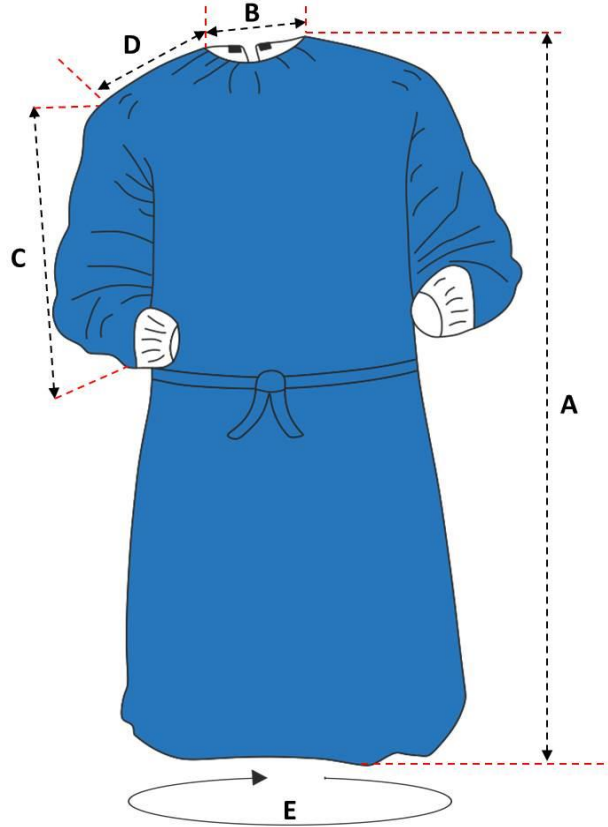


# PRODUCT SPECIFICATION SHEET

DATE	2.02.2021
DOC.NO	FR-FD-BYM-003
PAGE NO	1
REV.NO	
REV.DATE	

## PRODUCT NAME

STANDARD SURGICAL GOWN - SMS 43 gsm Sterile - 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	-	-	-	-	-	-

UDI	PRODUCT NAME	SIZE	REF. CODE
8681744101325	Standard Surgical Gown	S	SG-01201-01
8681744101318	Standard Surgical Gown	M	SG-01201-02
8681744101301	Standard Surgical Gown	L	SG-01201-03
8681744101332	Standard Surgical Gown	XL	SG-01201-04
8681744101288	Standard Surgical Gown	XXL	SG-01201-05
8681744101295	Standard Surgical Gown	XXXL	SG-01201-06



BAYTEKS TEKNIK TEKSTIL SAN. VE TIC. A.Ş.

TITLE: STANDARD SURGICAL GOWN - SMS 43 gsm Sterile - 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

AB-0583-T

21007884-  
ING

03-21

**Customer name:**

BAYTEKS TEKSTİL SAN. VE TİC. A.Ş.

**Address:**

ORGANİZE SAN.BÖLG. 19 NOLU CAD. NO:9 MERKEZ/KİLİS

**Buyer name:**

TSE GAZİANTEP BELGELENDİRME MÜDÜRLÜĞÜ/İBRAHİM AÇAR

**Contact Person:**

KADİR KARAGÜL

**Order No:**

-

**Article No:**

-

**Name and identity of test item:**

Blue non-woven surgical gown

**The date of receipt of test item:**

01.03.2021

**Re-submitted/re-confirmation  
date:**

-

**Date of test:**

01.03.2021-11.03.2021

**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:** 6

*The Turkish Accreditation Agency (TURKAK) 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**  
11.03.2021

**Customer Representative**  
Zahide TAPAN

**Head of Testing Laboratory**  
Sevim A. RAZAK  
11.03.2021

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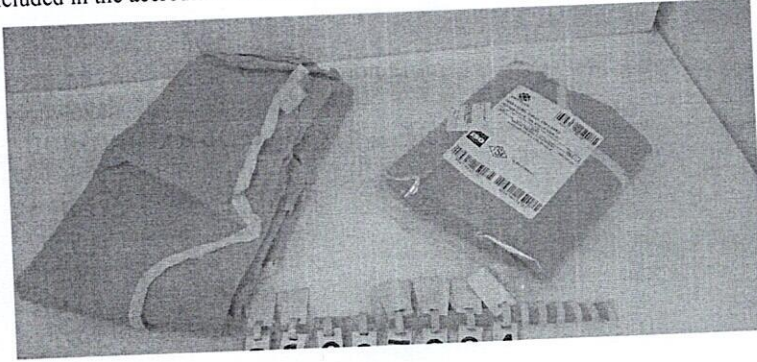
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REQUIRED TESTS	RESULT	COMMENTS
<b>PHYSICAL PROPERTIES</b>		
Water Permeability	P	
Lint and Other Particles Generation From Nonwoven	P	
<b>MICROBIOLOGICAL TESTS</b>		
Wet- Bacterial Penetration	P	
Dry-Bacterial Penetration	P	
Microbial Cleanliness (Bioburden)	P	
P: Pass F: Fail R: Refer to retailer technologist. Test results were evaluated according to EN 13795-1:2019 Standard Performance Properties limit values		

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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**TEST RESULTS**

**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)

**RESULT**

Sample 1  
Sample 2  
Sample 3  
Sample 4  
Sample 5

54,1 cm H<sub>2</sub>O  
56,2 cm H<sub>2</sub>O  
53,7 cm H<sub>2</sub>O  
63,7 cm H<sub>2</sub>O  
60,1 cm H<sub>2</sub>O

Average

57,5 cm H<sub>2</sub>O

**REQUIREMENT**

≥ 20 cm H<sub>2</sub>O

**MICROBIAL CLEANLINESS (Bioburden)**

**Test Metod:** Ref: EN ISO 11737-1:2018 /TS 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.

	<b><u>RESULTS</u></b>	<b><u>REQUIREMENT</u></b>
Microbial cleanliness (cfu/ 100 cm <sup>2</sup> )	14 cfu/100 cm <sup>2</sup>	≤300 cfu/100 cm <sup>2</sup>

\*cfu= Colony forming unit.



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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 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>	$5 \times 10^3$ kob / ml
<b>Incubation Conditions:</b>	( $36 \pm 1$ ) °C 48 hours

RESULTS			
Number of Populating Bacteria (cfu)		Penetration Rate	
X <sub>1</sub>	45	R <sub>CUM1</sub>	0,04
X <sub>2</sub>	59	R <sub>CUM2</sub>	0,09
X <sub>3</sub>	93	R <sub>CUM3</sub>	0,17
X <sub>4</sub>	124	R <sub>CUM4</sub>	0,28
X <sub>5</sub>	135	R <sub>CUM5</sub>	0,40
Z	659		
T		1115	
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: X <sub>1</sub> + X <sub>2</sub> + X <sub>3</sub> + X <sub>4</sub> + X <sub>5</sub> + Z			
R <sub>CUM1</sub> = X <sub>1</sub> /T			
R <sub>CUM2</sub> = (X <sub>2</sub> + X <sub>1</sub> )/T			
R <sub>CUM3</sub> = (X <sub>3</sub> + X <sub>2</sub> + X <sub>1</sub> )/T			
R <sub>CUM4</sub> = (X <sub>4</sub> + X <sub>3</sub> + X <sub>2</sub> + X <sub>1</sub> )/T			
R <sub>CUM5</sub> = (X <sub>5</sub> + X <sub>4</sub> + X <sub>3</sub> + X <sub>2</sub> + X <sub>1</sub> )/T			
BARRIER INDEX (I <sub>B</sub> )			Expected value
	Result		≥2,8
I <sub>B</sub>	4,99		
I <sub>B</sub> = 6 - (CUM1 + CUM2 + CUM3 + CUM4 + CUM5)			



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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  $0.5 \text{ g} \pm 0.1 \text{ g}$  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  $35^\circ \text{C}$  for 24 hours.

Sample amount:	6 pieces 20x20 cm <sup>2</sup>
Mikroorganism:	<i>Bacillus subtilis</i> ATCC 9372
Bacterial concentration (cfu/ml):	$1 \times 10^8$
Incubation conditions:	$35^\circ \text{C}$ / 24 hours
<b>RESULTS</b>	
<b>Number of Populationg Bacteria (cfu)</b>	
1	0
2	0
3	0
4	0
5	0
6 (Control)	0
Total	-
Logarithm	
* EN 13795-1:2019 Surgical gowns and drapes - Requirements and test methods are evaluated according to Table-1.	
<b>RESULT</b>	
Result (cfu/g)	Expected Value
0 cfu/g	$\leq 300 \text{ cfu/g}$



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## 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	:8	Total linting	:44
Standard deviation	: 5	Standard deviation	:35
Coefficient of variation	: 62%	Coefficient of variation	: 81%
Coefficient of linting (CL):1		Coefficient of linting (CL)	: 2
SAMPLE, MATERIAL (TOTAL)			
Total linting	51		
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.