ZEYNİ MEDİKAL TEKSTİL İNŞ.SAN. VE TİC. LTD. ŞTİ.

YUNUSEMRE MAH. 12 YILDIRIM SOKAK NO:17 YILDIRIM/BURSA

Report No. 111699085

Buyer /

Test Item. : Bilayered and Absorbent Drapes

Item No. : /

Colour Name. : /

Condition at delivery. : Samples tested as received.

Test Scope. : Parameters selected by customer

Test Specification : Determination of hydrostatic pressure

Applicant's Provided Care Instruction/Label: -

Sample Receiving date: 2021-10-18 (p.m)

Testing Period: 2021 10-21 to 2021-10-25

Test Result: Passed

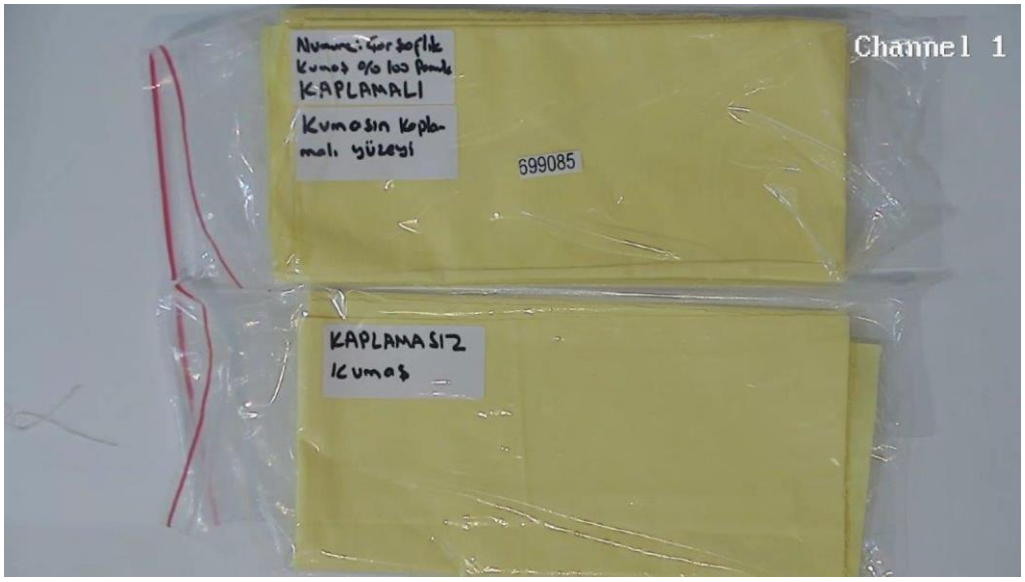
Digitally signed by Dicusar Vladimir
Date: 2023.09.16 10:41:36 EEST
Reason: MoldSign Signature
Location: Moldova

For and on behalf of
TÜV Rheinland Uluslararası Standartlar Sertifikasyon ve Denetim A.Ş

Tomris Hasançebi / Customer Relations Manager

Abdullah Akil / Physical Laboratory Manager

TÜV Rheinland Uluslararası Standartlar Sertifikasyon ve Denetim A.Ş.
Kozyatagi Mah. Saniye Ermutlu Sok. No:12
Colakoglu Plaza B Blok 34742 Kadikoy Istanbul,
Tel. +902166653200, Fax +902166653299, e-mail: info@tr.tuv.com



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Material No.	Material	Color	Location
M001	Textile	-	Textile
M002	Textile + coating	-	Textile w /coating

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Conclusion:

TEST PROPERTY	M001	M002
Hydrostatic Pressure Test	#	#

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1.Hydrostatic Pressure Test

Test method : EN 20811:1993

Face Side: Original
Test Conditions: 65 cm2 Test
Speed:65 cmH2O/dak

	M001	M002	Requirement
Pressure			
Average	65 cm H2O	65cm H2O	-

- END -

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

EKOTEKS

TEST REPORT
DENEY RAPORU

20018576 – ing-Add
12-05

Customer name:	ZEYNİ MEDİKAL TEKTSİL İNŞ. SANAYİ VE TİC. LTD. ŞTİ.
Address:	Yunusemre Mah. 12. Yıldırım Sk. No:17 Yıldırım - BURSA
Buyer name:	-
Contact Person:	Davut Daşdan
Order No:	-
Article No:	-
Name and identity of test item:	Surgical Gowns-SMS
The date of receipt of test item:	12.05.2021
Re-submitted/re-confirmation date:	-
Date of test:	12.05.2021-12.05.2021
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:	14

Seal	***Date***	***Customer Representative***	***Head of Testing Laboratory***
	12.05.2021	Servin YURTSEVEN	Sevim A. RAZAK 12.05.2021

EKOTEKS LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş.

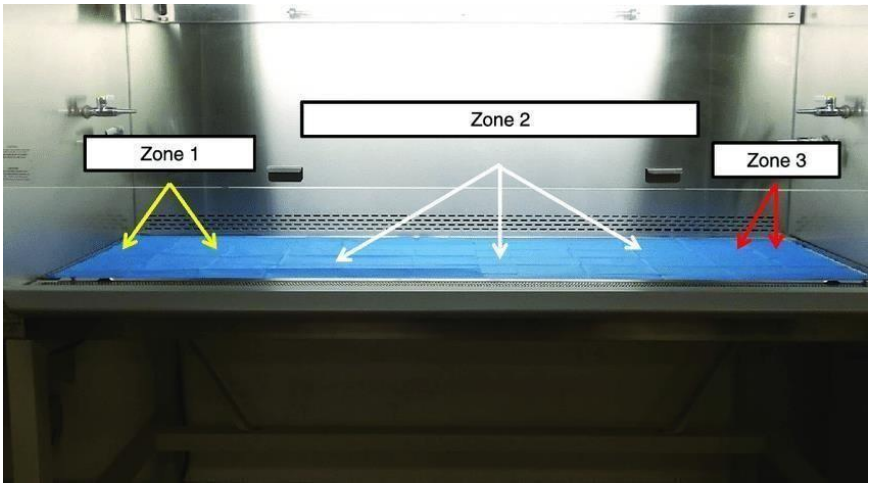
20018576 – ing-Add
05-26

REQUIRED TESTS	RESULT	COMMENTS
MICROBIOLOGICAL TEST		
Microbial Cleanliness (Bioburden) (1)	P	
Wet-Bacterial Penetration(1)	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.

(1) This report was reissued to add this test result.
(2) 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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20018576 – ing-Add
12-05

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)	206 cfu/100 cm^2	≤300 cfu/100 cm^2
1	208	
2	211	
3	206	
4	204	
5	198	
6	202	
7	203	
8	202	
9	201	
10	200	

***cfu= Colony forming unit.**

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12-05

TEST RESULTS

Test Method: BS EN 22610: 2006 (Surgical gowns, 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	55	RCUM1	0,01
X2	72	RCUM2	0,15
X3	154	RCUM3	0,34
X4	178	RCUM4	0,56
X5	156	RCUM5	0,74
Z	212		
T	827		

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	4,14	≥2,8

IB = 6 – (CUM1 + CUM2 + CUM3 + CUM4 + CUM5)

* EN 13795-1:2019 Surgical gowns - Requirements and test methods are evaluated according toTable-1.

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12-05

TEST RESULTS

TEST METHOD : EN 13795-1:2019

SURGICAL GOWN –REQUIREMENTS AND TEST METHODS

ANNEX 1: SURGICAL GOWNS(*);

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	52.2 N	≥ 20N (Dry)
Warp	93.6 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	55.0 N	≥ 20N (Wet)
Warp	101.9 N	≥ 20N (Wet)

BURSTING STRENGTH;; ISO 13938-1:1999

SDL ATLAS M229 tester. Test area: 30.5 mm diameter
Rate of increase in volume; 29 cm^3/min.
The average results are given of five samples.
Performed in the conditioned room (20±2°C-65%±4).

	RESULT	REQUIREMENT
Dry ;	141.2 kPa	≥ 40 kPa (Dry)
Height at Burst*	12.9 mm	

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12-05

TEST RESULTS

TEST METHOD : EN 13795-1:2019

SURGICAL GOWN –REQUIREMENTS AND TESTMETHODSANNEX 1: SURGICAL GOWN (*);

BURSTING STRENGTH;; ISO 13938-1:1999

SDL ATLAS M229 tester. Test area: 30.5 mm diameter
Rate of increase in volume; 45.2 cm^3/min.
The average results are given of five samples.
Performed in the conditioned room (20±2°C-65%±4).

	RESULT	**REQUIREMENT**
Wet ;	139.4 kPa	≥ 40 kPa (Wet)
Height at Burst*	14.3 mm	

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12-05

The resistance to dry microbial penetration

[Material]Test Method: EN ISO 22612:2005

Test principle:

The test is carried out on test pieces each fixed in a container. In every container except one a portion of talc contaminated with Bacillus subtilis is poured on the test piece. One container is left uncontaminated as a control. A sedimentation plate is inserted at the base of each container at a short distance below the test piece. The apparatus supporting the containers is then vibrated by a pneumatic ball vibrator. The talc that penetrates is captured on the sedimentation plate, the sedimentation plates are removed and incubated. The numbers of colonies produced are counted.

Test equipment:

Resistance to dry microbial penetration test
Incubator
Electronic balance
Autoclave

The environmental conditions of the laboratory and test condition:

Test environment temperature: 24.5℃, Relative humidity: 56.0%

Test environment monitoring: total bacteria: 0 CFU/plate, total fungi: 0 CFU/plate, blank experiment: aseptic growth

Culture medium: TGE agar medium; Other materials: talc and ethyl alcohol.

Dimensions of the test specimens: 200mm×200mm

Sample: 12 pieces

Vibration frequency: 20800 times/min; Vibration time: 30 min.

Test bacteria: The fourth generation of spores of bacillus subtilis ATCC 9372

Concentration of bacterium: 1.8×10^{8} CFU/g

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Results:

Sample	Measured value (CFU)	Requirement (CFU)	Conclusion
1	19	≤300 (Surgical Gown performance less critical productarea) EN 13795-1:2019	**Pass**
2	17		
3	31		
4	15		
5	10		
6	25		
7	16		
8	28		
9	17		
10	8		

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20018576 – ing-Add
12-05

The resistance to wet bacterial penetration[Material]Test Method: EN ISO 22610:2006

Test principle:

A test specimen is placed on an agar plate. A sheet of donor material, of corresponding size and carrying the bacteria, is placed on the test specimen with the contaminated side face down and covered by a sheet of approximately 10 μm high density polyethylene (HDPE) film. Two tithing conical steel rings hold the three sheets together, applying a tensile force. An abrasion-resistant finger is placed on top of the materials with a specified force to bring the test specimen in contact with the agar. The finger is moved over the entire surface of the plate in less than 15 min by means of a pivoted lever moved by an exocentric cam. The assemblage of materials, stretched by the weight of the steel rings, ensures that only a small area of the test specimen is brought into contact with the agar surface at any one time. Due to the combined effect of rubbing and liquid migration, bacteria may pass from the donor material through the test specimen down to the agar surface. After being tested for 15 min, the agar plate is replaced by a fresh one, and the test is repeated with the same donor and test specimen. Allowing 15 min for each test, five tests are performed with the same pair of donor and test specimen. In this way, the test allows for an estimation of the penetration over time. Finally, the bacterial contamination on the top side of the test specimen is estimated using the same technique. The agar plates are incubated in order to observe the bacterial colonies, which are then enumerated.

Test equipment:

The resistance to wet bacterial penetration test
Incubator
Electronic balance
Autoclave

The environmental conditions of the laboratory and test condition:

Test environment temperature: 24.5℃, Relative humidity: 56.0%
Test environment monitoring: total bacteria: 0 CFU/plate, total fungi: 0 CFU/plate, blank experiment: aseptic growth
Culture medium: Tryptone Soya Agar, Tryptic Soy Broth, peptone water and nutrient agar medium.
Dimensions of the test specimens: 25cm×25cm
The carrier material: solvent-cast polyurethane (PU) film of 30 μm thickness
Nutrient agar to from the brim: 3 mm
Test bacteria: The fifth generation of staphylococcus aureus ATCC 29213
Concentration of bacterium: 2.3×10^4 CFU/ml

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Results:

Sample	Barrier index	Requirement Barrier index	Conclusion
1	6.7	≥6 (Surgical Gown: performance critical product area) EN 13795-1:2019	**Pass**
2	6.6		
3	6.6		
4	6.6		
5	6.6		

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12-05

Lint and other particles generation in the dry state[Material]

Test Method: EN ISO 9073-10:2004

Test principle:

This procedure describes a modified Flex method in which the sample is subjected to a combined twisting and compression action in a test chamber. During the flexing, air is withdrawn from chamber and particulates in the air stream are counted and classified in a particle counter. Depending on the choice of counter, the size ranges can fall within the limits of 0.3 μm or 0.5 μm to 25 μm.

Test equipment:

Flex tester with particle counter

The environmental conditions of the laboratory:

Test environment temperature: 20.2℃, Relative humidity: 64.7%

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12-05

Results:

Size of particles counted (µm)	**Sample**		**Measured value Coefficient of linting log_{10}**	**Requirement Coefficient of linting log_{10}**	**Conclusion**
3～25	A: Face	1	2.1	≤4.0 (Surgical Gown: performance critical product area) EN 13795-1:2019	**Pass**
		2	2.1		
		3	2.1		
		4	2.1		
		5	2.2		
	B: Face	1	2.0		
		2	2.1		
		3	2.0		
		4	2.2		
		5	2.1		

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12-05

Static hydrostatic resistance[Material]Test
Method: EN ISO 811:2018

Test principle:

The hydrostatic head supported by a fabric is a measure of the opposition to the passage of water through the fabric. A specimen is subjected to a steadily increasing pressure of water on one side of the fabric, under standard conditions, until penetration occurs in three places. The pressure at which the water penetrates the fabric at the third place is noted.

Test equipment:

Hydrostatic tester

Water, grade 3 water in accordance with ISO 3696.

The environmental conditions of the laboratory and test condition:

Pretreatment: Condition the test specimens at 20.1℃ air at 65.2% RH for 24 h

Face side tested

Temperature of the water: 20.0℃

Rate of increasing water pressure: 10cmH_2 O/min

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20018576–ing-Add
12-05

Results:

Sample	Measured value (cmH_2O)	Requirement (cmH_2O)	Conclusion
1	125 18	≥100 ≥10 (Surgical Gown performance critical product area) EN 13795-1:2019	**Pass**