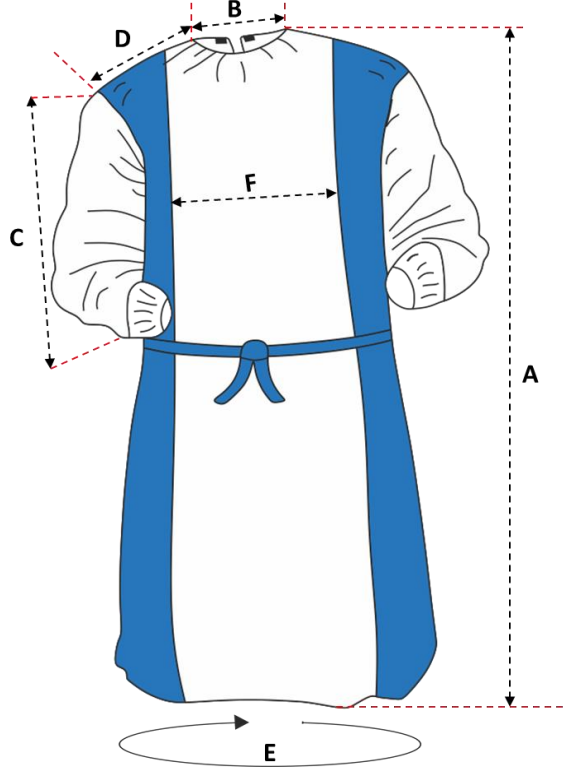


# PRODUCT SPECIFICATION SHEET

DATE	2.02.2021
DOC.NO	FR-FD-BYM-002
PAGE NO	1
REV.NO	
REV.DATE	

## PRODUCT NAME

REINFORCED SURGICAL GOWN - 43 gsm SMS - Full Ultrasonic



	S	M	L	XL	XXL	XXXL
A	125,0	125,0	130,0	135,0	140,0	145,0
B	33,0	34,0	36,0	36,0	37,0	39,0
C	57,0	58,0	59,0	60,0	63,0	65,0
D	17,5	18,0	19,5	21,0	22,5	24,0
E	142,0	146,0	155,0	160,0	167,0	170,0
F	53,0	53,0	53,0	53,0	53,0	53,0

UDI	PRODUCT NAME	SIZE	REF. CODE
8681744101615	Reinforced Surgical Gown	S	SG-01202-01
8681744101608	Reinforced Surgical Gown	M	SG-01202-02
8681744101592	Reinforced Surgical Gown	L	SG-01202-03
8681744101622	Reinforced Surgical Gown	XL	SG-01202-04
8681744101639	Reinforced Surgical Gown	XXL	SG-01202-05
8681744101646	Reinforced Surgical Gown	XXXL	SG-01202-06



BAYTEKS TEKNIK TEKSTİL SAN. VE TİC. A.Ş.

TITLE: REINFORCED SURGICAL GOWN - 43 gsm SMS - Full Ultrasonic

UNIT: cm

SIZE: A4

TOLERANCE %  $\pm 2$

Tolerances vary according to customer demand. If the customer does not have a special request, the tolerance value in the specification is accepted.

DRAWING:	DEPARTMENT	NAME / SURNAME	SIGN	DATE	DWG NO:
	PRODUCTION	A.AKAR			1
DATE:	QUALITY CONTROL	K.KARAGUN			Technical File
					1



**EKOTEKS**

**EKOTEKS LABORATUVAR ve GÖZETİM  
HİZMETLERİ A.Ş.**

Esenyurt Firuzköy Bulvarı No:29 34325 Avcılar  
İstanbul/ TÜRKİYE



Test  
TS EN ISO/IEC 17025  
AB-0583-T

**TEST REPORT**  
*DENEY RAPORU*

AB-0583-T

20035727  
-ing

10-20

**Customer name:** BAYTEKS TEKNİK TEKSTİL SAN. VE TİC. A.Ş.  
**Address:** -  
**Buyer name:** ORGANİZE SAN. MAH. 19 NOLU CAD. NO:11 MERKEZ /KİLİS  
**Contact Person:** KADİR KARAGÜN  
**Order No:** REF:SG-01222-05 LOT:50815  
**Article No:** PROTECTED SURGICAL APRON  
**Name and identity of test item:** Coated medical blue surgical gown.  
**The date of receipt of test item:** 29.09.2020  
**Re-submitted/re-confirmation date:** -  
**Date of test:** 29.09.2020-12.10.2020  
**Remarks:** -  
**Sampling:** The results given in this report belong to the received sample by vendor.  
**End-Use:** -  
**Care Label:** Not specified.  
**Number of pages of the report:** 7

*The Turkish Accreditation Agency (TÜRKAK) is signatory to the multilateral agreements of the European co-operation for the Accreditation (EA) and of the International Laboratory Accreditation (ILAC) for the Mutual recognition of test reports.*

*EKOTEKS LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş. accredited by TÜRKAK under registration number [AB-0583-T] for ISO 17025:2017 as test laboratory.*

*The test and/or measurement results, the uncertainties (if applicable) with confidence probability and test methods are given on the following pages which are part of this report.*

**Seal**

**Date**  
12.10.2020

**Customer Representative**  
Hatice ACARALP

**Head of Testing Laboratory**  
Sevim A. RAZAK  
12.10.2020

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AB-0583-T
20035727 -ing
10-20

REQUIRED TESTS	RESULT	COMMENTS
<b>PHYSICAL PROPERTIES</b>		
Tensile Strength / <b>Dry</b>	P	
Tensile Strength / <b>Wet</b>	P	
Bursting Strength / <b>Dry</b>	P	
Bursting Strength / <b>Wet</b>	P	
Water Permeability	P	
<b>MICROBIOLOGICAL TESTS</b>		
Microbial Cleanliness (Bioburden)	P	
Wet-Bacterial Penetration	P	
Dry-Bacterial Penetration	P	
P: Pass F: Fail R: Refer to retailer technologist. (1)Test results were evaluated according to EN 13795-1:2019 Standard Performance Properties Critical Sample Group limit values (Table 1)		

REMARK: Original samples are kept for 3 months and all technical records are kept for 5 years unless otherwise specified.If requested, measurement uncertainty will be reported. But unless otherwise specified, measurement uncertainty is not considered while stating compliance with specification or limit values The reported uncertainty is based on a standard uncertainty multiplied by a coverage factor k=2, providing a level of confidence of approximately 95 %. Tests marked (\*) in this report are not included in the accreditation schedule.



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## TEST RESULTS

### TENSILE STRENGTH; EN 29073-3:1996

Instron 5969 (Load: 50 kN), Strip Method.  
Speed: 100 mm/min $\pm$ 10, Gauge length 200 mm.  
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 $\pm$ 2°C-65% $\pm$ 4).

**Dry ;**

	<b><u>RESULT</u></b>	<b><u>REQUIREMENT</u></b>
<b>Weft</b>	72.5 N	$\geq$ 20N (Dry)
<b>Warp</b>	162.8 N	$\geq$ 20N (Dry)

### TENSILE STRENGTH; EN 29073-3:1996

Instron 5969 (Load: 50 kN), Strip Method.  
Speed: 100 mm/min $\pm$ 10, Gauge length 200 mm.  
Pre-load was not applied. With wetting samples.  
The average results are given for weft and warp direction of five samples  
Performed in the conditioned room (20 $\pm$ 2°C-65% $\pm$ 4).

**Wet ;**

	<b><u>RESULT</u></b>	<b><u>REQUIREMENT</u></b>
<b>Weft</b>	75.1 N	$\geq$ 20N (Wet)
<b>Warp</b>	160.1 N	$\geq$ 20N (Wet)

### BURSTING STRENGTH;; ISO 13938-1:1999

SDL ATLAS M229 tester. Test area: 30.5 mm diameter  
Rate of increase in volume; 29 cm<sup>3</sup>/min.  
The average results are given of five samples.  
Performed in the conditioned room (20 $\pm$ 2°C-65% $\pm$ 4).

	<b><u>RESULT</u></b>	<b><u>REQUIREMENT</u></b>
<b>Dry ;</b>	201.4 kPa	$\geq$ 40 kPa (Dry)
<b>Height at Burst*</b>	14.9 mm	

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10-20

## TEST RESULTS

**TEST METHOD: EN 13795-1: 2019**

**SURGICAL CLOTHING AND DRAPES –REQUIREMENTS AND TEST METHODS**

**ANNEX 1: SURGICAL CLOTHING AND DRAPES ;**

### **BURSTING STRENGTH; ISO 13938-1:1999**

SDL ATLAS M229 tester. Test area: 30.5 mm diameter

Rate of increase in volume; 45.2 cm<sup>3</sup>/min.

The average results are given of five samples.

Performed in the conditioned room (20±2°C-65%±4).

	<b><u>RESULT</u></b>	<b><u>REQUIREMENT</u></b>
<b>Wet ;</b>	190.2 kPa	≥ 40 kPa (Wet)
<b>Height at Burst*</b>	13.8 mm	

### **WATER PERMEABILITY; ISO 811:2018**

Hydrostatic Head Tester, Textest marka Fx 3000 model

Temperature of water 20°C. Pressure increase ratio 10 mbar/min.

Performed in the conditioned room (20±2°C-65%±4)

	<b><u>RESULT</u></b>	<b><u>REQUIREMENT</u></b>
<b>Sample 1</b>	147.0 cmSS	≥ 100cmSS
<b>Sample 2</b>	150.0 cmSS	
<b>Sample 3</b>	157.2 cmSS	
<b>Sample 4</b>	163.3 cmSS	
<b>Sample 5</b>	160.1 cmSS	
<b>Average</b>	158.6 cmSS	

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AB-0583-T
20035727 -ing
10-20

## TEST RESULTS

**TEST METHOD : EN 13795-1:2019**

**SURGICAL CLOTHING AND DRAPES –REQUIREMENTS AND TEST METHODS**

**ANNEX 1: SURGICAL CLOTHING AND DRAPES (\*);**

**MICROBIAL CLEANLINESS (Bioburden)**

**Test Metod:** Ref: EN ISO 11737-1:2018 (\*)

The sample is put in extraciton liquid after shaking well, inoculated on the agar.  
After incubation at  $30 \pm 1$  ° C for 72 hours, growth microorganisms are counted on the agar.

	<b><u>RESULTS</u></b>	<b><u>REQUIREMENT</u></b>
<b>Microbial cleanliness (cfu/g)</b>	32 cfu/g	$\leq 300$ cfu/g Type I and Type II mask

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20035727 -ing
10-20

## 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 placed 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 ( $3N \pm 0.02$ ). 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.

<b>Sample amount:</b>	5 pieces 25x25cm <sup>2</sup>
<b>Carrier Material:</b>	30 µm thin, 25x25cm <sup>2</sup> Polyurethane Film
<b>Coating Material:</b>	25x25cm <sup>2</sup> HDPE Film
<b>Microorganism:</b>	Staphylococcus aureus ATCC 29213
<b>Bacterial Concentration (kob / ml):</b>	2x10 <sup>4</sup> kob / ml
<b>Incubation Conditions:</b>	(36 ± 1) ° C 48 hours

RESULTS			
Number of Populating Bacteria (cfu)		Penetration Rate	
X <sub>1</sub>	0	R <sub>CUM1</sub>	0
X <sub>2</sub>	0	R <sub>CUM2</sub>	0
X <sub>3</sub>	0	R <sub>CUM3</sub>	0
X <sub>4</sub>	0	R <sub>CUM4</sub>	0
X <sub>5</sub>	0	R <sub>CUM5</sub>	0
Z	459		
T	459		
<i>X1 ..... X5: Number of colonies growing in 5 parallel petri in the same sample</i> <i>Z: number of colonies growing in the sixth petri dish</i> <i>T: X<sub>1</sub> + X<sub>2</sub> + X<sub>3</sub> + X<sub>4</sub> + X<sub>5</sub> + Z</i>			
<i>R<sub>CUM1</sub> = X1/T</i> <i>R<sub>CUM2</sub> = (X2 + X1)/T</i> <i>R<sub>CUM3</sub> = (X3 + X2 + X1)/T</i> <i>R<sub>CUM4</sub> = (X4 + X3 + X2 + X1)/T</i> <i>R<sub>CUM5</sub> = (X5 + X4 + X3 + X2 + X1)/T</i>			
BARRIER INDEX (I <sub>B</sub> )			
	Result	Expected value (*)	
I <sub>B</sub>	6	≥2,8	
<i>I<sub>B</sub> = 6 – (CUM1 + CUM2 + CUM3 + CUM4 + CUM5)</i>			
<i>* EN 13795-1:2019 Surgical gowns and drapes - Requirements and test methods are evaluated according to Table-1.</i>			

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AB-0583-T
20035727 -ing
10-20

**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  $\pm$  0.1 g are added to five samples from the powder contaminated 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 for 24 hours.

<b>Sample amount:</b>	6 pieces 20x20 cm <sup>2</sup>
<b>Mikroorganism:</b>	<i>Bacillus subtilis</i> ATCC 9372
<b>Bacterial concentration (cfu/ml):</b>	1x10 <sup>8</sup>
<b>Incubation conditions:</b>	35°C / 24 hours
<b>RESULTS</b>	
<b>Number of Populationg Bacteria (cfu)</b>	
1	1
2	2
3	1
4	3
5	2
6 (Control)	0
Total	9
Logarithm	0.95
* EN 13795-1:2019 Surgical gowns and drapes - Requirements and test methods are evaluated according to Table-1.	
<b>RESULT</b>	
<b>Result (cfu/g)</b>	<b>Expected Value</b>
9 kob/gr	$\leq 300$ kob/gr





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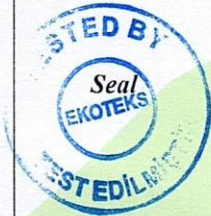
Esenyurt Firuzköy Bulvarı No:29 34325 Avcılar  
İstanbul/ TÜRKİYE

**TEST REPORT**  
*DENEY RAPORU*

21001832

01-21

**Customer name:** BAYTEKS TEKNİK TEKSTİL SAN. TİC. AŞ.  
**Address:** ORGANİZE SANAYİ BÖLGESİ 19 NO'LU CADDE NO:11  
MERKEZ/KİLİS  
**Buyer name:** -  
**Contact Person:** KADİR KARAGÜN  
**Order No:** REF:SG-01222-05/LOT:50815  
**Article No:** PROTECTED SURGICAL GOWN  
**Name and identity of test item:** Blue non-woven gown. (Claimed to be;MEDICAL BLUE)  
**The date of receipt of test item:** 18.01.2021  
**Re-submitted/re-confirmation date:** -  
**Date of test:** 18.01.2021-25.01.2021  
**Remarks:** -  
**Sampling:** The results given in this report belong to the received sample by vendor.  
**End-Use:** -  
**Care Label:** Not Specified  
**Number of pages of the report:** 3



**Date**  
25.01.2021

**Customer Representative**  
Yeşim ŞAHİN

**Head of Testing Laboratory**  
Sevim A. RAZAK  
25.01.2021

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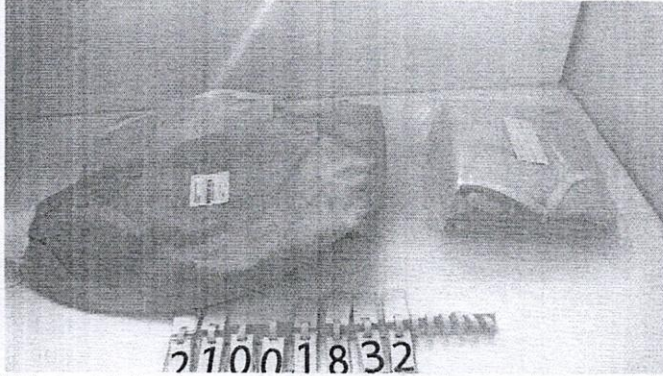
**EKOTEKS LABORATUVAR ve GÖZETİM  
HİZMETLERİ A.Ş.**

21001832

01-21

REQUIRED TESTS	RESULT	COMMENTS
<b>PHYSICAL PROPERTIES TESTS</b>		
Lint and Other Particles Generation From Nonwoven	P	
P: Pass F: Fail R: Refer to retailer technologist. Test results were evaluated according to EN 13795-1:2019 Standard Performance Properties Critical Sample Group limit values (Table 1)		

**REMARK:** Original samples are kept for 3 months and all technical records are kept for 5 years unless otherwise specified. If requested, measurement uncertainty will be reported. But unless otherwise specified, measurement uncertainty is not considered while stating compliance with specification or limit values. The reported uncertainty is based on a standard uncertainty multiplied by a coverage factor  $k=2$ , providing a level of confidence of approximately 95 %. The declaration of conformity was given in accordance with the Simple Acceptance Decision Rule. Tests marked (\*) in this report are not included in the accreditation schedule.



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Gen.fl136-2/03



## TEST RESULTS

### LINT AND OTHER PARTICLES GENERATION FROM NONWOWEN;

**Test Metod:** 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	: 23	Total linting	: 16
Standard deviation	: 4	Standard deviation	: 7
Coefficient of variation	: 18%	Coefficient of variation	: 46%
Coefficient of linting (CL)	: 1	Coefficient of linting (CL)	: 1
SAMPLE, MATERIAL (TOTAL)			
Total linting	: 39		
Coefficient of linting (CL)*	: 2		

\*According to EN ISO 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.