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 GOWN
Ürün Tanımı *CERRAHİ ÖNLÜK*

Product Reference Numbers : NG-001-1 / NG-001-2 / NG-001-3 / NG-001-4 / NG-001-5 / NG-001-6
Ürün Referans Numaraları
NG-002-1 / NG-002-2 / NG-002-3 / NG-002-4 / NG-002-5 / NG-002-6
NG-003-1 / NG-003-2 / NG-003-3 / NG-003-4 / NG-003-5 / NG-003-6
NG-004 / NG-005-1 / NG-005-2 / NG-005-3 / NG-006-1 / NG-006-2
NG-006-3
SG-001-1 / SG-001-2 / SG-001-3 / SG-001-4 / SG-001-5 / SG-001-6
SG-002-1 / SG-002-2 / SG-002-3 / SG-002-4 / SG-002-5 / SG-002-6
SG-003-1 / SG-003-2 / SG-003-3 / SG-003-4 / SG-003-5 / SG-003-6
SG-004 / SG-006-1

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

Digitally signed by Tutunaru Diana
Date: 2021.09.08 09:01:04 MSK
Reason: MoldSign Signature
Location: Moldova

Classification/ *Sınıflandırma* : Class IIb
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

CE

SUMMARY OF TEST REPORTS

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

Contact Information : Orhangazi mah. 1673. Sok. No:20/ 2-3 Esenyurt Istanbul 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 : Surgical Gown

Product Specifications : Blue Nonwoven Gown

We can confirm that:
The mentioned medical devices (gowns) 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.

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
Water Permeability	Pass	EN ISO 811 : 2018	20020444-ing
Particle release	Pass	EN ISO 9073-10 : 2004	TURT200077690

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

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

TEST REPORT
DENEY RAPORU

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

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
Name and identity of test item:	One sample of blue non-woven gown (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:	-
Sampling:	The results given in this report belong to the received sample by vendor.
End-Use:	-
Care Label:	-
Number of pages of the report:	7

Seal	*Date*	*Customer Representative*	*Head of Testing Laboratory*
TESTED BY EKOTEKS TEST EDİLMİŞTİR	01.07.2020	Hatice ACARALP	Sevim A. RAZAK 01.07.2020

Gen.f136-2/03

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: 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.

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 cm^2)	102 cfu/100 cm^2	≤300 cfu/100 cm^2

***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

Gen.f136-2/03

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 (*);

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)

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	

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
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 ;	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)

	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	

20018421-ing
06-20

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

Breakthrough time, *t* min	Number of Populating Bacteria (cfu)		Penetration Rate	
15	X_1	0	R_{CUM1}	0
30	X_2	0	R_{CUM2}	0
45	X_3	0	R_{CUM3}	0
60	X_4	35	R_{CUM4}	0.06
75	X_5	49	R_{CUM5}	0.15
	Z	457		
	T	541		

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: $X_1 + X_2 + X_3 + X_4 + X_5 + Z$

$R_{CUM1} = X1/T$

$R_{CUM2} = (X2 + X1)/T$

$R_{CUM3} = (X3 + X2 + X1)/T$

$R_{CUM4} = (X4 + X3 + X2 + X1)/T$

$R_{CUM5} = (X5 + X4 + X3 + X2 + X1)/T$

EVALUATION

Result	Class (*)
45 < *t* ≤ 60	4

(*) BS EN 14126:2003 Protective Clothing —Performance requirements and tests methods for protective clothing against infective agents

Class	Breakthrough time, *t* min
6	*t* > 75
5	60 < *t* ≤ 75
4	45 < *t* ≤ 60
3	30 < *t* ≤ 45
2	15 < *t* ≤ 30
1	≤ 15 min

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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http://www.intertek-turkey.com

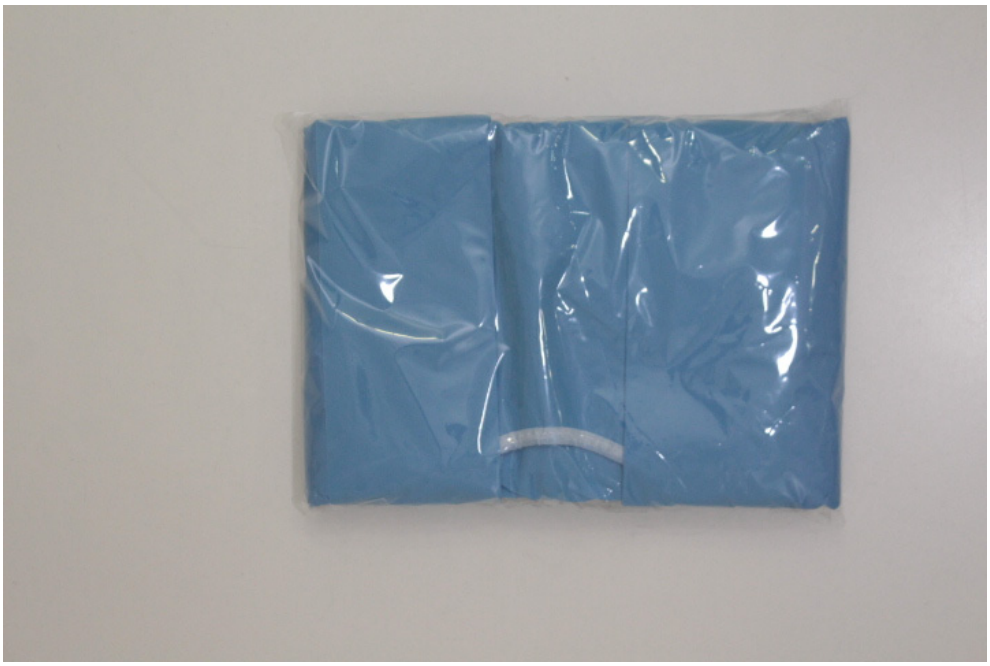
Test Method	Results	Requirements

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.



END OF TEST REPORT

Intertek Test Hizmetleri A.S.
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