



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

**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

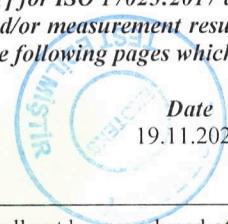
**Customer name:** MAE GİYİM SAN. TİC. LTD. ŞTİ.  
**Address:** KAYABAŞI MAH. KAYAŞEHİR BULV. PARK MAVERA 2 SİTESİ B2 BLOK  
D:30 34494 BAŞAKŞEHİR/İSTANBUL  
**Buyer name:**  
**Contact Person:** -  
**Order No:** -  
**Article No:** SG 1389  
**Name and identity of test item:** White gown(Claimed to be; D-Lab Bioclean Isolation Gown AAMI Level 3 Lot  
Number: 202000003.)  
**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 (TÜRKAK) 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

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REQUIRED TESTS	RESULT	COMMENTS
<b>MICROBIOLOGICAL TEST</b>		
Microbial Cleanliness (Bioburden)	P	
Wet-Bacterial Penetration	P	
Dry- Bacterial Penetration	P	
<b>PHYSICAL PROPERTIES TESTS</b>		
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

Gen.fl36-2/03



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## 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  $30 \pm 1$  °C for 72 hours, and 7 days at (20 to 25) °C for TSA and SDA plates respectively.

Total microorganisms counts are calculated.

	<u>RESULTS</u>	<u>REQUIREMENT</u>
Microbial cleanliness (cfu/ cm <sup>2</sup> )	20cfu/100 cm <sup>2</sup>	$\leq 300$ cfu/100 cm <sup>2</sup>

\*cfu= Colony forming unit.

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## 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 <sup>2</sup>
Carrier Material:	30 $\mu$ m thin, 25x25cm <sup>2</sup> Polyurethane Film
Coating Material:	25x25cm <sup>2</sup> HDPE Film
Microorganism:	Staphylococcus aureus ATCC 29213
Bacterial Concentration (kob / ml):	$2 \times 10^5$ kob / ml
Incubation Conditions:	(36 $\pm$ 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	

$X_1 \dots X_5$ : Number of colonies growing in 5 parallel petri in the same sample

$Z$ : number of colonies growing in the sixth petri dish

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

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

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

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

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

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

### BARRIER INDEX ( $I_B$ )

	Result	Expected value (*)
$I_B$	6	$\geq 2,8$

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

\* 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  $0.5 \text{ g} \pm 0.1 \text{ g}$  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  $35^\circ\text{C}$  for 24 hours.

<b>Sample amount:</b>	6 pieces $20 \times 20 \text{ cm}^2$
<b>Mikroorganism:</b>	<i>Bacillus subtilis</i> ATCC 9372
<b>Bacterial concentration (cfu/ml):</b>	$1 \times 10^8$
<b>Incubation conditions:</b>	$35^\circ\text{C} / 24 \text{ hours}$

**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	$\leq 300 \text{ cfu/g}$

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## 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>	<u>REQUIREMENT</u>
Width	33.7 N	$\geq$ 20N (Dry)
Length	85.7 N	$\geq$ 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>	<u>REQUIREMENT</u>
Width	30.8 N	$\geq$ 20N (Wet)
Length	81.2 N	$\geq$ 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).

Dry ;

	<u>RESULT</u>	<u>REQUIREMENT</u>
	166.9 kPa	$\geq$ 40 kPa (Dry)

Height at Burst\*

10.8 mm

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## 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).

	<u>RESULT</u>	<u>REQUIREMENT</u>
Wet ;	141.5 kPa	≥ 40 kPa (Wet)
Height at Burst*	10.4 mm	

### **WATER PERMEABILITY; ISO 811:2018**

Hydrostatic Head Tester, Texttest marka FX 3000-IV model

Pressure increase ratio 10 mbar/dk.

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

	<u>RESULT</u>	<u>REQUIREMENT</u>
Sample 1	2040.0 mmSS	>200 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	