT; ISO 13938-1:1999
SDL ATLAS M229 tester. Test area: 30.5 mm diameter.
Rate of increase in volume; 29 cm3/min.
The average results are given of five samples.
Performed in the conditioned room (20±2°C-65%±4).

	RESULT	REQUIREMENT
Dry;	151,3 kPa	⩾ 40 kPa(Dry)
Height at Burst*	18,6 mm	

Surgical Gown Level 4

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TEST RESULT

TEST METHOD: EN 13795-1:2019

SURGICAL CLOTHING AND DRAPES-REQUIREMENTS AND TEST METHODS

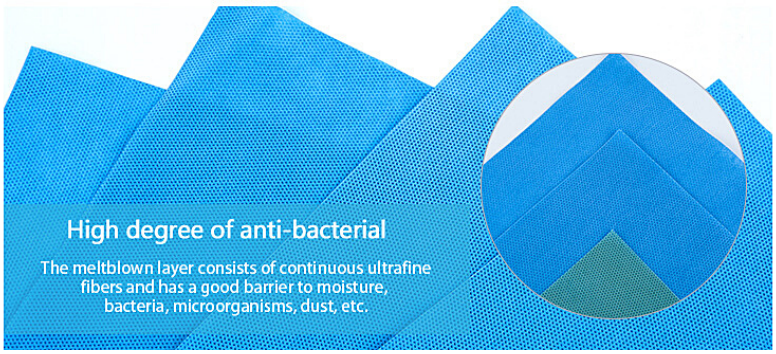
ANNEX 1: SURGICAL CLOTHING AND DRAPES;

BURSTING STRENGHT; ISO 13938-1:1999
SDL ATLAS M229 tester. Test area: 30.5 mm diameter.
Rate of increase in volume; 45.2 cm3/min.
The average results are given of five samples.
Performed in the conditioned room (20±2°C-65%±4).

	RESULT	REQUIREMENT
Wet;	126,6 kPa	⩾ 40 kPa (Wet)
Height at Burst*	19,6 mm	

WATER PERMEABILITY; ISO 811:2018
Hydrostatic Head Tester, Texted mark Fx 3000 model
Temperature of water 20°C. Pressure increase ratio 10mbar/min.
Performed in the conditioned room (20±2°C-65%±4).

	RESULT	REQUIREMENT
Sample 1	164,2 cmH_2O	⩾ 20 cmH_2O
Sample 2	175,4 cmH_2O	
Sample 3	156,1 cmH_2O	
Sample 4	161,2 cmH_2O	
Sample 5	180,5 cmH_2O	
Average	164,2 cmH_2O	



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Single Use

Surgical Gown Level 4

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TEST RESULT

LINT AND OTHER PARTICLES GENERATION FROM NONWOVEN;
Test Method: ISO 9073-10: 2003 (*)

5 test samples that in cross direction are maintained to twisting and compression action with Gelbo Flex for inner and outer surface in a clean room condition (according to ISO 14644-1 Class 5).
Lint and particles detached from the sample are counted with counter device and classified to size range.
Min. measuring size of SOLAIR 3100 particles measuring device: 0,3 µm,
Max. measuring size of SOLAIR 3100 particles measuring device: 25 µm,
Air flow: 28,3 ± 1,4 L/min
Working mode: 30 s x 10 consecutive periods

SAMPLE, INNER SURFACE (3 *µm – 25 µm*)		**SAMPLE, OUTER SURFACE** ((3 *µm – 25 µm*)	
Total linting	**: 38**	**Total linting**	**: 5**
Standard deviation	**: 28**	**Standard deviation**	**: 3**
Coefficient of variation	**: 73%**	**Coefficient of variation**	**: 54%**
Coefficient of linting (CL)	**: 2**	**Coefficient of linting (CL)**	**: 1**

SAMPLE, MATERIAL (TOTAL)	
Total linting	: 43
Coefficient of linting (CL)*	: 2

*According to EN ISO 13795-1:2019, Coefficient of linting (CL) (log 10) should be ⩽ 4 for analysis of critical product area and less critical product area of both standard performance and high performance testing.

Test Method: EN 13795-1:2019

SURGICAL CLOTHING AND DRAPES-REQUIREMENTS AND TEST METHODS

ANNEX 1: SURGICAL CLOTHING AND DRAPES;

MICROBIAL CLEANLINESS (Bioburden)

Test Method: Ref: EN ISO 11737-1:2018

The sample is put in extraction liquid after shaking well, incubated on the agar.
After incubation at 30 ± 1 °C for 72 hours, growth microorganism are counted on the agar.

	RESULTS	REQUIREMENTS
Microbial cleanliness (cfu/g)	13 cfu/g	≤ 300 cfu/g

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TEST RESULT

Test Method: BS EN 22610: 2006 (Surgical drapes, garments and fresh air clothes used as medical devices for patients, hospital staff and equipment - Test method for determination of resistance to wet bacterial permeability).

A test sample is placed on the agar plate on a rotating disc. Bacteria carrier material and coating film are places on the test sample and all parts are fixed on the disk. A finger is placed on the test sample to apply a certain force (3N ± 0.02). The finger moves on the test sample over the entire surface of the agar within 15 minutes. 5 studies are carried out for 15 minutes. 6. The study is repeated by inverting the sample.

Sample Amount:	5 pieces 25 x 25 cm^2
Carrier Material:	30 µm thin, 25 x 25 cm^2 Polyurethane Film
Coating Material:	25 x 25 cm^2 HDPE Film
Microorganism:	Staphylococcus aureus ATCC 29213
Bacterial Concentration (kob / ml):	1-4x 104 kob / ml
Incubation Conditions:	(36 ± 1) °C 48 hours

RESULTS			
Number of Populating Bacteria (cfu)		**Penetration Rate**	
X1	0	Rcum1	0
X2	0	Rcum2	0
X3	0	Rcum3	0
X4	0	Rcum4	0
X5	0	Rcum5	0
Z	432		
T		432	

X1 ..... X5: Number of colonies growing in 5 parallel petri in the same sample.
Z: Number of colonies growing in the sixth petri dish.
T: X1 + X2 + X3 + X4 + X5 + Z

Rcum1 = X1/T
Rcum2 = (X2 +X1)/T
Rcum3 = (X3 + X2 + X1)/T
Rcum4 = (X4 + X3 + X2 + X1)/T
Rcum5 = (X5 + X4 + X3 + X2 + X1)/T

BARRIER INDEX (Ia)		
	Result	**Expected Value (*)**
Ia	6	≥2,8

Ia = 6 - (CUM1 + CUM2 + CUM3 + CUM4 + CUM5)

*EN 13795-1:2019 Surgical gowns and drapes - Requirements and test methods are evaluated according to Table-1.

Surgical Gown Level 4

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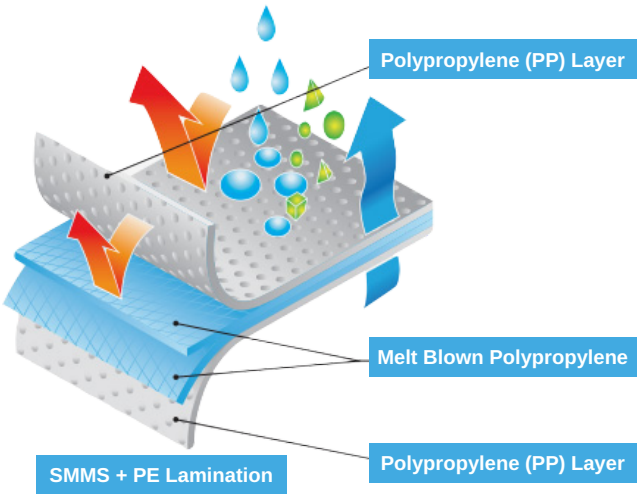
TEST RESULT

Test Method: ISO 22612: 2005 (Clothing for protection against infectious agents - Test method for resistance to dry microbial penetration)

Samples and containers are sterilized. Agar plates are placed in each container. Samples are placed aseptically in the apparatus. The covers are closed. After making a pot in the sample with the piston, the pistons are removed and 0.5 g ± 0.1 g are added to five samples from the powder contaiminated with bacteria and the six to the non-contaminated powder. Then all openings are closed with a plastic bag. The device is operated to give 20,800 vibrations per-minute. The test time is 30 minutes. After the test is over, all agar plates are incubated at 35 °C 24 hours.

Sample amount:	6 pieces 20 x 20 cm^2
Microorganism:	Bacillus Subtilis ATCC 9372
Bacterial concentration (cfu/ml):	1 x 10^8
Incubation conditions:	35 °C / 24 hours
RESULTS	
Number of Populating Bacteria (cfu)	
1	0
2	0
3	0
4	0
5	0
6 (Control)	0
Total	0
Logarithm	-
*EN 13795-1:2019 Surgical gowns and drapes – Requirements and test methods are evaluated according to Table-1.	
RESULT	
Result (cfu/g)	**Expected Value**
0	≤ 300 cfu/g



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AB-0690-T
TR1825194-RV2
11-20

TEST REPORT

Job No./Report No TR1825194-RV Date: 24 November 2020

Surgical Gown
Level 4

The following sample(s) was (were) submitted and identified by/on behalf of the client as:

Sample No.	Sample Description
A	Surgical Gown / Level - 4

Client's Reference No. : TR 1825194-RV2
Model No. : CH-1983WST-SURG
Brand Name : Carter Health Disposables, LLC
Sample Receiving Date : 06 November, 2020
Resubmit Date : 18 November, 2020-24 November 2020
Test Performing Period : 06 November 2020-17 November 2020
Overall Conclusion **: SEE RESULTS**

Test Results : Please refer to the next page(s).
Performed Test Summary : Selected test(s) as requested by client against client's performance stadnard

Test Parameters	Result
Physical Tests	A
Tensile Strength	*
Seam Strength (Fabric)	*
Flammability of Textiles	*
Water Resistance: Hydrostatic Pressure Test	M
Tear Strength	*
Water Resistance: Impact Penetration Test	M
Resistance of Materials Used in Protective Clothing to Penetration	M

Remarks	M = Meets client's requirement
	F = Does not meet client's requirement
	I = Inconclusive
	*= No specified requirement
Notes:	Conclusions on meet/fail are based on the test result from the actual sampling of the received sample(s).
	Residual sample can be returned to client if requested.

Technical Information

All combining stitches are made with ultrasonic sewing stitch. the velcro, label, rib and tape are sewn with single needle sewing machine.

Machinery and Equipment Used;

- Flat Machine
- Ultrasonic Stitch Machine
- Cutting Engine
- Marker Table
- Model Room Mold Drawing Machine

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AB-0690-T
TR1825194-RV2
11-20

TEST REPORT

Job No./Report No TR1825194-RV Date: 24 November 2020

Surgical Gown
Level 4

Flammability of Textiles[1]

Test Method : 16 CFR 1610
Sample ID & Color : Medical Blue Surgical Gown
Fabric Surface : PLAIN FABRIC FACE

	As Received Lenght		After Dry-cleaning and Laundering* Lenght	
	Flame Spread (sec.)	Burn Code	Flame Spread (sec.)	Burn Code
(1)	9,1	-	9,9	-
(2)	9,0	-	9,7	-
(3)	9,2	-	9,8	-
(4)	9,3	-	9,6	-
(5)	9,4	-	9,1	-
(Avg.)	9,2	-	9,6	-

Flammability Classification: Class 1 **Client's Requirement:** No Requirement

Class 1 **Normal Flammability** : Class 1 textiles exhibit normal flammability and are acceptable for use in clothing.

Class 2 **Intermediate Flammability** : Class 2 fabrics are considered to of intermediate flammability, but may be used for clothing.

Class 3 **Rapid and Intense Burning** : Class 3 textiles exhibit rapid and intense burning are dangerously flammable and shall not be used for clothing.

*Drycleaning / Laundering procedure is according to 16 CFR 1610:6(b)

The test results relate to the tested items only.
Test reports without SGS seal and authorised signatures are invalid.

Issued in Istanbul
Signed for and on behalf of
SGS Supervise Gözetme Etüd Kontrol Servisleri A.Ş.

IN THIS REVISED-2 REPORT, RESISTANCE OF MATERIALS USED IN PROTECTIVE CLOTHING TO PENETRATION TEST WAS PERFORMED BY THE REQUEST OF THE APPLICANT.

THIS REPORT SUPERSEDES OUR REPORT NO: TR1825194-RV1 DATED 24.11.2020

Mert Kurtuluş Customer Services Supervisor	Bora Şirinbilek Hardline & CPCH Testing Services Manager
	

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AB-0690-T
TR1825194-RV2
11-20

TEST REPORT

Job No./Report No TR1825194-RV Date: 24 November 2020

Surgical Gown

Level 4

Tear Strenght[1]
Test Method : ASTM D5587-15 (2019)

Sample ID & Color	Warp	Weft	Requirement by the Client
A	37,998 lbf	13,973 lbf	No Requirement
Conclusion	**See Results**		

Tensile Strenght[1]
Test Method : ASTM D5034-09 (2017)

Sample ID & Color	Warp	Weft	Requirement by the Client
A	34,890 lbf	18,380 lbf	No Requirement
Conclusion	**See Results**		

Seam Strength (Fabric)t[1]
Test Method : ASTM D1683 / D1683M-17 (2018)

Sample ID & Color	Right	Left	Requirement by the Client
SIDE SEAM	Seam Strength: 15,1 lbf Seam Slippage: 11,1 lbf	Seam Strength: 14,2 lbf Seam Slippage: 12,6 lbf	No Requirement
SHOULDER SEAM	Seam Strength: 19,4 lbf Seam Slippage: 19,4 lbf	Seam Strength: 18,4 lbf Seam Slippage: 18,4 lbf	
Conclusion	**See Results**		

Water Resistance: Impact Penetration Test[1]
Test Method: AATCC 127:2017 Option 2
Test Conditions: 60 cm H_2O / face

	Specimen 1	Specimen 2	Specimen 3	Specimen 4	Specimen 5	
Critical Zone – Front Panel	417,7	397,7	406,7	420,3	392,5	**Requirement**
Critical Zone – Sleeve Panel	417,6	397,6	406,5	420,1	392,6	
Critical Zone – Black Panel	417,5	397,8	406,4	420,0	392,7	≥ 50 cm
Critical Zone – Sleeve Seam	262,7	272,2	245,3	289,8	258,7	
Critical Zone – Point off Attachment (Belt)	262,6	272,1	245,1	289,7	258,6	
Conclusion	**Pass**					

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AB-0690-T
TR1825194-RV2
11-20

TEST REPORT

Surgical Gown
Level 4

Job No./Report No TR1825194-RV Date: 24 November 2020

Water Resistance: Impact Penetration Test
Test Method: AATCC 42:2007

Test Side: Face Side
As Received
Observation:

Weight of Blotter Gained (g)

	Specimen 1	Specimen 2	Specimen 3
Critical Zone – Front Panel	0.02	0.02	0.02
Critical Zone - Sleeve Panel	0.02	0.02	0.02
Critical Zone – Black Panel	0.02	0.01	0.01
Critical Zone – Sleeve Seam	0	0	0
Critical Zone – Point off Attachment (belt)	0.02	0.02	0.02

Remark: Liquid barrier performance and classification of protective apparel as per ANSI/AAMI PB70-2012

1) Level 4: All critical zone components shall have a blotter weight gain of no more than 1.0 grams (g).

	Impact Penetration Test AATCC 42 (g)	Level	Water Resistance Hydrostatic Pressure Test	Level	Final Classification
Critical Zone – Front Panel	0,2	Level 4	420,3	Level 4	Level 4
Critical Zone – Sleeve Panel	0,2	Level 4	420,2	Level 4	
Critical Zone – Black Panel	0,2	Level 4	420,1	Level 4	
Critical Zone – Sleeve Seam	0	Level 4	289,8	Level 4	
Critical Zone – Point off Attachment (belt)	0,2	Level 4	289,7	Level 4	

Note: Lowest test results from the submitted garment for the final classification.

Remark: The barrier performance of all critical zone components, including seams and points of attachment, shall be determined. The classification of surgical gown shall be a number denoting the performance of the critical zone component having the lower barrier performance.

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TR1825194-RV2
11-20

TEST REPORT

Job No./Report No TR1825194-RV Date: 24 November 2020

Surgical Gown
Level 4

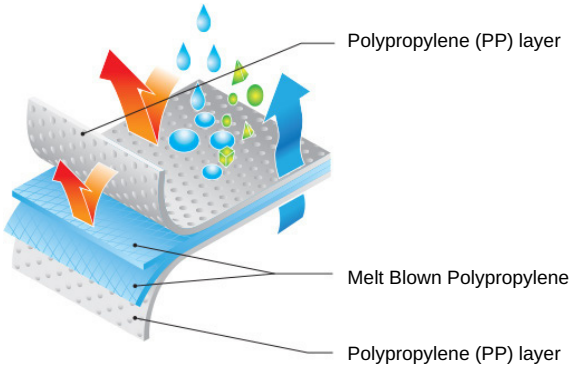
Resistance of Materials Used in Protective Clothing to Penetration

Sampling Method: The three samples used in this test.

Sample Size: 75 mm x 75 mm

Requirement:

Test Method	: F1671 / F1671M-13
Procedure Used	: Procedure A
Loading Suspension	: 60 mL Phl-X174 Bacteriophage
Test Conditions	: Min 24sa, (21±5) °C, (60±10) RG
Test Microorganism	: Bacteriophage Phl-X 174
Penetration Survey Method	: Plaque-forming Units (PFU)



SMMS + PE Lamination

Test Equipment:
Penetration Test Cell

Assessment:

No of Sample	Hydrostatic Pressure	Pre-Challenge Concentration (PFU/mL)	Post-Challenge Concentration (PFU/mL)	Assay Titer (PFU/mL)	Visual Penetration	Result
Sample 1	13.8 kPa	3.5×10^8	2.1×10^8	[a] < 1	No	**Pass**
Sample 2	13.8 kPa	3.5×10^8	2.1×10^8	[a] < 1	No	**Pass**
Sample 3	13.8 kPa	3.5×10^8	2.1×10^8	[a] < 1	No	**Pass**
Negative Control	13.8 kPa	3.5×10^8	2.1×10^8	[a] < 1	No	**Acceptable**
Positive Control	13.8 Kpa	3.5×10^8	2.1×10^8	[b] TNTC	Yes	**Acceptable**

***Pass:** The sample resists penetration and synthetic blood does not pass through the fabric.

***Fail:** The sample does not resist to penetration and synthetic blood passes through the fabric.

[a] **TNTC:** PFU were to numerous to county.

[b] A value of > 1 plaque forming units (PFU)/mL is reported for assay plates showing no plaques.

Material Compatibility Rate = 1.5

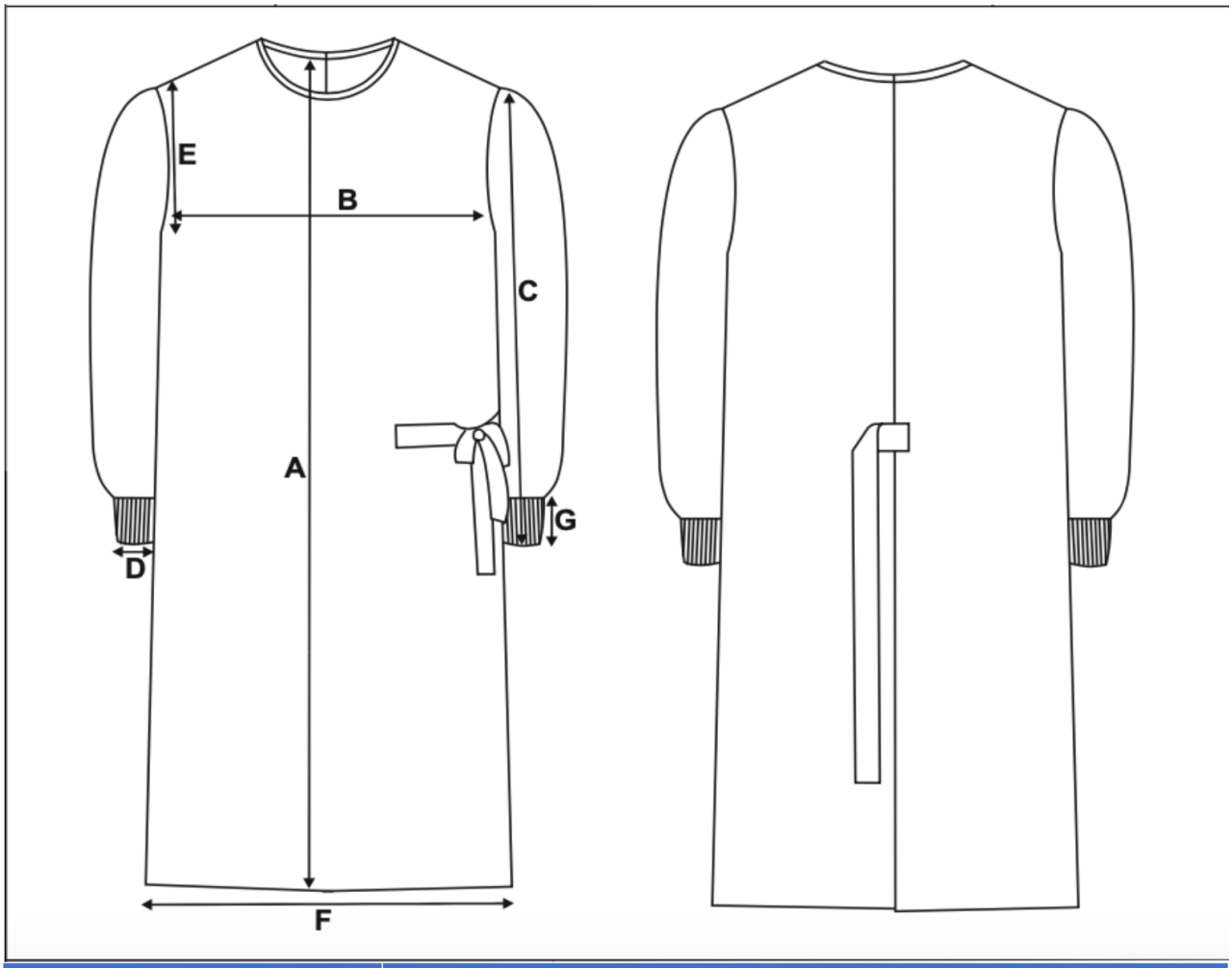
It is SUITABLE for the product according to the criteria.

**This test has been performed at accredited laboratory as subcontracted.

Surgical Gown

SIZE CHART

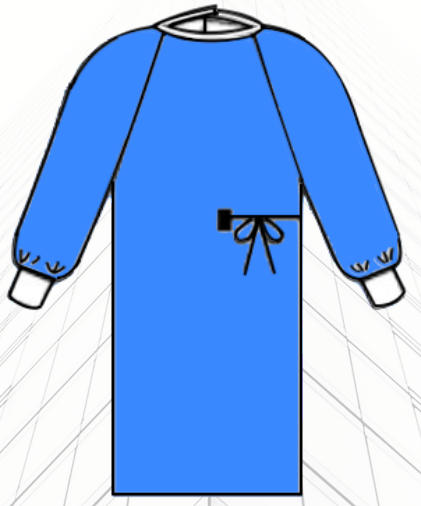
Level 4



MEASUREMENTS		SIZES						
		Small	Medium	Large	X Large	2X Large	3X Large	Tolerance
A	Length	45”	47”	49”	51”	53”	55”	-/+ 0.6”
B	Chest Width	28”	29.5”	30”	31”	32”	32.5”	-/+ 0.4”
C	Arm Length (RIB INCLUDED)	22.5”	23.5”	24”	24.5”	25”	25.5”	-/+ 0.4”
D	Cuff Width	5”	5.3”	5.6”	5.8”	6”	6.5”	-/+0.2”
E	Arm Hole	11”	11.5”	12”	12.2”	12.5”	13”	-/+ 0.2”
F	Hem Width	28.5”	29.5”	30”	31”	31.5”	32.5"	-/+ 0.4”
G	Cuff Height	2.5”	2.5”	2.5”	2.5”	2.5”	2.5”	-/+ 0.2”

CARTER-HEALTH™
DISPOSABLES

CH-1983WST-SURG



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