



**EKOTEKS LABORATUVAR ve GÖZETİM  
HİZMETLERİ A.Ş.**  
Esenyurt Firuzköy Bulvarı No:29 34325 Avcılar  
İstanbul/ TÜRKİYE



**TEST REPORT**  
DENEY RAPORU

AB-0583-T
21031671-ing
11-21

**Customer name:**

BİOTEX MEDİKAL TEKSTİL İTHALAT İHRACAT SANAYİ VE TİCARET A.Ş.

**Address:**

MERKEZ:İSLAMPAŞA MAH. 2.NOLU ŞEHİTLER CAD. NO:41/G  
MERKEZ/RİZE  
FABRİKA:AKSU OSB.MAH. 3 NOLU CAD.NO:14 KALKANDERE /RİZE

**Buyer name:**

-

**Contact Person:**

-

**Order No:**

-

**Article No:**

RMD-326

**Name and identity of test item:**

Blue non-woven fabric.(Claimed to be; General Surgical cover set ,Lot  
no:CN559;BLUE)

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

22.10.2021

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

-

**Date of test:**

22.10.2021-04.11.2021

**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:**

8

*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  
04.11.2021

Customer Representative  
Servin YUKSEVEN

Head of Testing Laboratory  
Sevim A. RAZAK  
04.11.2021

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REQUIRED TESTS	EVALUATION	COMMENTS
<b>MICROBIOLOGICAL TEST</b>		
Microbial Cleanliness (Bioburden)	P	
Resistance to Microbial Penetration-Wet Method	P	
Resistance to Microbial Penetration-Dry Method	P	
<b>PHYSICAL PROPERTIES TESTS</b>		
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 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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## TEST RESULTS

### MICROBIAL CLEANLINESS (Bioburden) ; EN ISO 11737-1:2018

The sample is put in extraciton liquid after shaking well after shaking well (250 rpm,5 min), inoculated on the suitable agar.The plates are incubated for 3 days at  $30 \pm 1$  ° C for 72 hours, and 7 days at (20 to 25) °C for TSA and SDA plates respectively. Total microoragnisms counts are calculated.

	<b>RESULTS</b>	<b>REQUIREMENT</b>
<b>Microbial cleanliness (cfu/100 cm<sup>2</sup>)</b>	57 cfu/100 cm <sup>2</sup>	≤300 cfu/100 cm <sup>2</sup>

\*cfu= Colony forming unit.

Gen.fl136-2/03

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**TEST RESULTS**

**RESISTANCE TO BACTERIAL PENETRATION-WET METHOD ;  
BS EN ISO 22610: 2006**

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 25x25cm2
<b>Carrier Material:</b>	30 µm thin, 25x25cm2 Polyurethane Film
<b>Coating Material:</b>	25x25cm2 HDPE Film
<b>Microorganism:</b>	Staphylococcus aureus ATCC 29213
<b>Bacterial Concentration (kob / ml):</b>	$5 \times 10^5$ kob / ml
<b>Incubation Conditions:</b>	( $36 \pm 1$ ) ° 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	650		
T			650

X<sub>1</sub> ..... X<sub>5</sub>: 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

$$R_{CUM1} = X_1/T$$

$$R_{CUM2} = (X_2 + X_1)/T$$

$$R_{CUM3} = (X_3 + X_2 + X_1)/T$$

$$R_{CUM4} = (X_4 + X_3 + X_2 + X_1)/T$$

$$R_{CUM5} = (X_5 + X_4 + X_3 + X_2 + X_1)/T$$

**BARRIER INDEX (I<sub>B</sub>)**

	Result	Expected value (*)
I <sub>B</sub>	6	≥2,8

$$I_B = 6 - (CUM1 + CUM2 + CUM3 + CUM4 + CUM5)$$

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## TEST RESULTS

### RESISTANCE TO MICROBIAL PENETRATION-DRY METHOD; ISO 22612:2005

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):	$1 \times 10^8$ kob/ml
Incubation conditions:	$35^\circ \text{C}$ / 24 hours
<b>RESULTS</b>	
<b>Number of Populating Bacteria (cfu)</b>	
1	0
2	0
3	0
4	0
5	0
6 (Control)	0
Total	0
Logarithm	-
<b>RESULT</b>	
Result (cfu/g)	Expected Value
0 cfu/g	$\leq 300$ cfu/g

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## TEST RESULTS

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

Instron 5969 (Load: 5 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 width and length direction of three samples  
Performed in the conditioned room (20 $\pm$ 2°C-65% $\pm$ 4).

Dry ;

	<u>RESULT</u>	<u>REQUIREMENT</u>
Width	54.3 N	$\geq$ 20N (Dry)
Length	97.5 N	$\geq$ 20N (Dry)

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

Instron 5969 (Load: 5 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 width and length direction of three samples  
Performed in the conditioned room (20 $\pm$ 2°C-65% $\pm$ 4).

Wet;

	<u>RESULT</u>	<u>REQUIREMENT</u>
Width	57.9 N	$\geq$ 20N (Wet)
Length	104.8 N	$\geq$ 20N (Wet)

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

SDL ATLAS M229 tester. Test area: 30.5 mm diameter  
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 ;	169.6 kPa	$\geq$ 40 kPa (Dry)
Height at Burst*	18.5 mm	

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## TEST RESULTS

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

SDL ATLAS M229 tester. Test area: 30.5 mm diameter  
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 ;	156.7 kPa	≥ 40 kPa (Wet)
Height at Burst*	19.0 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	174.4 cm H <sub>2</sub> O	≥ 20 cm H <sub>2</sub> O
Sample 2	192.8 cm H <sub>2</sub> O	
Sample 3	184.6 cm H <sub>2</sub> O	
Sample 4	189.7 cm H <sub>2</sub> O	
Sample 5	182.6 cm H <sub>2</sub> O	
Average	184.8 cm H <sub>2</sub> O	

## TEST RESULTS

### LINT AND OTHER PARTICLES GENERATION FROM NONWOWEN; ISO 9073-10: 2003

5 samples in longitudinal direction (separate for inner and outer surface) are tested. The samples are placed in the Gelbo Flex device, which makes twisting and compression movements, in a clean room in Class 5 category according to ISO 14644-1. Lint and particles detached from the sample are counted with counter device and classified to size range.

SOLAIR 3100 particles measuring device

Min. measuring size: 0,3 µm,

Maks. measuring size: 25 µm

Air Flow: : 28,3 ± 1,4 L/dk

Working mode: 30 sec x 10 consecutive periods

<u>SAMPLE (INNER SURFACE)</u>		<u>SAMPLE (OUTER SURFACE)</u>	
Total linting :	155	Total linting :	143
Standard deviation :	21	Standard deviation :	55
Coefficient of variation :	%14	Coefficient of variation :	%38
Coefficient of linting (CL):	2	Coefficient of linting (CL):	2
<u>SAMPLE (TOTAL)</u>			
Total linting :	298		
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.