QUALITY CERTIFICATION

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EASY & SAFE

SU BIYOMEDIKAL SISTEMLER VE SAGLIK HIZMETLERI SAN. TIC. LTD. STI.

Contact Information : Orhangazi mah. 1673. Sok. No:20/ 2-3 Esenyurt Istanbul Turkey
İletişim Bilgileri
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 : Surgical Drapes
Ürün Tanımı

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 amented 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 : MEDICAL DEVICES DIRECTIVE 93/42/EEC
Geçerli AT Direktifleri *TIBBİ CİHAZLAR DİREKTİFİ 93/42/EEC*

Applicable National Technical Standards and Specifications
Uygulanabilir Ulusal Teknik Standartlar ve Özellikler

Classification/ *Sını£andırma* : CLASS I / Is
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 : Istanbul, 06.08.2020
Name : Yusuf Yiğit Akkuş
Position : General Manager

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

Digitally signed by Chirtoacă Iurie
Date: 2021.12.20 18:05:43 EET
Reason: MoldSign Signature
Location: Moldova

CE

SUMMARY OF TEST REPORTS

SU BIYOMEDIKAL SISTEMLER VE SAGLIK HIZMETLERI SAN. TIC. LTD. STI.

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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 : 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 perfomance 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 Stregth / Dry	Pass	EN 29073-3 : 1996	20020444-ing
Tensile Stregth / 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
Resitance 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.

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

Test
TS EN ISO/IEC 17025
AB-0583-T

TEST REPORT
DENEY RAPORU

20020444-ing

07-20

Customer name:	SU BİYOMEDİKAL 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 oftest item:	üne sample of blue non-woven gown and drape (Claimed to be; Color Code: Blue)
The date ofreceipt oftest item:	22.06.2020
Re-submittedlre-confirmation date:	-
Date oftest:	22.06.2020-01.07.2020
Remarks:	-
Sampling:	The results given in this report belong to the received sample by vendor.
End-Use:	-
Care Label:	-
Number ofpages ofthe report:	7

Gen.f136-2/03

TESTED BY Seal EKOTEKS TESTİR

Date	***Customer Representative***	***Head of Testing Laboratory***
01.07.2020	Hatice ACARALP	Sevim AKAZAK 01.07.2020

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20020444-ing
07-20

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: Orı gı nal samples are kepi for 3 months and ali technıcal records are kepi for 5 years unlcss olherwısc specıficd.If rcqucst♦d• measuremenl uncertainty will be reported. But unless olherwise spccified, measurement uncertainty is not considered while stating compliancc with specification or limit values The rcported uncertainty is based on a standard unccrtainty multiplicd by a coverage factor k=2, providing a level of confidence of approximately 95 %. Tesis marked (*) in this report are not included in the accreditation schcdulc.

Gen.fl36-2/03

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20020444-ing
07-20

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.

Gen.f136-2/03

	RESULTS	REQUIREMENT
Microbial cleanliness (cfu/100 cm²)	102 cfu/100 cm²	≤300 cfu/100 cm²

***cfu= Colony forming unit.**

20020444-ing
07-20

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	1
2	2
3	7
4	8
5	12
6 (Control)	0
Total	30
Logarithm	1.47

EVALUATION	
Result	**Class (*)**
1 < log kob ≤ 2	2

** 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**
30	≤300 cfu/g

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07-20

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	51.1 N	≥ 20N (Dry)
Warp	83.3 N	≥ 20N (Dry)

Gen.f136-2/03

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	53.4 N	≥ 20N (Wet)
Warp	88.0 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 ;	155.7 kPa	≥ 40 kPa (Dry)
Height at Burst*	11.6 mm	

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20020444-ing
07-20

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 ofincrease in volume; 45.2 cm^3/min.
The average results are given offive samples.
Performed in the conditioned room (20±2°C-65%±4).

	RESULT	REQUIREMENT
Wet;	154.5 kPa	;:: 40 kPa (Wet)
Height at Burst*	11.7 mm	

Gen.f136-2/03

WATER PERMEABILITY; ISO 811:2018

Hydrostatic Head Tester, Textest marka Fx 3000 model
Temperature ofwater 20°C. Pressure increase ratio I O mbar/min.
Performed in the conditioned room (20±2°C-65%±4)

	RESULT	REQUIREMENT
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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20018421-ing
06-20

TEST RESULTS

Test Method: BS EN 2261 O: 2006 (Surgical drapes, garments and fresh air clothes used as medical devices tor patients, hospital staff and equipment - Test method tor 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 ali parts are fıxed on the disk. A fınger is placed on the test sample to apply a certain torce (3N ± 0.02). The fınger moves on the test sample over the entire surface of the agar within 15 minutes. 5 studies are carried out tor 15 mınutes. 6 The studıy ıs repeated b,y ınvertınçı the sample.

Samole amount:	5 pieces 25x25cm2
Carrier Material:	30 µm thin, 25x25cm2 Polyurethane Film
Coatin2: Material:	25x25cm2 HDPE Film
Microor2:anism:	Staphylococcus aureus ATCC 29213
Bacterial Concentration (kob / mi):	I-4xI04kob/ml
Incubation Conditions:	(36 ± 1) ° C 48 hours

RESULTS

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

X1 ..... XS: Number of colonies growing in 5 para/le/ petri in the same samp/e
Z: number of co/onies growing in the sixth petri dish
T: X, + X_2 + X_J + X, + Xs + Z

RcuMı = X1/T

RcuM2 = (X2 + X1)/T

RcuMJ = (X3 + X2 + X1)/T

RcuM< = (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 tesis methods for protective clothing against infective aoents

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	:515min

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TEST REPORT

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

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

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 Altindag Plaza Yenibosna-34197 /ISTANBUL
Phone : **+90 212 496 46 46** ***Fax:*** **+90 212 452 80 55**
e-mail : intertekcg.turkiye@intertek.com
http://www.intertek-turkey.com

200077690

Test Method	Results	Requirements

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.

Intertek Test Hizmetleri A.S.
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Phone : **+90 212 496 46 46** ***Fax:*** **+90 212 452 80 55**
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http://www.intertek-turkey.com

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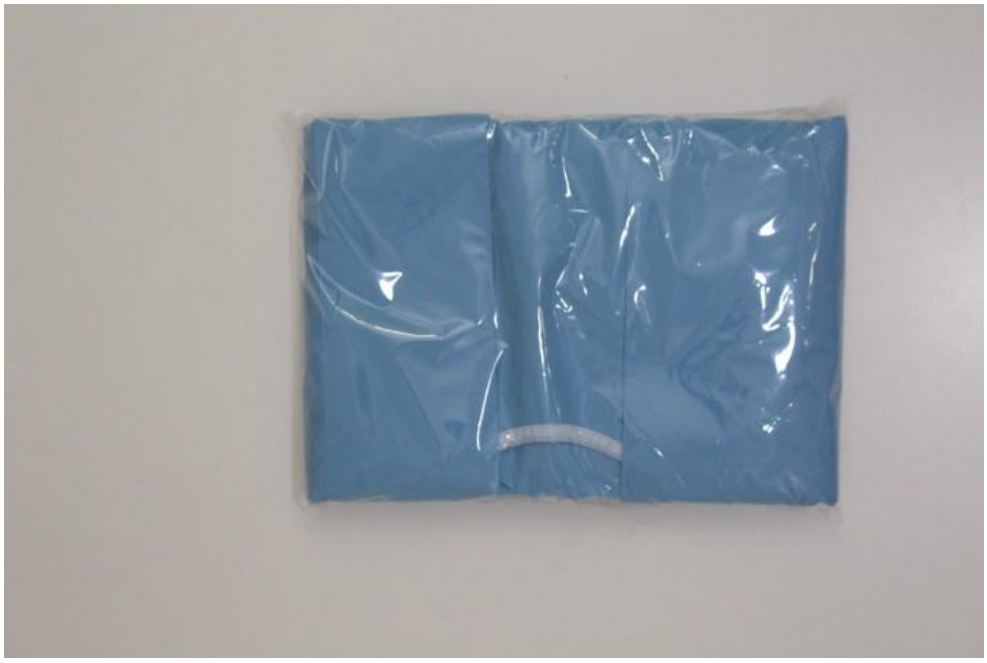

END OF TEST REPORT

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