



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

Esenyurt Firuzköy Bulvarı No:29 34325 Avcılar
İstanbul/ TÜRKİYE

**TEST REPORT
DENEY RAPORU**

20021619-
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07-20

Customer name: İBİŞLER TEKSTİL SAN. VE DİŞ TİC A.Ş
Address: ORHANGAZI MAH. TUNÇ CAD. NO:5 HADIMKÖY
ESENYURT/İSTANBUL
Buyer name: -
Contact Person: SALİH KAŞMER
Order No: -
Article No: -
Name and identity of test item: Blue non-woven gown
The date of receipt of test item: 26.06.2020
Re-submitted/re-confirmation date: -
Date of test: 26.06.2020-08.07.2020
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

Gen.Π136-2/03



Date
08.07.2020

Customer Representative
Hatice ACARALP

Head of Testing Laboratory
Sevim A. RAZAK

08.07.2020

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| REQUIRED TESTS | RESULT | COMMENTS |
|---|--------|----------|
| MICROBIOLOGICAL TEST | | |
| Microbial Cleanliness (Bioburden) | P | |
| Wet-Bacterial Penetration | P | |
| Dry-Bacterial Penetration ⁽¹⁾ | P | |
| PHYSICAL PROPERTIES TESTS | | |
| Tensile Strength / Dry | P | |
| Tensile Strength / Wet | P | |
| Bursting Strength / Dry | P | |
| Bursting Strength / Wet | P | |
| Water Permeability | P | |
| P: Pass F: Fail R: Refer to retailer technologist. | | |
| Test results were evaluated according to EN 13795-1:2016 Standard Performance Properties Critical Sample Group limit values (Table 1) | | |
| ⁽¹⁾ Test results were evaluated according to EN 13795-1:2016 Standard Performance Less 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 specifications 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

TEST METHOD : EN 13795-1:2019

SURGICAL CLOTHING AND DROPEs –REQUIREMENTS AND TEST METHODS

ANNEX 1: SURGICAL CLOTHING AND DROPEs (*);

MICROBIAL CLEANLINESS (Bioburden)

Test Method: 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 microorganism are counted on the agar.

| | RESULTS | REQUIREMENT |
|--|----------------------------|-----------------------------|
| Microbial cleanliness (cfu/100 cm²) | 27 cfu/100 cm ² | ≤30 cfu/100 cm ² |

*cfu- Colony forming unit.

TEST RESULTS

WET-BACTERIAL PENETRATION

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 ($3N \pm 0.02$). 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 | R _{CUM1} | 0 |
| X ₂ | 0 | R _{CUM2} | 0 |
| X ₃ | 0 | R _{CUM3} | 0 |
| X ₄ | 25 | R _{CUM4} | 0.05 |
| X ₅ | 28 | R _{CUM5} | 0.12 |
| Z | 368 | | |
| T | | | 421 |

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

$$R_{CUM1} = X_1/T$$

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

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

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

$$R_{CUM5} = (X_5 + X_4 + X_3 + X_2 + X_1)/T$$

BARRIER INDEX (I_B)

| | Result | Expected value (*) |
|----------------|--------|--------------------|
| I _B | 5.81 | ≥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.

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TEST RESULTS

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: | <i>Bacillus subtilis</i> ATCC 9372 | |
| Bacterial concentration (cfu/ml): | 1x10 ⁸ | |
| Incubation conditions: | 35°C / 24 hours | |
| RESULTS | | |
| Number of Populating Bacteria (cfu) | | |
| 1 | | 1 |
| 2 | | 1 |
| 3 | | 0 |
| 4 | | 0 |
| 5 | | 4 |
| 6 (Control) | | 0 |
| Total | | 6 |
| Logarithm | | 0.77 |
| EVALUATION | | |
| Result | | Class (*) |
| Log ≤ 1 | | 3 |
| * EN 14126: 2003 Protective Clothing - Performance Properties and Test Methods of Protective Clothing Against Infectious Agents are evaluated according to Table-4. | | |
| Sınıf | | Penetrasyon (log kob) |
| 3 | | ≤ 1 |
| 2 | | 1 < log kob ≤ 2 |
| 1 | | 2 < log kob ≤ 3 |
| * EN 13795-1:2019 Surgical gowns and drapes - Requirements and test methods are evaluated according to Table-1. | | |
| RESULT | | |
| Result (cfu/g) | | Expected Value |
| 6 cfu/g | | ≤300 cfu/g |

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TEST RESULTS

TEST METHOD : EN 13795-1:2019

SURGICAL CLOTHING AND DROPEES –REQUIREMENTS AND TEST METHODS

ANNEX 1: SURGICAL CLOTHING AND DROPEES (*);

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 ;

| | <u>RESULT</u> |
|------|---------------|
| Weft | 48.3 N |
| Warp | 103.3 N |

REQUIREMENT

≥ 20N (Dry)

≥ 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 ;

| | <u>RESULT</u> |
|------|---------------|
| Weft | 48.3 N |
| Warp | 109.8 N |

REQUIREMENT

≥ 20N (Wet)

≥ 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±2°C-65%±4).

| | <u>RESULT</u> |
|------------------|---------------|
| Dry ; | 150.1 kPa |
| Height at Burst* | 12.0 mm |

REQUIREMENT

≥ 40 kPa (Dry)

TEST RESULTS

TEST METHOD : EN 13795-1:2019

SURGICAL CLOTHING AND DROPESES –REQUIREMENTS AND TEST METHODS

ANNEX 1: SURGICAL CLOTHING AND DROPESES (*);

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 ; | 139.0 kPa |
| Height at Burst* | 11.5 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 | 22.4 cmSS |
| Sample 2 | 21.9 cmSS |
| Sample 3 | 23.0 cmSS |
| Sample 4 | 21.9 cmSS |
| Sample 5 | 22.4 cmSS |
| Average | 22.3 cmSS |

REQUIREMENT
≥ 20cmSS

ATTESTATION OF CONFORMITY

Certificate No: MDD - 103

In conformance to the European Economic Commission 93/42/EEC Medical Devices Directive on harmonisation of laws, regulations and administrative documentation of Member States on Medical Devices and European Economic Commission directive 93/68/EEC amending Medical Devices Directive dated 22 July 1993,

the products manufactured by

**İBİŞLER TEKSTİL SANAYİ VE DIŞ TİCARET
ANONİM ŞİRKETİ**

at the following address

Orhangazi Mahallesi Tunç Caddesi No:5 34358 Esenyurt / İSTANBUL

**EN 13795-1:2019 Surgical Clothing and Drapes - Requirements
and Test Methods - Part 1: Surgical Drapes and Gowns**

Brand Name : A&Z MED, Model: OLI - 2023

(Standard Performance)are tested according to the following initial type tests by the manufacturer

For the assessment of conformity, the following documents were also reviewed:

Laboratory test results for Microbial Penetration (wet/dry), Bioburden,
Bursting and Tensile Strengths (wet/dry)

UNIVERSAL CERTIFICATION has evaluated production, design, intended use, risk evaluation according to safety purpose, product itself and add-on components (if exists) and product technical drawings of the surgical gowns manufactured and designed for use to prevent the transmission of infective agents between clinical staff and patients during surgical and other invasive procedures. With this certificate, it is approved that the product fulfils all essential requirements and the related rules of 93/42/EEC Medical Devices Directive (MDD) Class I are applied. The information on the packaging for the above listed products covers the necessary information stated in Annex 1, §13, of the Medical Devices Directive (93/42/EEC) or Annex 1, §23, of the Medical Device Regulation (EU) 2017/745. This information includes; performance level and other relevant information given in EN ISO 15223-1:2016 and EN 1041:2008+A1:2013. It is considered to be suitable to attach a CE mark, as seen below, on your products in accordance with the information given in this certificate with publishing an EU Declaration of Conformity.

This certificate is issued on 08/05/2020 and valid until 07/05/2021 with the conditions that no change has been made with the product references and no change in the production process or not suspended or withdrawn for any reason.

İSTANBUL - 08/05/2020



Suat KACMAZ
UNIVERSAL CERTIFICATION
Director



Verify the validity with the QR Code

EU DECLARATION OF CONFORMITY

MANUFACTURER

İBİŞLER TEKSTİL SANAYİ VE DİŞ TİCARET ANONİM ŞİRKETİ
Gürsel Mahallesi Tümlüç Caddesi No:1 Kağıthane İSTANBUL / TURKEY

PRODUCT DESCRIPTION

Brand Name : A&Z MED, Model: OLI - 2023

Surgical Gowns with standard performance to be used to prevent the transmission of infective agents between clinical staff and patients during surgical and other invasive procedures, classified as Medical Device (Class I)

The Manufacturer declares on his sole responsibility that the product above is, under conditions of normal use and conditions defined by the Producer / the Manufacturer, safe and meets all the necessary legal conditions and requirements. The product, a medical device that is intended for single use and solely in accordance with the Manufacturer's instructions.

The Conformity is assessed especially with the following provisions:

- European Regulation (EU) 2017/745 and 93/42/EEC Medical Devices Directive establishing technical requirements for medical devices, in effective wording
- Technical standard EN 13795-1:2019 Surgical clothing and drapes - Requirements and test methods - Part 1: Surgical drapes and gowns
- Other relevant harmonized legislation and standards
- For the assessment of conformity, the following documents were also applied to:
- Results of laboratory tests for Microbial Penetration (Dry/Wet) and Microbial Cleanliness, Bioburden by Ekoteks Laboratuvar ve Gözetim Hizmetleri A.Ş.
- Results of laboratory tests for Bursting and Tensile Strengths (wet/dry) by Ekoteks Laboratuvar ve Gözetim Hizmetleri A.Ş.

MARKING, LABELLING

Annex I, §13, of the Medical Devices Directive (93/42/EEC) or Annex I, §23, of the Medical Device Regulation (EU) 2017/745 specifies the information that should be specified on the packaging in which the surgical gown is supplied. The information supplied with the product considering EN ISO 15223-1:2016 and EN 1041:2008+A1:2013.

MEASURES TO ENSURE CONFORMITY

The Manufacturer declares that he has taken all necessary measures to ensure the conformity of products placed on the market with technical documentation and basic requirements for this type of product.

İhan İBİŞ
General Manager
İSTANBUL 08/05/2020

