



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



TEST REPORT
DENEY RAPORU

| |
|------------------|
| AB-0583-T |
| 21011183- ing |
| 04-21 |

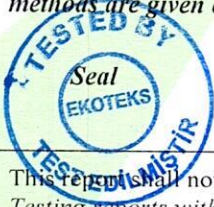
Customer name: NURTEKS TEKSTİL VE MEDİKAL SAN. DŞ. TİC. A.Ş.
Address: Veliköy OSB Mah. 9. Cad. No:35/1 ÇERKEZKÖY-TEKİRDAĞ
Buyer name: -
Contact Person: DİLEK SARICA
Order No: -
Article No: SATERILE DISPOSABLE SURGICAL REINFORCED GOWN
LOT NO: 2103107327B19
Name and identity of test item: Blue non-woven surgical gown.
The date of receipt of test item: 31.03.2021
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: 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
12.04.2021

Customer Representative
Tuğba AKTAS

Head of Testing Laboratory
Sevim A. RAZAK
12.04.2021

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Testing reports without signature and seal are not valid.*

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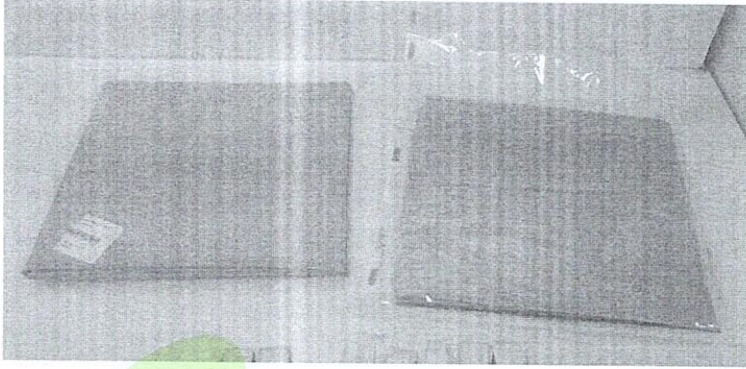
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| REQUIRED TESTS | RESULT | COMMENTS |
|---|--------|----------|
| PHYSICAL PROPERTIES | | |
| Tensile Strength / Dry | P | |
| Tensile Strength / Wet | P | |
| Bursting Strength / Dry | P | |
| Bursting Strength / Wet | P | |
| Water Permeability | P | |
| Lint and Other Particles Generation From Nonwoven | P | |
| Tear Strength ⁽¹⁾ | - | |
| MICROBIOLOGICAL TESTS | | |
| Wet-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(*) High Performance Properties Critical limit values (1)No requirement was given by vendor. | | |

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

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 ;

| | <u>RESULT</u> | <u>REQUIREMENT</u> |
|------|---------------|--------------------|
| Weft | 69,6 N | ≥ 20N (Dry) |
| Warp | 159,6 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. 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

Wet ;

| | <u>RESULT</u> | <u>REQUIREMENT</u> |
|------|---------------|--------------------|
| Weft | 74,6 N | ≥ 20N (Wet) |
| Warp | 160,2 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

| | <u>RESULT</u> | <u>REQUIREMENT</u> |
|------------------|---------------|--------------------|
| Dry ; | 240,9 kPa | ≥ 40 kPa (Dry) |
| Height at Burst* | 19,5 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).

Critical area

| | <u>RESULT</u> | <u>REQUIREMENT</u> |
|------------------|---------------|--------------------|
| Wet ; | 225,5 kPa | ≥ 40 kPa (Wet) |
| Height at Burst* | 21,0 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

| | <u>RESULT</u> | <u>REQUIREMENT</u> |
|----------|--------------------------|--------------------------|
| Sample 1 | 192,8 cmH ₂ O | ≥ 100 cmH ₂ O |
| Sample 2 | 185,6 cmH ₂ O | |
| Sample 3 | 183,6 cmH ₂ O | |
| Sample 4 | 190,7 cmH ₂ O | |
| Sample 5 | 180,5 cmH ₂ O | |
| Average | 186,6 cmH ₂ O | |

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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 |
|--|---------------------------|------------------------------|
| Microbial cleanliness (cfu/ 100 cm²) | 8 cfu/100 cm ² | ≤300 cfu/100 cm ² |

*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 µm,

Maks. measuring size: 25 µm

Air Flow: : 28,3 ± 1,4 L/dk

Working mode: 30 sec x 10 consecutive periods

| SAMPLE (INNER SURFACE) | | SAMPLE (OUTER SURFACE) | |
|-------------------------------------|-----|-------------------------------------|-----|
| <u>Total linting :</u> | 12 | <u>Total linting :</u> | 14 |
| <u>Standard deviation :</u> | 11 | <u>Standard deviation :</u> | 6 |
| <u>Coefficient of variation :</u> | 90% | <u>Coefficient of variation :</u> | %45 |
| <u>Coefficient of linting (CL):</u> | 1 | <u>Coefficient of linting (CL):</u> | 1 |
| NUMUNE (TOPLAM) | | | |
| <u>Total linting :</u> | 26 | | |
| <u>Coefficient of linting (CL)*</u> | 1 | | |

* 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.

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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 25x25cm ² |
| Carrier Material: | 30 µm thin, 25x25cm ² Polyurethane Film |
| Coating Material: | 25x25cm ² HDPE Film |
| Microorganism: | Staphylococcus aureus ATCC 29213 |
| Bacterial Concentration (kob / ml): | 1-4x10 ⁴ kob / ml |
| Incubation Conditions: | (36 ± 1) ° C 48 hours |

| RESULTS | | | |
|-------------------------------------|-----|------------------|-----|
| Number of Populating Bacteria (cfu) | | Penetration Rate | |
| X ₁ | 0 | RCUM1 | 0 |
| X ₂ | 0 | RCUM2 | 0 |
| X ₃ | 0 | RCUM3 | 0 |
| X ₄ | 0 | RCUM4 | 0 |
| X ₅ | 0 | RCUM5 | 0 |
| Z | 621 | | |
| T | | | 621 |

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 | 6,0 | ≥6,0 |

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

*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 |

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TEST RESULT

TRAPEZOIDAL TEAR STRENGTH

Clause: 4.7. Trapezoidal Tear Resistance TS EN ISO 9073-4:2002

Instron 5969 Speed:100±10 mm/min, Gauge length:5cm

The average results are given for width and length direction of five samples.

2 pre-tension applied

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

| | <u>RESULT</u> | <u>CLASS</u> |
|--------|---------------|--------------|
| Width | 28,9 N | - |
| Length | 61,9 N | - |