

Esenyurt Firuzköy Bulvarı No:29 34325 Avcılar İstanbul/ TÜRKİYE



EKOTEKS

TEST REPORT DENEY RAPORU

AB-0583-T 21011182ing 04-21

NURTEKS TEKSTİL VE MEDİKAL SAN. DŞ. TİC. A.Ş.

Customer name:

Veliköy OSB Mah. 9. Cad. No:35/1 ÇERKEZKÖY-TEKİRDAĞ

Buyer name:

Address:

Contact Person:

DİLEK SARICA

Order No:

Article No:

CHEMICAL BONDED POLYETHYLENE LAMINATED VISCOSE NONWOVEN

FABRIC

31.03.2021

LOT NO: LOT NO: 210310736B264

Name and identity of test item:

Blue non-woven surgical fabric.

The date of receipt of test item:

Re-submitted/re-confirmation

date:

Date of test:

31.03.2021-12.04.2021

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:

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 EKCHEKS

Date 12.04.2021 Customer Representative

Head of Testing Laboratory Sevim A. RAZAK

12.04.2021

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AB-0583-T 21011182ing 04-21

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	
Lint and Other Particles Generation From Nonwoven	P	
MICROBIOLOGICAL TESTS		
Wet-Bacterial Penetration	P	
Microbial Cleanliness (Bioburden)	P	H 122

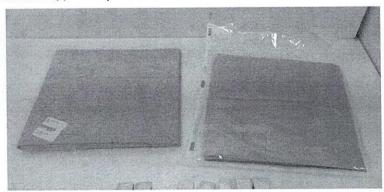
P: Pass

F: Fail

R: Refer to retailer technologist.

Test results were evaluated according to EN 13795-1:2019(*) High Performance Properties Critical 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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AB-0583-T 21011182ing 04-21

TEST RESULTS

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 five samples

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

Critical area

Dry;

	RESULT	REQUIREMENT
Weft	33,1 N	≥ 20N (Dry)
Warp	108,5 N	≥ 20N (Dry)

TENSILE STRENGTH; EN 29073-3:1996

Instron 5969 (Load: 50 kN), Strip Method.
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Performed in the conditioned room (20±2°C-65%±4).

Critical area

Wet ;

	RESULT	REQUIREMENT
Weft	62,0 N	\geq 20N (Wet)
Warp	139,2 N	≥ 20N (Wet)

*Test conditions are detailed as following upon customer request.

Gauge Size (Front)	25 mm x75 mm	
Gauge Size (Back)	25 mm x75 mm	
Sample Size	300 mm x 50 mm	

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±2°C-65%±4).

Critical area

	RESULT	REQUIREMENT
Dry;	155,8 kPa	≥ 40 kPa (Dry)
Height at Burst*	15.1 mm	

AB-0583-T 21011182ing 04-21

TEST RESULTS

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).
Critical area

Wet; <u>R</u>1

RESULT 111,9 kPa REQUIREMENT

≥ 40 kPa (Wet)

Height at Burst*

20,6 mm

^{*} Test conditions are detailed as following upon customer request.

Gauge length	50 mm	
Speed	100 mm/dk	
Gauge Size (Front)	25 mm x75 mm	
Gauge Size (Back)	25 mm x75 mm	
Sample Size	300 mm x 50 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) Critical area

	RESULT	REQUIREMENT
Sample 1	143,8 cmH ₂ O	$\geq 100 \text{ cmH}_2\text{O}$
Sample 2	161,2 cmH ₂ O	 _
Sample 3	174,4 cmH ₂ O	
Sample 4	147,9 cmH ₂ O	
Sample 5	166,3 cmH ₂ O	
Average	158,7 cmH ₂ O	

AB-0583-T 21011182ing 04-21

TEST RESULTS

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.

Critical area

	RESULTS	REQUIREMENT
ficrobial cleanliness (cfu/ 100 cm²)	3 cfu/100 cm ²	≤300 cfu/100 cm²

^{*}cfu= Colony forming unit.

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: $0.3 \mu m$, Maks. measuring size: $25 \mu m$ Air Flow: : $28.3 \pm 1.4 L/dk$

Working mode: 30 sec x 10 consecutive periods

SAMPLE (INNER SURI	FACE)	SAMPLE (OUTER SU	RFACE)
<u>Total linting</u> :	41	Total linting:	53
Standard deviation:	24	Standard deviation:	34
Coefficient of variation:	59%	Coefficient of variation:	64
Coefficient of linting (CL):	2	Coefficient of linting (CL):	2
	NUMU	NE (TOPLAM)	
<u>Total linting</u> :	95		
efficient 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.

AB-0583-T 21011182ing 04-21

TEST RESULT

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.

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):	1-4x104 kob / ml	
Incubation Conditions:	(36 ± 1) ° C 48 hours	

	RESU	LTS	
Number of Populating	Bacteria (cfu)	Penetratio	on Rate
\mathbf{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	710		All and a second
T	_ , , , , , , , , , , , , , , , , , , ,	710	

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:
$$X_1 + X_2 + X_3 + X_4 + X_5 + Z$$

 $R_{CUM1} = X_1/T$

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

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

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

 $R_{\text{CUM5}} = (X5 + X_4 + X_3 + X_2 + X_1)/T$

BARRIER INDEX (I_B)		
	Result	Expected value
I _B	6,0	≥6,0

*Test conditions are detailed as following upon customer request.

Agar Length	200 mm x 200 mm	
Carrier Material	Gestalt Ins	
Microorganism suspension	5x10 ³ kob/ml	