

SU BIYOMEDİKAL SİSTEMLER VE SAĞLIK HİZMETLERİ SAN. TIC. LTD. STİ.

Contact Information

İletişim Bilgileri

: Orhangazi mah. 1673. Sok. No:20/ 2-3 Esenyurt İstanbul Turkey
Tel : +90 212 320 37 53 Fax : +90 212 320 53 51
E-Mail : info@submed.com.tr Web Site : www.submed.com.tr

Description of The Product

Ürün Tanımı

: Surgical Drapes

Product Reference

Numbers / Product Names

Ürün Referans Numaraları / Ürün Adları

We declare that the products mentioned above comply with Medical Devices Directive 93/42/EEC with amended Directive 2007/47/EEC and EN 13795-1:2019 standard.

Yukarıda belirtilen ürünlerin 93/42/EEC Medikal Cihazlar Kararnamesinin 2007/47/EC güncellemeleri ve EN 13795-1:2019 standart gerekliliklerini karşıladığını beyan ederiz.

EN 13795-1:2019

Certificate of Compliance

Applicable EC Directives

Geçerli AT Direktifleri

: MEDICAL DEVICES DIRECTIVE 93/42/EEC
TIBBİ CİHAZLAR DİREKTİFİ 93/42/EEC

Applicable National Technical Standards and Specifications

Uygulanabilir Ulusal Teknik Standartlar ve Özellikler

Classification/ Sınıflandırma : CLASS I / I
Certificate Number/ Sertifika Numarası : 14-266
Certificate Code/ Sertifika Kodu : S2014266
Certificate Issue Date/ Sertifika Yayın Tarihi : 01.06.2020
Certificate Validity Date/ Sertifikanın Geçerlilik Tarihi : 27.05.2024

(Authorized Signature and Title) / (Yetkili İmza ve Ünvan)

City, Date : İstanbul, 06.08.2020
Name : Yusuf Yiğit Akkuş
Position : General Manager

SUBMED
BİYOMEDİKAL SİSTEMLER
PAZARLAMA DİŞTİC. A.Ş.
Orhangazi Mahallesi 1673 Sok. No: 20/2-3
Esenyurt/İST. Esenyurt V.D. 7821159861



SUMMARY OF TEST REPORTS

SU BIYOMEDİKAL SİSTEMLER VE SAĞLIK HİZMETLERİ SAN. TİC. LTD. ŞTİ.

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Description of The Product : Surgical Drapes

Product Specifications :

We can confirm that:

The mentioned medical devices (Universal Drape Set) are designed and manufactured in such way as to guarantee the characteristics and performance referred to in Section I of "General requirements" of MDD 93/42/EEC. The submitted products have been tested by external qualified laboratories according to EN ISO 13795-1: 2019 standard. The tests were performed in normal operation mode. Surgical gowns that were used in the tests are produced with same fabric of Universal Drape Set products. As a result of this, these tests and test reports are valid for Universal Drape Set products.

Tests carried out for EN 13795-1:2019:

Performed Tests	Result	Test Standard	Test Report Number
Microbial Cleanliness (Bioburden)	Pass	EN ISO 11737-1 : 2018	20020444-ing
Dry-Bacterial Penetration	Pass	EN ISO 22612 : 2005	20020444-ing
Wet-Bacterial Penetration	Pass	EN ISO 22610 : 2006	20018421-ing
Tensile Strength / Dry	Pass	EN 29073-3 : 1996	20020444-ing
Tensile Strength / Wet	Pass	EN 29073-3 : 1996	20020444-ing
Bursting Strength / Dry	Pass	EN ISO 13938-1 : 1999	20020444-ing
Bursting Strength / Wet	Pass	EN ISO 13938-1 : 1999	20020444-ing
Resistance to liquid penetration	Pass	EN ISO 811 : 2018	20020444-ing
Particle release (Lint)	Pass	EN ISO 9073-10 : 2004	TURT200077690

According to test results, the Universal Drape Set provide all necessary high performance requirements according to EN ISO 13795-1: 2019 standard requirements.



**EKOTEKSLABORATUVARveGÖZETİM
HİZMETLERİ A.Ş.**
Esenyurt Firuzköy Bulvarı No:29 34325 Avcılar
İstanbul/ TÜRKİYE

**TEST REPORT
DENETİM RAPORU**



Test
TS EN ISO/IEC 17025
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Customer name: SU BIYOMEDİKAL SİSTEMLER VE SAĞLIK HİZMETLERİ SAN.VE
TİC.LTD. ŞTİ.
Address: Orhangazi Mah. 1673 Sok.No:20/2-3 ESENYURT/İSTANBUL
Buyer name: -
Contact Person: BURCU YILMAZ
Order No: -
Article No: EASY SURGICAL GOWN AND DRAPES
Name and identity of test item: Üne sample of blue non-woven gown and drape (Claimed to be;
Color Code: Blue)
The date of receipt of test item: 22.06.2020
Re-submitted/re-confirmation date: -
Date of test: 22.06.2020-01.07.2020
Remarks: -
Sample: The results given in this report belong to the received sample by vendor.
End-Use: -
Care Label: -
Number of pages of the report: 7



Date
01.07.2020

Customer Representative
Hatice ACARALP

Head of Testing Laboratory
Sevim A. RAZAK
01.07.2020

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REQUIRED TESTS	RESULT	COMMENTS
MICROBIOLOGICAL TEST (1)		
Microbial Cleanliness (Bioburden)	p	
Dry-Bacterial Penetration	p	
Wet-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	
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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**EKOTEKS LABORATUVAR ve GÖZETİM
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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 (*)

MICROBIAL CLEANLINESS (Bioburden)

Test Method: Ref: 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/100 cm²)	102 cfu/100 cm ²	≤300 cfu/100 cm ²

*cfu= Colony forming unit.

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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 g $\pm$ 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
Mikroorganizm:	<i>Bacillus subtilis</i> ATCC 9372
Bacterial concentration (cfu/ml):	1x10 ⁸
Incubation conditions:	35°C / 24 hours
RESULTS	
Number of Populating Bacteria (cfu)	
1	1
2	2
3	7
4	8
5	12
6 (Control)	0
Total	30
Logarithm	1.47
EVALUATION	
Result	Class (*)
1 < log kob $\leq$ 2	2
<i>* EN 14126: 2003 Protective Clothing - Performance Properties and Test Methods of Protective Clothing Against Infectious Agents are evaluated according to Table-4.</i>	
Sınıf	Penetrasyon (log kob)
3	≤ 1
2	1 < log kob $\leq$ 2
1	2 < log kob $\leq$ 3
<i>* EN 13795-1:2019 Surgical gowns and drapes - Requirements and test methods are evaluated according to Table-1.</i>	
RESULT	
Result (cfu/g)	Expected Value
30	≤ 300 cfu/g

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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 (*);

TENSILE STRENGTH; EN 29073-3:1996 (*)

Instron 5969 (Load: 50 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 weft and warp direction of five samples
Performed in the conditioned room (20 $\pm$ 2°C-65% $\pm$ 4).

Dry ;

	<u>RESULT</u>	<u>REQUIREMENT</u>
Weft	51.1 N	$\geq$ 20N (Dry)
Warp	83.3 N	$\geq$ 20N (Dry)

TENSILE STRENGTH; EN 29073-3:1996 (*)

Instron 5969 (Load: 50 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 weft and warp direction of five samples
Performed in the conditioned room (20 $\pm$ 2°C-65% $\pm$ 4).

Wet ;

	<u>RESULT</u>	<u>REQUIREMENT</u>
Weft	53.4 N	$\geq$ 20N (Wet)
Warp	88.0 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).

	<u>RESULT</u>	<u>REQUIREMENT</u>
Dry ;	155.7 kPa	$\geq$ 40 kPa (Dry)
Height at Burst*	11.6 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

SOL ATLAS M229 tester. Test area: 30.5 mm diameter

Rate of increase in volume; 45.2 cm³/min.

The average results are given offive samples.

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

	<u>RESULT</u>	<u>REQUIREMENT</u>
Wet;	154.5 kPa	;; 40 kPa (Wet)
Height at Burst*	11.7 mm	

WATER PERMEABILITY; ISO 811:2018

Hydrostatic Head Tester, Textest marka Fx 3000 model

Temperature of water 20°C. Pressure increase ratio 10 mbar/min.

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

	<u>RESULT</u>	<u>REQUIREMENT</u>
Sample 1	224.4 cmSS	;; 20cmSS
Sample 2	231,5 cmSS	
Sample 3	226,4cmSS	
Sample 4	196,8 cmSS	
Sample 5	224,4 cmSS	
Average	220,7 cmSS	


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TEST RESULTS

Test Method: BS EN 2261 O: 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):	1-4x10 ⁴ kob/ml
Incubation Conditions:	(36 ± 1) °C 48 hours

RESULTS

Breakthrough time, t min	Number of Populating Bacteria (cfu)		Penetration Rate	
15	X1	0	RcuM1	0
30	X2	0	RcuM2	0
45	X3	0	RcuM3	0
60	X4	35	RcuM4	0.06
75	Xs	49	RcuMs	0.15
	Z	457		
	T			541

X1 XS: 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 + X_s + Z

$RcuM1 = X1/T$

$RcuM2 = (X2 + X1)/T$

$RcuM3 = (X3 + X2 + X1)/T$

$RcuM4 = (X4 + X3 + X2 + X1)/T$

$RcuMs = (Xs + X4 + X3 + X2 + X1)/T$

EVALUATION

Result	Class (*)
45 < t :s; 60	4

(") BS EN 14126:2003 Protective Clothing-Performance requirements and test methods for protective clothing against infective agents

Class	Breakthrough time, t min
6	t > 75
5	60 < t :s; 75
4	45 < t :s; 60
3	30 < t :s; 45
2	15 < t :s; 30
1	:15min

TEST REPORT

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REPORT NUMBER : TURT200077690
APPLICANT NAME : Su Biyomedikal Sistemler ve Sağlık Hiz. San. ve Tic. Ltd.Şti.
ADDRESS : Orhangazi Mh. 1673 Sk. No:20 K:2-3 Esenyurt İstanbul / TURKEY
TEL:0212 320 37 53
Attention : Burcu Yılmaz (burcu.yilmaz@submed.com.tr)
BUYER Medical
SAMPLE DESCRIPTION : One sample of blue coated non-woven gown
DATE IN : 22 June ,2020 (08:12:00)
DATE OUT : 5 August ,2020
END USE : SURGICAL GOWN
REFERENCE : MEDICAL GOWN
FIBER COMPOSITION : Not Given
PROVIDED CARE LABEL : Not Given

TEST	SAMPLE
Lint And Other Particles Generation In The Dry State (±)	1
	P

P = MEETS BUYER' S REQUIREMENT / F = DOES NOT MEET BUYER' S REQUIREMENT / NR = NO REQUIREMENT / SC=STILL CONTINUES / X=NOT PERFORMED / NA = NOT APPLICABLE / LS = LACK OF SAMPLE / NC = NO COMMENT / I = INCONCLUSIVE / # = SEE RESULT / NF = NEEDS FURTHER TESTING / A = ABSENT / M = MARGINAL ACCEPT / SD = SEE DETAILS ENCLOSED / FS: FURTHER STEPS

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Asli EGILMEZ
Customer Care Executive

İsmail AVCIOĞLU
Textile Laboratory Assistant
Manager

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Esenyurt/İST. Esenyurt V.D. 7821159861

Intertek Test Hizmetleri A.S.
Merkez Mahallesi Sanayi Cad. No.23 Altındag Plaza Yenibosna-34197 /İSTANBUL
Phone : +90 212 496 46 46 Fax: +90 212 452 80 55
e-mail : intertekcg.turkiye@intertek.com
<http://www.intertek-turkey.com>



200077690

RESULTS
REPORT :TURT200077690

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Medical

Test Method	Results	Requirements
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Lint And Other Particles Generation In The Dry State (‡)

EN ISO 9073-10:2004 Idt ISO 9073-10:2003
EN ISO 9073-10:2004, Size Of Particles Counted: 3µm~25µm

Material

Coefficient Of Linting log ₁₀		Requirement
A: Face		Coefficient Of Linting log ₁₀ ≤4.0 *
1	2.1	
2	2.4	
3	2.3	
4	-	
5	-	
B: Face		
1	2.1	
2	2.5	
3	2.4	
4	-	
5	-	

(‡)The test was subcontracted to Intertek UK

* Client Requirement

Remark: Test according to client requirement when sample is not enough.

R E S U L T S

REPORT :TURT200077690

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END OF TEST REPORT

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Intertek Test Hizmetleri A.Ş.
Merkez Mahallesi Sanayi Cad. No.23 Altındag Plaza Yenibosna-34197 /İSTANBUL
Phone : +90 212 496 46 46 **Fax:** +90 212 452 80 55
e-mail : intertekcg.turkiye@intertek.com
<http://www.intertek-turkey.com>