



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

TEST REPORT
DENEY RAPORU

20016085-
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06-20

Customer name: TOTAL İTHALAT VE İHRACAT PAZARLAMA LTD. ŞTİ.
Address: ÇALI SANAYİ SİTESİ BÖL. EFLATUN CAD. NO:18 NİLÜFER/ BURSA
Buyer name: -
Contact Person: TUNCA BİLGİÇ
Order No: -
Article No: -
Name and identity of test item: One sample of blue drape.
The date of receipt of test item: 21.05.2020
Re-submitted/re-confirmation date: -
Date of test: 21.05.2020-01.06.2020
Remarks: -
Sampling: The results given in this report belong to the received sample by vendor.
End-Use: -
Care Label: -
Number of pages of the report: 6



Date
01.06.2020

Customer Representative
Zuhide TAPAN

Head of Testing Laboratory
Sevim A. RAZAK

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REQUIRED TESTS	RESULT	COMMENTS
MICROBIOLOGICAL TEST		
Microbial Cleanliness (Bioburden)	P	
Wet-Bacterial Penetration	P	
PHYSICAL PROPERTIES TESTS		
Tensile Strength / Dry	P	
Tensile Strength / Wet	P	
Bursting Strength / Dry	P	
Bursting Strength / Wet	P	
Water Permeability	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 %. Tests marked (*) in this report are not included in the accreditation schedule.



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TEST RESULTS

TEST METHOD : EN 13795-1:2019

SURGICAL CLOTHING AND DROAPES –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 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/100 cm ²)	109 cfu/100 cm ²	≤300 cfu/100 cm ²

*cfu= Colony forming unit.

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TEST RESULTS

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 determining the 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 over the entire surface of the agar on the test specimen within 15 minutes. 5 studies are carried out for 15 minutes. 6. The study is repeated by inverting the sample.

Sample amount:	5 adet 25x25cm ²
Carrier Material:	30 µm inceliğinde , 25x25cm ² Poliüretan Film
Carrier Material:	25x25cm ² HDPE Film
Microorganism:	Staphylococcus aureus ATCC 29213
Bacteria Concentration (kob / ml):	1-4x10 ⁴ kob/ml
Incubation Conditions:	(36±1)°C 48 saat

RESULTS

Number of Populating Bacteria (cfu)		Population Rate	
X ₁	0	R _{CUM1}	0
X ₂	0	R _{CUM2}	0
X ₃	0	R _{CUM3}	0
X ₄	260	R _{CUM4}	0,27
X ₅	230	R _{CUM5}	0,51
Z	461		
T			951

X₁ X₅: Number of colonies grown in 5 parallel petri in the same sample

Z : number of colonies growing in sixth petri

T: X₁ + X₂ + X₃ + X₄ + X₅ + Z

R_{CUM1} = X₁/T

R_{CUM2} = (X₂ + X₁)/T

R_{CUM3} = (X₃ + X₂ + X₁)/T

R_{CUM4} = (X₄ + X₃ + X₂ + X₁)/T

R_{CUM5} = (X₅ + X₄ + X₃ + X₂ + X₁)/T

BARRIER INDEX (IB)

	Result	Requirement(*)
I _B	5,2	≥2,8

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

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

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TEST METHOD : EN 13795-1:2019

SURGICAL CLOTHING AND DRAPES –REQUIREMENTS AND TEST METHODS

ANNEX 1: SURGICAL CLOTHING AND DRAPES (*);

TENSILE STRENGTH; EN 29073-3:1996 (*)

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

Dry ;

	<u>RESULT</u>	<u>REQUIREMENT</u>
Weft	58.3 N	≥ 20N (Dry)
Warp	121.6 N	≥ 20N (Dry)

TENSILE STRENGTH; EN 29073-3:1996 (*)

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

Wet ;

	<u>RESULT</u>	<u>REQUIREMENT</u>
Weft	55.9 N	≥ 20N (Wet)
Warp	137.4 N	≥ 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±2°C-65%±4).

	<u>RESULT</u>	<u>REQUIREMENT</u>
Dry ;	148.0 kPa	≥ 40 kPa (Dry)
Height at Burst*	15.4 mm	

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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

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 ;	148.3 kPa	≥ 40 kPa (Wet)
Height at Burst*	16.1 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	47.9 cmSS	≥ 20cmSS
Sample 2	48.4 cmSS	
Sample 3	53.5 cmSS	
Sample 4	49.5 cmSS	
Sample 5	27.5 cmSS	
Average	45.4 cmSS	