Digitally signed by Granaci Boris
Date: 2021.09.07 15:07:59 EEST
Reason: MoldSign Signature
Location: Moldova

**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

**EKOTEKS**

**TEST REPORT**
*DENEY RAPORU*

| |
|---|
| AB-0583-T |
| 20035727 -ing |
| 10-20 |

| | |
|---|---|
| ***Customer name:*** | BAYTEKS TEKNİK TEKSTİL SAN. VE TİC. A.Ş |
| ***Address:*** | - |
| ***Buyer name:*** | ORGANİZE SAN. MAH. 19 NOLU CAD. NO:11 MERKEZ /KİLİS |
| ***Contact Person:*** | KADİR KARAGÜN |
| ***Order No:*** | REF:SG-01222-05 LOT:50815 |
| ***Article No:*** | PROTECTED SURGICAL APRON |
| ***Name and identity of test item:*** | Coated medical blue surgical gown. |
| ***The date of receipt of test item:*** | 29.09.2020 |
| ***Re-submitted/re-confirmation date:*** | - |
| ***Date of test:*** | 29.09.2020-12.10.2020 |
| ***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*** |
|---|---|---|---|
| | 12.10.2020 | Hatice ACARALP | Sevim A. RAZAK<br>12.10.2020 |

**EKOTEKS LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş.**

| |
|---|
| AB-0583-T |
| 20035727 -ing |
| 10-20 |

| 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 | |
| **MICROBIOLOGICAL TESTS** | | |
| Microbial Cleanliness (Bioburden) | P | |
| Wet-Bacterial Penetration | P | |
| Dry-Bacterial Penetration | P | |

P: Pass
F: Fail
R: Refer to retailer technologist.
(1)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.

| |
|---|
| AB-0583-T |
| 20035727 -ing |
| 10-20 |

## 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** | 72.5 N | ≥ 20N (Dry) |
| **Warp** | 162.8 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** | 75.1 N | ≥ 20N (Wet) |
| **Warp** | 160.1 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 ;** | 201.4 kPa | ≥ 40 kPa (Dry) |
| **Height at Burst*** | 14.9 mm | |

| |
|---|
| AB-0583-T |
| 20035727 -ing |
| 10-20 |

# 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
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 ;** | 190.2 kPa | ≥ 40 kPa (Wet) |
| **Height at Burst*** | 13.8 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)

| | **RESULT** | **REQUIREMENT** |
|---|---|---|
| **Sample 1** | 147.0 cmSS | ≥ 100cmSS |
| **Sample 2** | 150.0 cmSS | |
| **Sample 3** | 157.2 cmSS | |
| **Sample 4** | 163.3 cmSS | |
| **Sample 5** | 160.1 cmSS | |
| **Average** | 158.6 cmSS | |

# TEST RESULTS

## 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/g)** | 32 cfu/g | ≤300 cfu/g<br>Type I and Type II mask |

**EKOTEKS LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş.**

| |
|---|
| AB-0583-T |
| 20035727 -ing |
| 10-20 |

# TEST RESULT

**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 determination of 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 ± 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):** | 2x104 kob / ml |
| **Incubation Conditions:** | (36 ± 1) ° C 48 hours |

| **RESULTS** | | | |
|---|---|---|---|
| **Number of Populating Bacteria (cfu)** | | **Penetration Rate** | |
| $X_1$ | **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** | **459** | | |
| **T** | 459 | | |

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

*$R_{CUM1} = X1/T$*
*$R_{CUM2} = (X2 + X1)/T$*
*$R_{CUM3} = (X3 + X2 + X1)/T$*
*$R_{CUM4} = (X4 + X3 + X2 + X1)/T$*
*$R_{CUM5} = (X5 + X4 + X3 + X2 + X1)/T$*

| **BARRIER INDEX ($I_B$)** | | |
|---|---|---|
| | **Result** | **Expected value (*)** |
| $I_B$ | 6 | ≥2,8 |

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

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

**EKOTEKS LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş.**

| |
|---|
| AB-0583-T |
| 20035727 -ing |
| 10-20 |

**Test Method: ISO 22612: 2005 (Clothing for protection against infectious agents - Test method for resistance to dry microbial penetration)**
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):** | $1x10^8$ | |
| **Incubation conditions:** | 35°C / 24 hours | |
| **RESULTS** | | |
| **Number of Populationg Bacteria (cfu)** | | |
| **1** | 1 | |
| **2** | 2 | |
| **3** | 1 | |
| **4** | 3 | |
| **5** | 2 | |
| **6 (Control)** | 0 | |
| **Total** | 9 | |
| **Logarithm** | 0.95 | |
| ** EN 13795-1:2019 Surgical gowns and drapes - Requirements and test methods are evaluated according to Table-1.* | | |
| **RESULT** | | |
| **Result (cfu/g)** | | **Expected Value** |
| 9 kob/gr | | ≤300kob/gr |