



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



TEST REPORT
DENEY RAPORU

AB-0583-T

21016193

05-21

Customer name: BRBEN TEKSTİL SAN. VE TİC. A.Ş.
Address: 2. ORG. SANAYİ BÖLG. 83207 n1 Cad. No:2/10 ŞEHİTKAMİL/
GAZİANTEP
Buyer name: -
Contact Person: ADEM ALTAN
Order No: -
Article No: BRTLM 003
Name and identity of test item: Blue non-woven disposable coverall.
The date of receipt of test item: 20.05.2021
Re-submitted/re-confirmation date: -
Date of test: 20.05.2021-31.05.2021
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: 7

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.

Date
31.05.2021

Customer Representative
Özlem ULUS

Head of Testing Laboratory
Sevim A. RAZAK
31.05.2021

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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		
Microbial Cleanliness (Bioburden)	P	
Wet-Bacterial Penetration	P	
Dry-Bacterial Penetration	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

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	44,8 N	\geq 20N (Dry)
Warp	93,7 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	47,1 N	\geq 20N (Wet)
Warp	87,3 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 ;	85,9 kPa	\geq 40 kPa (Dry)
Height at Burst*	20,2 mm	

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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).

	<u>RESULT</u>
Wet ;	64,8 kPa
Height at Burst*	21,4 mm

REQUIREMENT

≥ 40 kPa (Wet)

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>
Sample 1	32,6 cmH ₂ O
Sample 2	35,2 cmH ₂ O
Sample 3	33,5 cmH ₂ O
Sample 4	33,7 cmH ₂ O
Sample 5	35,5 cmH ₂ O
Average	34,2 cmH ₂ O

REQUIREMENT

≥ 20 cmH₂O

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TEST RESULT

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>	
<u>Total linting :</u>	63	<u>Total linting :</u>	22
<u>Standard deviation :</u>	50	<u>Standard deviation :</u>	3
<u>Coefficient of variation :</u>	%80	<u>Coefficient of variation :</u>	%12
<u>Coefficient of linting (CL):</u>	2	<u>Coefficient of linting (CL):</u>	1
<u>NUMUNE (TOPLAM)</u>			
<u>Total linting :</u>		85	
<u>Coefficient of linting (CL)*</u>		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.

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/100cm²)	3 cfu/100cm ²	≤ 300 cfu/100cm ²

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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.

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

RESULTS			
Number of Populating Bacteria (cfu)		Penetration Rate	
X ₁	214	RCUM1	0,11
X ₂	236	RCUM2	0,25
X ₃	258	RCUM3	0,39
X ₄	269	RCUM4	0,54
X ₅	275	RCUM5	0,69
Z	538		
T			1790

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: X₁ + X₂ + X₃ + X₄ + X₅ + Z

RCUM1 = X₁/T
RCUM2 = (X₂ + X₁)/T
RCUM3 = (X₃ + X₂ + X₁)/T
RCUM4 = (X₄ + X₃ + X₂ + X₁)/T
RCUM5 = (X₅ + X₄ + X₃ + X₂ + X₁)/T

BARRIER INDEX (I _B)		
	Result	Expected value (*)
I _B	3,98	≥2,8

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

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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°C for 24 hours.

Sample amount:	6 pieces $20 \times 20 \text{ cm}^2$
Mikroorganism:	<i>Bacillus subtilis</i> ATCC 9372
Bacterial concentration (cfu/ml):	$1-4 \times 10^4 \text{ kob/ml}$
Incubation conditions:	$35^\circ \text{C} / 24 \text{ hours}$

RESULTS

Number of Populating Bacteria (cfu)

1	0
2	0
3	0
4	0
5	0
6 (Control)	0
Total	0
Logarithm	-

RESULT

Result (cfu/g)
0

Expected Value
 $\leq 300 \text{ cfu/gr}$