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

Test
TS EN ISO/IEC 17025
AB-0583-T

# TEST REPORT
*DENEY RAPORU*

| |
|---|
| AB-0583-T |
| 21016934-ing-RER |
| 07-21 |

| | |
|---|---|
| ***Customer name:*** | DEXXON ENERJI SANAYI VE TİCARET A.Ş. |
| ***Address:*** | Vizyon Park, Yenibosna Merkez Mah. 29 Ekim Cad. 1. Plaza, D:No:3/84, 34180 Bahçelievler/ İSTANBUL |
| ***Buyer name:*** | - |
| ***Contact Person:*** | HULUSİ GÜVEN/ MURAT KOÇ |
| ***Order No:*** | DEXXON 20210525-DSGB |
| ***Article No:*** | SMMS DISPOSABLE NON-STERILE SURGICAL GOWN MODEL NO:DXNMD-DSSG-SMMS08 / SMMS DISPOSABLE STERILE SURGICAL GOWN MODEL NO: DXNMD-DSSG-SMMS05 / SMMS DISPOSABLE NON-STERILE SURGICAL SCRUB SUITS MODEL NO:DXNMD-DNSSS17 |
| ***Name and identity of test item:*** | Blue non-woven gown.( Claimed to be; Blue, DISPOSABLE SURGICAL GOWN AND SURGICAL SCRUB SUITS) |
| ***The date of receipt of test item:*** | 26.05.2021 |
| ***Re-submitted/re-confirmation date:*** | - |
| ***Date of test:*** | 25.05.2021-03.06.2021 |
| ***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.***

| ***Seal*** | ***Date*** | ***Customer Representative*** | ***Head of Testing Laboratory*** |
|---|---|---|---|
| TESTED BY EKOTEKS TEST REPORT | 27.07.2021 | Özlem ULUS | Sevim A. RAZAK 27.07.2021 |



Gen.f136-2/03

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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 | |
| Water Permeability/AATCC 127[(1)] | P | Level 2 |
| Water Penetration-/AATCC 42[(1)] | P | Level 2 |
| **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)
[(1)]Evaluation was performed according to the AAMIPB70 guidelines.

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.


Note: The report issued on 03.06.2021 with the report number 21016934-ing was withdrawn and replaced with the report 210169334-ing-RER issued on 27.07.2021 due to vendor's required to change Article No and Name and identity of test item parts.

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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).
**Dry ;**

| | RESULT | REQUIREMENT |
|---|---|---|
| **Weft** | 53,4 N | ≥ 20N (Dry) |
| **Warp** | 82,9 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 five samples
Performed in the conditioned room (20±2°C-65%±4).
**Wet ;**

| | RESULT | REQUIREMENT |
|---|---|---|
| **Weft** | 51,5 N | ≥ 20N (Wet) |
| **Warp** | 82,7 N | ≥ 20N (Wet) |

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

SDL ATLAS M229 tester. Test area: 30.5 mm diameter
Rate of increase in volume; 29 $cm^3$/min.
The average results are given of five samples.
Performed in the conditioned room (20±2°C-65%±4).

| | RESULT | REQUIREMENT |
|---|---|---|
| **Dry ;** | 129 kPa | ≥ 40 kPa (Dry) |
| **Height at Burst*** | 17,3 mm | |

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

SDL ATLAS M229 tester. Test area: 30.5 mm diameter
Rate of increase in volume; 45.2 $cm^3$/min.
The average results are given of five samples.
Performed in the conditioned room (20±2°C-65%±4).

| | RESULT | REQUIREMENT |
|---|---|---|
| **Wet ;** | 142,4 kPa | ≥ 40 kPa (Wet) |
| **Height at Burst*** | 15,7 mm | |

## TEST RESULTS

### 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)

| | RESULT | REQUIREMENT |
| --- | --- | --- |
| **Sample 1** | 34,0 $cmH_2O$ | ≥ 20 $cmH_2O$ |
| **Sample 2** | 32,6 $cmH_2O$ | |
| **Sample 3** | 24,3 $cmH_2O$ | |
| **Sample 4** | 30,5 $cmH_2O$ | |
| **Sample 5** | 32,9 $cmH_2O$ | |
| **Average** | 30,9 $cmH_2O$ | |

### WATER PERMEABILITY; AATCC 127:2017-OPTION 2

Hydrostatic Head Tester, Textest marka Fx 3000 model
Temperature of water 20°C. Pressure increase ratio 10 mbar/dk.
Performed in the conditioned room (21±2°C-65%±5)

| | RESULT | REQUIREMENT |
| --- | --- | --- |
| Sample 1 | 36,8 $cmH_2O$ | ≥ 20 $cmH_2O$ |
| Sample 2 | 36,4 $cmH_2O$ | (Level 2) |
| Sample 3 | 34,0 $cmH_2O$ | |
| Average | 35,8 $cmH_2O$ | |

## TEST RESULTS

### WATER RESISTANCE-IMPACT PENETRATION TEST; AATCC 42:2017

Test samples were conditioned for at least 4 hours prior to testing (65 ± 5% RH, 21 ± 2 ° C).
Water temperature : 27±1°C
Amount of sprayed water: 500 ml

| | RESULT | REQUIREMENT |
| --- | --- | --- |
| Sample 1 | 0,28 g | ≤1,0 g |
| Sample 2 | 0,14 g | (Level 2) |
| Sample 3 | 0,17 g | |
| Water penetration (g) | 0,19 g | |

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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

| SAMPLE (INNER SURFACE) | | SAMPLE (OUTER SURFACE) | |
|---|---|---|---|
| Total linting : | **44** | Total linting : | **48** |
| Standard deviation : | **18** | Standard deviation : | **28** |
| Coefficient of variation : | %40 | Coefficient of variation : | %58 |
| Coefficient of linting (CL): | 2 | Coefficient of linting (CL): | 2 |

| SAMPLE (TOTAL) | |
|---|---|
| Total linting : | 92 |
| 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.

## 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.

| | RESULTS | REQUIREMENT |
|---|---|---|
| **Microbial cleanliness (cfu/100cm²)** | 7 cfu/100cm² | ≤300 cfu/100cm² |

# 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 ± 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** | |
| $X_1$ | 308 | **RCUM1** | **0,1** |
| $X_2$ | 365 | **RCUM2** | **0,22** |
| $X_3$ | 410 | **RCUM3** | **0,36** |
| $X_4$ | 562 | **RCUM4** | **0,55** |
| $X_5$ | 621 | **RCUM5** | **0,76** |
| **Z** | 699 | | |
| **T** | 2965 | | |

$X_1$ …… $X_5$: Number of colonies growing in 5 parallel petri in the same sample
Z: number of colonies growing in the sixth petri dish
T: $X_1 + X_2 + X_3 + X_4 + X_5 + Z$

$R_{CUM1} = X_1/T$
$R_{CUM2} = (X_2 + X_1)/T$
$R_{CUM3} = (X_3 + X_2 + X_1)/T$
$R_{CUM4} = (X_4 + X_3 + X_2 + X_1)/T$
$R_{CUM5} = (X5 + X_4 + X_3 + X_2 + X_1)/T$

| **BARRIER INDEX ($I_B$)** | | |
|---|---|---|
| | **Result** | **Expected value (*)** |
| $I_B$ | 3,98 | ≥2,8 |

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

# 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 g ± 0.1 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 20x20 $cm^2$ |
| **Mikroorganism:** | *Bacillus subtilis ATCC 9372* |
| **Bacterial concentration (cfu/ml):** | 1-4x$10^4$ kob/ml |
| **Incubation conditions:** | 35°C / 24 hours |

**RESULTS**

| **Number of Populationg Bacteria (cfu)** | |
| --- | --- |
| **1** | 0 |
| **2** | 0 |
| **3** | 0 |
| **4** | 0 |
| **5** | 0 |
| **6 (Control)** | 0 |
| **Total** | 0 |
| **Logarithm** | - |

**RESULT**

| **Result (cfu/g)** | **Expected Value** |
| --- | --- |
| 0 | ≤300 cfu/gr |