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

EKOTEKS

20015444-ing
05-20

TEST REPORT
DENEY RAPORU

Customer name:	GLOBICHEM KİMYA İTH. İHR. SAN. TİC. LTD. ŞTİ.
Address:	BARAKFAKİH MAH. 7.CAD. NO:2 KESTEL/BURSA
Buyer name:	-
Contact Person:	TALHA UĞUR
Order No:	-
Article No:	-
Name and identity of test item:	Blue surgical gown
The date of receipt of test item:	15.05.2020
Re-submitted/re-confirmation date:	-
Date of test:	15.05.2020-22.05.2020
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:	6

Seal	***Date***	***Customer Representative***	***Head of Testing Laboratory***
	22.05.2020	Servin YURTSEVEN	Sevim A. RAZAK 22.05.2020

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REQUIRED TESTS	RESULT	COMMENTS
MICROBIOLOGICAL TEST		
Microbial Cleanliness (Bioburden)	P	
Wet-Bacterial Penetration	P	
PHYSICAL PROPERTIES TESTS		
Tensile Stregth **/ Dry**	P	
Tensile Stregth **/ Wet**	P	
Bursting Strength **/ Dry**	P	
Bursting Strength **/ Wet**	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 %. Tests marked (*) in this report are not included in the accreditation schedule.

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TEST RESULTS

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)	187 cfu/100 cm^2	≤300 cfu/100 cm^2

***cfu= Colony forming unit.**

TEST RESULTS

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):	1-4x104 kob / ml
Incubation Conditions:	(36 ± 1) ° C 48 hours

RESULTS			
Number of Populating Bacteria (cfu)		Penetration Rate	
X1	0	RCUM1	0
X2	0	RCUM2	0
X3	0	RCUM3	0
X4	158	RCUM4	0,27
X5	167	RCUM5	0,56
Z	253		
T	578		

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

RCUM1 = X1/T
RCUM2 = (X2 + X1)/T
RCUM3 = (X3 + X2 + X1)/T
RCUM4 = (X4 + X3 + X2 + X1)/T
RCUM5 = (X5 + X4 + X3 + X2 + X1)/T

BARRIER INDEX (IB)		
	Result	Expected value (*)
IB	5,16	≥2,8

IB = 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 : EN 13795-1:2019

SURGICAL CLOTHING AND DRAPES –REQUIREMENTS AND TEST METHODS

ANNEX 1: SURGICAL CLOTHING AND DRAPES (*);

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	61.2 N	≥ 20N (Dry)
Warp	90.2 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	61.9 N	≥ 20N (Wet)
Warp	95.4 N	≥ 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±2°C-65%±4).

	RESULT	REQUIREMENT
Dry ;	152.2 kPa	≥ 40 kPa (Dry)
Height at Burst*	11.3 mm	

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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
The average results are given of five samples.
Performed in the conditioned room (20±2°C-65%±4).

	RESULT	**REQUIREMENT**
Wet ;	142.5 kPa	≥ 40 kPa (Wet)
Height at Burst*	11.5 mm	