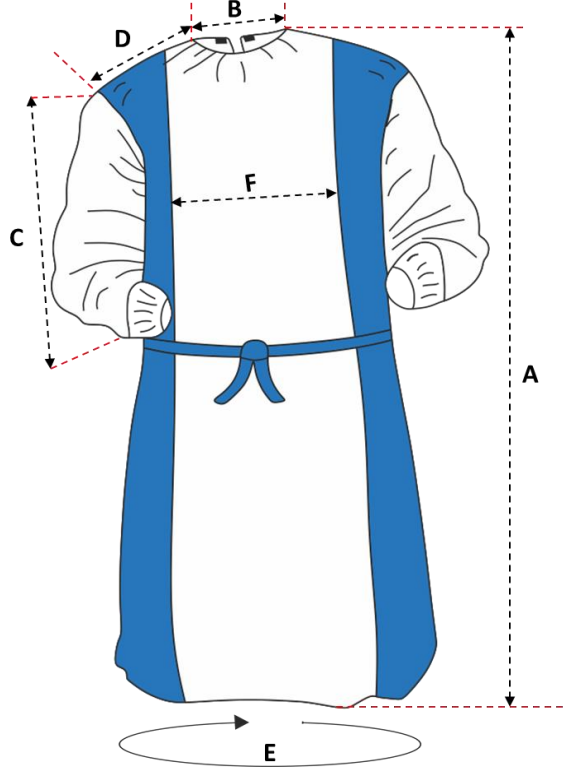


PRODUCT SPECIFICATION SHEET

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

AB-0583-T
20035727 -ing
10-20

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	
MICROBIOLOGICAL TESTS		
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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**EKOTEKS LABORATUVAR ve GÖZETİM
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20035727 -ing
10-20

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 ;

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

	<u>RESULT</u>	<u>REQUIREMENT</u>
Weft	75.1 N	\geq 20N (Wet)
Warp	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 cm³/min.
The average results are given of five samples.
Performed in the conditioned room (20 \pm 2°C-65% \pm 4).

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

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

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 ;

BURSTING STRENGTH; 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).

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

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

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

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 ± 1 ° C for 72 hours, growth microorganisms are counted on the agar.

	<u>RESULTS</u>	<u>REQUIREMENT</u>
Microbial cleanliness (cfu/g)	32 cfu/g	≤ 300 cfu/g Type I and Type II mask

**EKOTEKS LABORATUVAR ve GÖZETİM
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AB-0583-T
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.

Sample amount:	5 pieces 25x25cm2
Carrier Material:	30 µm thin, 25x25cm2 Polyurethane Film
Coating Material:	25x25cm2 HDPE Film
Microorganism:	Staphylococcus aureus ATCC 29213
Bacterial Concentration (kob / ml):	2x104 kob / ml
Incubation Conditions:	(36 ± 1) ° C 48 hours

RESULTS			
Number of Populating Bacteria (cfu)		Penetration Rate	
X ₁	0	R _{CUM1}	0
X ₂	0	R _{CUM2}	0
X ₃	0	R _{CUM3}	0
X ₄	0	R _{CUM4}	0
X ₅	0	R _{CUM5}	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: X₁ + X₂ + X₃ + X₄ + X₅ + Z</i>			
<i>R_{CUM1} = X1/T</i> <i>R_{CUM2} = (X2 + X1)/T</i> <i>R_{CUM3} = (X3 + X2 + X1)/T</i> <i>R_{CUM4} = (X4 + X3 + X2 + X1)/T</i> <i>R_{CUM5} = (X5 + X4 + X3 + X2 + X1)/T</i>			
BARRIER INDEX (I _B)			
	Result	Expected value (*)	
I _B	6	≥2,8	
I _B = 6 – (CUM1 + CUM2 + CUM3 + CUM4 + CUM5)			
* EN 13795-1:2019 Surgical gowns and drapes - Requirements and test methods are evaluated according to Table-1.			

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AB-0583-T
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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.

Sample amount:	6 pieces 20x20 cm ²
Mikroorganism:	<i>Bacillus subtilis</i> ATCC 9372
Bacterial concentration (cfu/ml):	1x10 ⁸
Incubation conditions:	35°C / 24 hours
RESULTS	
Number of Populationg Bacteria (cfu)	
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.	
RESULT	
Result (cfu/g)	Expected Value
9 kob/gr	≤300kob/gr



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

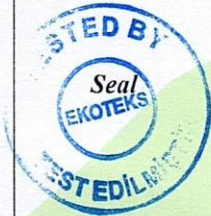
Esenyurt Firuzköy Bulvarı No:29 34325 Avcılar
İstanbul/ TÜRKİYE

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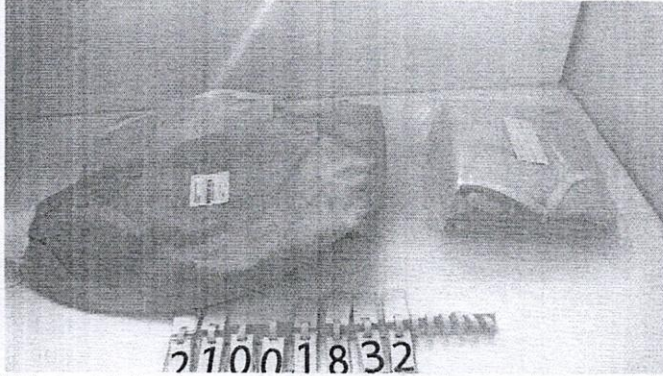
**EKOTEKS LABORATUVAR ve GÖZETİM
HİZMETLERİ A.Ş.**

21001832

01-21

REQUIRED TESTS	RESULT	COMMENTS
PHYSICAL PROPERTIES TESTS		
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.