



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

TEST REPORT
DENEY RAPORU



AB-0583-T
20042075-ing
11-20

Customer name: MAE GİYİM SAN. TİC. LTD. ŞTİ.
Address: KAYABAŞI MAH. KAYAŞEHİR BULV. PARK MAVERA 2 SİTESİ B2 BLOK
D:30 34494 BAŞAKŞEHİR/İSTANBUL
Buyer name:
Contact Person: -
Order No: -
Article No: SG 1389
Name and identity of test item: White gown(Claimed to be; D-Lab Bioclean Isolation Gown AAMI Level 3 Lot
Number: 2020000003.)
The date of receipt of test item: 10.11.2020
Re-submitted/re-confirmation date: -
Date of test: 10.11.2020-19.11.2020
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
19.11.2020

Customer Representative
ZAHİDE TAPAN

Head of Testing Laboratory
Sevim A. RAZAK
19.11.2020

This report shall not be reproduced other than in full except with the permission of the laboratory.
Testing reports without signature and seal are not valid.

EKOTEKS LABORATUVAR ve GÖZETİM
HİZMETLERİ A.Ş.

AB-0583-T

20042075-
ing

11-20

REQUIRED TESTS	RESULT	COMMENTS
MICROBIOLOGICAL TEST		
Microbial Cleanliness (Bioburden)	P	
Wet-Bacterial Penetration	P	
Dry- Bacterial Penetration	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 13795-1:2019 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 %. 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.



This report shall not be reproduced other than in full except with the permission of the laboratory.
Testing reports without signature and seal are not valid.

AB-0583-T

20042075-
ing

11-20

TEST RESULTS

Surgical clothing and drapes - Requirements and test methods – Part 1: Surgical drapes and gowns EN 13795-1 :2019

MICROBIAL CLEANLINESS (Bioburden)

Test Metod: EN ISO 11737-1:2018 /TS EN ISO 11737-1 :2018

The sample is put in extraciton liquid after shaking well after shaking well (250 rpm,5 min), inoculated on the suitable agar. The plates are incubated for 3 days at 30 ± 1 ° C for 72 hours, and 7 days at (20 to 25) °C for TSA and SDA plates respectively. Total microoragnisms counts are calculated.

	<u>RESULTS</u>	<u>REQUIREMENT</u>
Microbial cleanliness (cfu/ cm ²)	20cfu/100 cm ²	≤300 cfu/100 cm ²

*cfu= Colony forming unit.

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

AB-0583-T
20042075- ing
11-20

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):	2×10^5 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	430		
T			430

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

$R_{CUM1} = X_1/T$

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

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

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

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

BARRIER INDEX (I_B)

	Result	Expected value (*)
I _B	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.

Gen.f136-2/03

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

AB-0583-T

20042075-
ing

11-20

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 Populationg Bacteria (cfu)	
1	0
2	0
3	0
4	0
5	0
6 (Control)	0
Total	0
Logarithm	0
* EN 13795-1:2019 Surgical gowns and drapes - Requirements and test methods are evaluated according to Table-1.	
RESULT	
Result (cfu/g)	Expected Value
0 cfu/g	≤300 cfu/g

Gen. fl136-2/03

AB-0583-T

20042075-
ing

11-20

TEST RESULTS

TENSILE STRENGTH; EN 29073-3:1996

Instron 5969 (Load: 5 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 width and length direction of four samples

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

Dry ;

	<u>RESULT</u>
Width	33.7 N
Length	85.7 N

REQUIREMENT

\geq 20N (Dry)

\geq 20N (Dry)

TENSILE STRENGTH; EN 29073-3:1996

Instron 5969 (Load: 5 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 width and length direction of four samples

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

Wet ;

	<u>RESULT</u>
Width	30.8 N
Length	81.2 N

REQUIREMENT

\geq 20N (Wet)

\geq 20N (Wet)

BURSTING STRENGTH;; ISO 13938-1:1999

SDL ATLAS M229 tester. Test area: 30.5 mm diameter

The average results are given of five samples.

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

	<u>RESULT</u>
Dry ;	166.9 kPa

REQUIREMENT

\geq 40 kPa (Dry)

Height at Burst*	10.8 mm
------------------	---------

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

AB-0583-T

20042075-
ing

11-20

TEST RESULTS

BURSTING STRENGTH;; ISO 13938-1:1999

SDL ATLAS M229 tester. Test area: 30.5 mm diameter

The average results are given of five samples.

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

Wet ; RESULT
141.5 kPa

REQUIREMENT
≥ 40 kPa (Wet)

Height at Burst* 10.4 mm

WATER PERMEABILITY; ISO 811:2018

Hydrostatic Head Tester, Textest marka FX 3000-IV model

Pressure increase ratio 10 mbar/dk.

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

	<u>RESULT</u>
Sample 1	2040.0 mmSS
Sample 2	2162.4 mmSS
Sample 3	2121.6 .mmSS
Sample 4	1989.0 mmSS
Sample 5	2009.4 mmSS
Average	2064.5 .mmSS

REQUIREMENT
>200 mmSS