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
20024270-Add-ing
08-20

Customer name:	FELİKS PLASTİK LAM VE AMB MAL SAN VE TİC. LTD. ŞTİ.
Address:	ESKİŞEHİR ORG. SAN. BOL.26. CAD. NO:9 26110 ESKİŞEHİR
Buyer name:	-
Contact Person:	ALİ SERDAR SERTESER
Order No:	-
Article No:	BODYGUARD SFS SURGICAL GOWN LEVEL 3
Name and identity of test item:	Blue gown.
The date of receipt of test item:	14.07.2020
Re-submitted/re-confirmation date:	20.07.2020
Date of test:	20.07.2020-19.08.2020
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:	11

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*
ali serdar serteser Dijital olarak imzalayan ali serdar serteser Tarih: 2020.09.08 17:21:58 +03'00'	19.08.2020	Servin YURTSEVEN	Sevim A. RAZAK 19.08.2020

Gen.f136-2/03

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REQUIRED TESTS	RESULT	COMMENTS
MICROBIOLOGICAL TEST		
Microbial Cleanliness (Bioburden)	P	
Wet-Bacterial Penetration	P	
Dry- Bacterial Penetration	P	
PHYSICAL PROPERTIES TESTS		
Tensile Stregth **/ Dry**	P	
Tensile Stregth **/ Wet**	P	
Bursting Strength **/ Dry**	P	
Bursting Strength **/ Wet**	P	
Water Permeability	P	
Blood Splash Resistance[2]	P	
Seam Strength [1]	P	Class 2
Puncture Resistance[1] [2]	P	Class 1
Repellency to Liquids[1] [2]	-	See test result
Resistance To Penetration By Liquids[1] [2]	P	Class 3

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] Tests were classified according to BS EN 14325:2018
BS EN 14126 :2003 Protective clothing —Performance requirements and tests methods for protective clothing against infective agents
[2] This report was reissued to add this test result.

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.

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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 ± 1 ° C for 72 hours, and 7 days at (20 to 25) °C for TSA and SDA plates respectively.
Total microoragnisms counts are calculated.

	RESULTS	REQUIREMENT
Microbial cleanliness (cfu/g)	196 cfu/100 cm^2	≤300 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 ± 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):	1-4x10^4 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	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	6,0	≥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.*

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:	*Bacillus subtilis ATCC 9372*
Bacterial concentration (cfu/ml):	$1x10^8$
Incubation conditions:	35°C / 24 hours

RESULTS	
Number of Populationg Bacteria (cfu)	
1	2
2	0
3	0
4	0
5	0
6 (Control)	0
Total	2
Logarithm	0,30

EVALUATION	
Result	**Class (*)**
≤ 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**
2 cfu/g	≤300 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±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±2°C-65%±4).

Dry ;

	RESULT	REQUIREMENT
Width	34.2 N	≥ 20N (Dry)
Length	58.6 N	≥ 20N (Dry)

TENSILE STRENGTH; EN 29073-3:1996

Instron 5969 (Load: 5 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 width and length direction of four samples
Performed in the conditioned room (20±2°C-65%±4).

Wet ;

	RESULT	REQUIREMENT
Width	31.4 N	≥ 20N (Wet)
Length	59.5 N	≥ 20N (Wet)

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TEST RESULTS

BURSTING STRENGTH; ISO 13938-1:2019

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).

Dry	**RESULT**	**REQUIREMENT**
	100.8 kPa	≥ 40 kPa (Wet)
Height at Burst*	11.6 mm	

BURSTING STRENGTH; ISO 13938-1:2019

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**	**REQUIREMENT**
	109.1 kPa	≥ 40 kPa (Dry)
Height at Burst*	12.5 mm	

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WATER PERMEABILITY; ISO 811:2018

Hydrostatic Head Tester, Textest marka FX 3000-IV model
Temperature of wate 20°C. Pressure increase ratio 10 mbar/dk.
Performed in the conditioned room (20±2°C-65%±4)

	RESULT	**REQUIREMENT**
Sample 1	145.8 cmSS	≥ 20 cmSS
Sample 2	149.9 cmSS	
Sample 3	147.9 cmSS	
Sample 4	148.9 cmSS	
Sample 5	147.9 cmSS	
Average	148.1 cmSS	

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TEST RESULTS

DETERMINATION OF THE RESISTANCE TO PENETRATION BY BLOOD AND BODY FLUIDS-USING SYNTHETIC BLOOD; ISO 16603:2004

Textest, FX 3000-IV model + External Blood Cell
Test samples were conditioned at 60 ± 10% relative humidity and 21 ± 5 ° C for at least 24 hours before testing.

Test Procedure Applied: C procedure

Pressure (kPa)	**Time (Min.)**	**Test Result**			**Overall Result**
		Test 1	**Test 2**	**Test 3**	
0	5	Pass	Pass	Pass	PASS
1,75	5	Pass	Pass	Pass	
3,5	5	Pass	Pass	Pass	
7	5	Pass	Pass	Pass	
14	5	Pass	Pass	Pass	
20	5	Pass	Pass	Pass	
Thickness of material tested (mm):		0.4 mm	0.4 mm	0.4 mm	0.4 mm
Weight of material tested (g/m^2) :		5.7	5.7	5.7	5.7

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TEST RESULT

SEAM STRENGTH-GRAB METHOD

Clause 5.5 Seam Strength ISO 13935-2: 2014
Jaw Speed: 50±5 mm/min, Gauge Length: 100 mm±1 mm.
Seam Type : 301. 100 % Polyester core-spun sewing-thread was used.
5kN. Load was applied.
The average results are given for width and length direction of five samples.
Performed in the conditioned room(20±2°C-65%±4)

	Seam Strength (N)	Fail	CLASS
Sleeve side seam	59.3 N	FTS	2 Classified according to the Table-13
Shoulder seam	78.3 N	FTS	
Armhole	79.2 N	FTS	
Waistbelt	64.1 N	FTS	
Collar label	69.4 N	FTS	

FTS : Fabric Tear At The Seam
STB : Sewing Thread At Breakdown

Table 13- Classification of Seam Strength

CLASS	*Seam strength*
6	>500 N
5	>300 N
4	>125 N
3	>75 N
2	>50 N
1	>30 N

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TEST RESULT

PUNCTURE RESISTANCE

Clause 4.10.Puncture Resistance EN 863

RESULT	**CLASS**
6.1 N	2 Classified according to the Table-6

Table-4 Classification of Puncture Resistance
(Tablo-6)

Class	*Puncture Resistance*
6	>250 N
5	>150 N
4	>100 N
3	>50 N
2	>10 N
1	>5N

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TEST RESULT
REPELLENCY TO LIQUIDS

Clause 4.12 Repellency to Liquids (EN ISO 6530:2005)

When tested in accordance with EN ISO 6530 for repellency to the liquid chemicals given in Table -9, the material shall be classified According to the levels performance in given Table-10 for each chemical tested.
Use those liquids against which protection is required, water is also cenvenient and safe liquid for general screening purposes.
Performed in the conditioned room (20±2°C-65%±4).

For each test liquid ,cut six test specimens of (360±2)mm by (235±5)mm from the sample.
Chemicals shall be of analytical purity grade.
Discharged the test liquid (10cm 3) within (10±1)s

Table-9 List of reference chemicals for absorption ,penetration and repellency testing

Chemical	*Concentration weight %*	*Temperature of chemical (±2°C)*
Sulfuric Acid (H2SO4)	30	20
Sodium Hydroxide (NaOH)	10	20
o-Xylene	Undiluted	20

Table 10- Classification of Repellency to liquids

Class	*Repellency Index (I_R)*
3	> 90 %
2	>80 %
1	>70 %

Clause 4.13 Resistance to penetration by liquids (EN ISO 6530)

Table 11- Classification of Resistance to penetration by liquids

Class	*Penetration Index (Ip)*
3	< 1 %
2	< 5 %
1	<10 %

RESULT

Chemical	*Concentration weight %*	I_P	*Class*	I_R	*Class*
Sulfuric Acid (H2SO4)	30	0%	3	95.3 %	3
Sodium Hydroxide (NaOH)	10	0%	3	94.7 %	3
o-Xylene	Undiluted	0%	3	29.2 %	-

I_P :index of penetration
I_R : ındex of repellency
I_A : ındex of absorbtion