CERTIFICATE

EC Certificate

Production Quality Assurance System according to Medical Devices Directive 93/42/EEC Annex-V

Certificate Number: 1984-MDD-14-266

We hereby declare that an examination has been carried out following the requirements of the national legislation to which the undersigned is subject, transposing Annex-V of the Directive 93/42/EEC on medical devices. We certify that the production quality system conforms with the relevant provisions of the aforementioned legislation.

Organization:

[redacted]

Products: Sterile Surgical Gowns and drapes sets, Sterile dialysis set, Sterile catheter set, Sterile Drapes and Sterile procedure sets

The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

Report Number: M.4092.07
Date of first issue: 22 January 2014
Date of last issue: 01 June 2020
Revision Number: 06
Expiry Date: 27 May 2024

Kiwa Belgelendirme Hizmetleri A.Ş. has audited the quality system restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions in accordance with MDD Annex V and found that the quality system meets the applicable requirements in MDD Annex V for Class Is devices covered by this certificate.

01 June 2020, [redacted]

Muhteşem Gökhan Yücel
Head of Notified Body

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, İstanbul, Turkey
Tel.: +90 216 593 25 75 , Fax: +90 216 593 25 74
Web: www.kiwa.com.tr , e-mail: posta@kiwa.com

CERTIFICATE

AT Sertifikası

Üretim Kalite Güvence Sistemi

Tıbbi Cihaz Yönetmeliği 93/42/AT Ek-V

Sertifika Numarası: 1984-MDD-14-266

Aşağıda bahsi geçen kuruluşun üretim kalite güvence sistemine ait incelemesinin, tıbbi cihazlara dair 93/42/AT yönetmeliği Ek-V gereksinimlerine göre yapıldığını beyan ederiz. Üretim kalite güvence sisteminin yukarıda bahsi geçen yönetmeliğin ilgili koşullarına uygunluğunu tasdik ederiz.

Kuruluş:

[redacted]

Ürünler: Steril Cerrahi Örtü ve Önlükler, Steril diyaliz set, Steril kateter set, Steril Cerrahi Örtü ve Steril işlem setleri

Sertifika son kullanma tarihine kadar geçerli olup periyodik gözetim denetimlerinin başarı ile tamamlanmasına tabidir. Detaylar için lütfen Kiwa Belgelendirme Hizmetleri'ne başvurunuz.

Rapor No:	M.4092.07
İlk Yayım Tarihi:	22 Ocak 2014
Son Yayım Tarihi:	01 Haziran 2020
Revizyon Numarası:	06
Son Geçerlilik Tarihi:	27 Mayıs 2024

Bu sertifika kapsamında olan Sınıf Is ürünler için Kiwa Belgelendirme Hizmetleri A.Ş., Tıbbi Cihaz Yönetmeliği Ek V'e uygun olarak steril şartların güvence altına alınması ve muhafaza edilmesi ile ilgili üretim yönleriyle sınırlı olan kalite sistemini denetlemiş ve kalite sisteminin Tıbbi Cihaz Yönetmeliği Ek V'deki uygulanabilir şartları karşıladığını tespit etmiştir.

[redacted]

Muhteşem Gökhan Yücel
Onaylanmış Kuruluş Başkanı

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, İstanbul, Türkiye
Tel.: +90 216 593 25 75 , Faks: +90 216 593 25 74
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CERTIFICATE

kiwa

SU BİYOMEDİKAL SİSTEMLER VE SAĞLIK HİZMETLERİ SANAYİ VE TİCARET LİMİTED ŞİRKETİ

[redacted]

STERİL VE NON-STERİL TEK KULLANIMLIK UYGULAMA SETLERİ (KATETER BAKIM SETİ, HEMODİYALİZ GİRİŞ ÇIKIŞ SETİ, CERRAHİ ÖRTÜ VE ÖNLÜKLER, CERRAHİ ÖRTÜ VE İŞLEM SETLERİ) ÜRETİMİ, DAĞITIMI

kapsamında

EN ISO 13485:2016

Tıbbi Cihazlar - Kalite yönetim sistemleri – Düzenleyici amaçlar için gereklilikler

"Standardın aşağıda verilen maddeleri hariç tutulmuştur"
"7.5.3" "7.5.4" "7.5.9.2"

Sertifika No	: M 9902
İlk Belgelendirme Tarihi	: 21 Temmuz 2014
Sertifika Tarihi	: 17 Ocak 2020
Son Geçerlilik Tarihi	: 16 Ocak 2023

Genel Müdür

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cadde No. 15 Tepeören Tuzla - İstanbul - Türkiye
Tel: + 90 216 593 25 75 Faks : + 90 216 593 25 74
Web: www.kiwa.com.tr E-mail: info@kiwa.com.tr

Sertifikalar periyodik ara denetimlerin başarılı ile tamamlanması kaydıyla geçerlidir.
Detaylı bilgi için yukarıdaki numaralara başvurulabilir.

Sertifika Son Güncelleme Tarihi : 17 Ocak 2020 - R 05

TÜRKAK
Medikal Cihazlar K.Y.S.
TS EN ISO/IEC 17021-1
AB-0006-YS

TÜRKAK BDS NO
YS-8CD8-8A99

CERTIFICATE

kiwa

SU BİYOMEDİKAL SİSTEMLER VE SAĞLIK HİZMETLERİ SANAYİ VE TİCARET LİMİTED ŞİRKETİ

[redacted]

with a scope of

MANUFACTURING AND DISTRIBUTION OF STERILE AND NON-STERILE SINGLE USE PROCEDURE SETS (CATHETER SETS, HEMODIALYSIS CONNECTION & DISCONNECTION SETS, SURGICAL DRAPES AND GOWNS, SURGICAL DRAPE AND OPERATION SETS)

Medical devices - Quality management systems - Requirements for regulatory purposes

"Following elements of the standard are excluded"
"7.5.3" "7.5.4" "7.5.9.2"

EN ISO 13485:2016

Certificate No	: M 9902
Initial Certification Date	: 21 July 2014
Certification Date	: 17 January 2020
Expiration Date	: 16 January 2023

General Manager

Kiwa Certification Services Inc.
ITOSB 9. Cadde No. 15 Tepeören Tuzla - İstanbul - Turkey
Tel: + 90 216 593 25 75 Faks : + 90 216 593 25 74
Web: www.kiwa.com.tr E-mail: info@kiwa.com.tr

Certificate is valid till expiration date, subject to successful completion of periodical surveillance audits.
Please contact above numbers for detailed information.

Last Modified: 17 January 2020 - R 05

TÜRKAK
Medical Device Q.M.S.
15 EN ISO/IEC 17021-1
AB-0006-YS
TÜRKAK BDS NO
YS-8CD8-8A99

UYGUNLUK BEYANI

Bölüm No	TD-07/5.2-Tr
Rev. Tarihi	07.05.2020
Rev. No	03
Sayfa No	1 / 1

Üretici Adı : [redacted]
Adres : [redacted]
Tel [redacted] **Faks** : [redacted]
Web [redacted] **E-mail** [redacted]

ÜRÜN GRUBU	ÜRÜN REFERANS NO	ÜRÜN ADI	GMDN KODU	SINIF
EASY Cerrahi Önlükler	NG-001-1	Standart Cerrahi Önlük, S	35091	Sınıf 1
	NG-001-2	Standart Cerrahi Önlük, M	35091	Sınıf 1
	NG-001-3	Standart Cerrahi Önlük, L	35091	Sınıf 1
	NG-001-4	Standart Cerrahi Önlük, XL	35091	Sınıf 1
	NG-001-5	Standart Cerrahi Önlük, XXL	35091	Sınıf 1
	NG-001-6	Standart Cerrahi Önlük, XXXL	35091	Sınıf 1
	NG-002-1	Takviyeli Cerrahi Önlük, S	35091	Sınıf 1
	NG-002-2	Takviyeli Cerrahi Önlük, M	35091	Sınıf 1
	NG-002-3	Takviyeli Cerrahi Önlük, L	35091	Sınıf 1
	NG-002-4	Takviyeli Cerrahi Önlük, XL	35091	Sınıf 1
	NG-002-5	Takviyeli Cerrahi Önlük, XXL	35091	Sınıf 1
	NG-002-6	Takviyeli Cerrahi Önlük, XXXL	35091	Sınıf 1
	NG-003-1	Tam Takviyeli Cerrahi Önlük, S	35091	Sınıf 1
	NG-003-2	Tam Takviyeli Cerrahi Önlük, M	35091	Sınıf 1
	NG-003-3	Tam Takviyeli Cerrahi Önlük, L	35091	Sınıf 1
	NG-003-4	Tam Takviyeli Cerrahi Önlük, XL	35091	Sınıf 1
	NG-003-5	Tam Takviyeli Cerrahi Önlük, XXL	35091	Sınıf 1
	NG-003-6	Tam Takviyeli Cerrahi Önlük, XXXL	35091	Sınıf 1
	NG-004	Ekstra Takviyeli Cerrahi Önlük	35091	Sınıf 1
	NG-005-1	Hasta Önlüğü, Manşetsiz, 30 gr/m^2	35091	Sınıf 1
	NG-005-2	Hasta Önlüğü, Manşetsiz, 35 gr/m^2	35091	Sınıf 1
	NG-005-3	Hasta Önlüğü, Manşetsiz, 40 gr/m^2	35091	Sınıf 1
	NG-006-1	Hasta Önlüğü, Manşetli, 30 gr/m^2	35091	Sınıf 1
	NG-006-2	Hasta Önlüğü, Manşetli, 35 gr/m^2	35091	Sınıf 1
	NG-006-3	Hasta Önlüğü, Manşetli, 40 gr/m^2	35091	Sınıf 1
	NG-007	Muayene Önlüğü	35091	Sınıf 1

Sınıflandırma : Sınıf I (steril olmayan)
Uygunluk Değerlendirme : Ek VII

Yukarıda belirtilen ürünler Tıbbi Cihaz Direktifi 93/42/EEC ile 2007/47/EC Avrupa Parlamento ve Konsey Direktifi Hükümlerine uygun olduğunu beyan ederiz.

Şehir, Tarih : **İstanbul,07.05.2020**

İsim : **Yusuf Yiğit Akkuş**

Görev : **Genel Müdür**

İmza, Kaşe

SU BİYOMEDİKAL SİSTEMLER VE SAĞLIK HİZMETLERİ SAN. VE TİC. LTD. ŞTİ.
Orhangazi Mahallesi [illegible] Sokak No:20/2-3
Esenyurt / İST. Ts.No: [illegible] Tel: 0212 320 37 53
Fax: 0212 320 53 51 Beşyüzlü Kurumlar V.D.: [illegible]
Mersis No: [illegible]

UYGUNLUK BEYANI

Bölüm No	TD-06/5.2-Tr
Rev. Tarihi	28.04.2020
Rev. No	10
Sayfa No	1 / 1

Üretici Adı : [redacted]d. Şti.
Adres [redacted]
Tel [redacted] **Faks** : [redacted]
Web : [redacted] **E-mail** : [redacted]

ÜRÜN GRUBU	ÜRÜN REFERANS NO	ÜRÜN ADI	GMDN KODU	SINIF
EASY Cerrahi Önlükler	SG-001-1	Standart Cerrahi Önlük, S	35091	Sınıf 1s
	SG-001-2	Standart Cerrahi Önlük, M	35091	Sınıf 1s
	SG-001-3	Standart Cerrahi Önlük, L	35091	Sınıf 1s
	SG-001-4	Standart Cerrahi Önlük, XL	35091	Sınıf 1s
	SG-001-5	Standart Cerrahi Önlük, XXL	35091	Sınıf 1s
	SG-001-6	Standart Cerrahi Önlük, XXXL	35091	Sınıf 1s
	SG-002-1	Takviyeli Cerrahi Önlük, S	35091	Sınıf 1s
	SG-002-2	Takviyeli Cerrahi Önlük, M	35091	Sınıf 1s
	SG-002-3	Takviyeli Cerrahi Önlük, L	35091	Sınıf 1s
	SG-002-4	Takviyeli Cerrahi Önlük, XL	35091	Sınıf 1s
	SG-002-5	Takviyeli Cerrahi Önlük, XXL	35091	Sınıf 1s
	SG-002-6	Takviyeli Cerrahi Önlük, XXXL	35091	Sınıf 1s
	SG-003-1	Tam Takviyeli Cerrahi Önlük, S	35091	Sınıf 1s
	SG-003-2	Tam Takviyeli Cerrahi Önlük, M	35091	Sınıf 1s
	SG-003-3	Tam Takviyeli Cerrahi Önlük, L	35091	Sınıf 1s
	SG-003-4	Tam Takviyeli Cerrahi Önlük, XL	35091	Sınıf 1s
	SG-003-5	Tam Takviyeli Cerrahi Önlük, XXL	35091	Sınıf 1s
	SG-003-6	Tam Takviyeli Cerrahi Önlük, XXXL	35091	Sınıf 1s
	SG-004	Ekstra Takviyeli Cerrahi Önlük	35091	Sınıf 1s

Uygunluk Değerlendirme Yolu: Ek V

İlgili Standart Bilgileri: EN ISO 13485, EN ISO 9001, EN ISO 11135, EN ISO 14971

Yukarıda belirtilen ürünlerin 93/42/EEC Medikal Cihazlar Kararnamesinin 2007/47/EC güncellemeleri de dahil gerekliliklerini karşıladığını ve ürünlerle ilgili tüm sorumluluğun tarafımızda olduğunu beyan ederiz.

Onaylanmış Kurum : KIWA Belgelendirme Hizmetleri A.Ş.
Adres : İstanbul Tuzla Organize Sanayi Bölgesi (İTOSB) Eski Ankara Asfaltı Orhanlı, 34957 Tepeören - İstanbul TURKİYE
Onaylanmış Kurum Kimlik Numarası : 1984
CE Belgesi Sertifika Numarası : 1984-MDD-14-266

Şehir, Tarih : **İstanbul, 28.04.2020**

İsim : **Yusuf Yiğit Akkuş**

Görev : **Genel Müdür**

İmza, Kaşe

SU BİYOMEDİKAL SİSTEMLER VE SAĞLIK HİZMETLERİ SAN. VE TİC. LTD. ŞTİ.
Orhangazi Mahallesi [illegible]
Esenyurt / İST. Tel: 0212 320 37 53
Fax: 0212 320 63 51 Beylikdüzü Kurumlar V.D.: [illegible]
Mersis No: [illegible]

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

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

TEST REPORT
DENEY RAPORU

20020444-ing

07-20

Customer name:	[redacted]
Address:	[redacted]
Buyer name:	-
Contact Person:	[redacted]
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

TESTED BY EKOTEKS TEST EDİLMİŞTİR

Seal	*Date*	*Customer Representative*	*Head of Testing Laboratory*
	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.

Gen.fl36-2/03

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 (*);

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

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)

Gen.fl 36-2/03

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	

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	

Gen.f136-2/03

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	

0020444-ing
07-20

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

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

TEST REPORT
DENEY RAPORU

20018421-ing
06-20

Customer name:	[redacted]
Address:	
Buyer name:	-
Contact Person:	BURCU YILMAZ
Order No:	-
Article No:	SURGICAL GOWN
Name and identity of test item:	One sample of coated blue non-woven gown . (Claimed to be; Color Code: Blue , Surgical Gown)
The date of receipt of test item:	09.06.2020
Re-submitted/re-confirmation date:	-
Date of test:	09.06.2020-17.06.2020
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:	8

Seal	*Date*	*Customer Representative*	*Head of Testing Laboratory*
	17.06.2020	Hatice AÇARALP	Sevim A. RAZAK 17.06.2020

Gen.f136-2/03

20018421-ing
06-20

REQUIRED TESTS	RESULT	COMMENTS
PHYSICAL PROPERTIES TESTS		
Abrasion	-	Class 6
Water Permeability	-	Class 6
Tear Strength	-	Class 2
Tensile Strength	-	Class 1
Repellency to Liquids	-	Class 2
Resistance To Penetration By Liquids	-	Class 3
Seam Strength	-	Class 3
Puncture Resistance	-	Class 2
MICROBIOLOGICAL TESTS		
Wet-Bacterial Penetration	-	Class 4

P: Pass
F: Fail
R: Refer to retailer technologist
Tests were evaluated and classified according to BS EN 14325:2018 limit values.

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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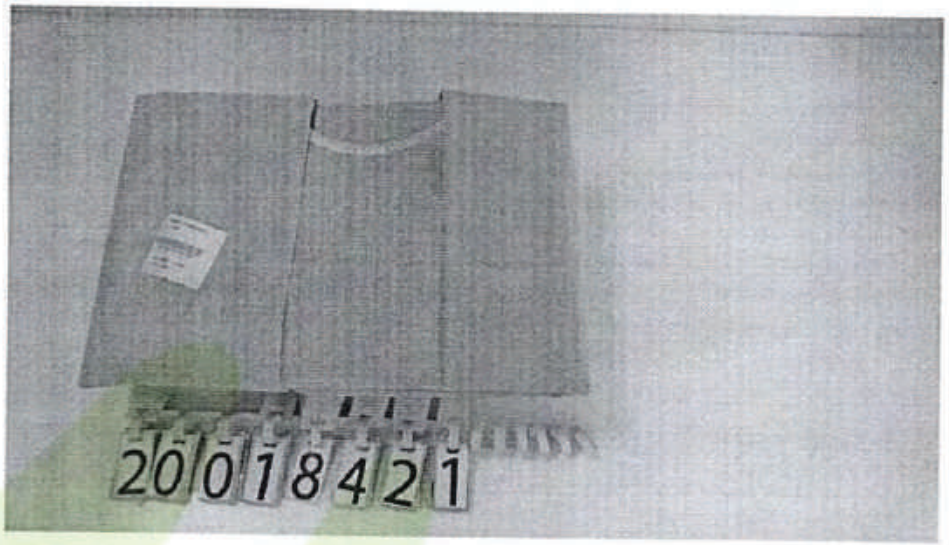

20018421-ing
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TEST RESULTS

Test Method : BS EN 14325:2018 (PROTECTIVE CLOTHING AGAINST CHEMICALS:TEST METHODS AND PERFORMANCE CLASSIFICATION OF CHEMICAL PROTECTIVE CLOTHING MATERIALS,SEAMS,JOINS AND ASSEMBLAGES (*)

ABRASION RESISTANCE AND LEAK TIGHTNESS

Clause 4.4.Abrasion Resistance (EN ISO 12947-2) ANNEX-B

Martindale Test Machine (47.5±2 rpm) with Lissajous Figure.
9 kPa pressure,
Performed in the conditioned room (20±2°C-65%±4).

RESULT	CLASS
No abrasion @ 2000 revs	6 Classified according to the Table-1

Determination of the highest number of abrasion rubs which does not cause damage to the material and which shall be used for the performance classification.
The abrasion resistance of sample shall be Classified according to the levels of performance given in Table-1

Table-1 Classification of Abrasion Resistance

Class	*Number of rubs*
6	>2000
5	>1000
4	>400
3	>100
2	>40
1	>10

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Clause 4.4.2.3 Hydrostatic head end –point determination (EN 20811)

If the average hydrostatic head exceeds 200mm,then the hydrostatic head method is applicable and the leak tightness shall be determined.

WATER PERMEABILITY ; EN ISO 811:2018

Hydrostatic Head Tester, Textest marka Fx 3000 model
Temperature of water10.°C. Pressure increase ratio 10 mbar/dk.
Performed in the conditioned room (20±2°C-65%±4)

	RESULT	REQUIREMENT
Sample 1	1876.8 mm SS	>200 mmSS
Sample 2	1632.0 mm SS	
Sample 3	1662.6 mm SS	
Sample 4	1530.0 mm SS	
Average	1668.7 mm SS	

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TEST RESULT

TRAPEZOIDAL TEAR STRENGTH

Clause: 4.7.Trapezoidal Tear Resistance TS EN ISO 9073-4:2002(*)

Instron 5969 Speed:100±10 mm/min, Gauge length:5cm
The average results are given for width and length direction of five samples.
2 pre-tension applied
Performed in the conditioned room. (20±2°C - 65% ±4)

	RESULT	CLASS
Width	30.0 N	1 Classified according to the Table-4
Length	45.8 N	

Table-4 Classification of Trapezoidal Tear Resistance

Class	*Tear Strength*
6	>150 N
5	>100 N
4	>60 N
3	>40 N
2	>20 N
1	>10 N

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TENSILE STRENGTH

Clause 4.9.Tensile Strenght EN ISO 13934-1:2013

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 width and length direction of five samples.
Performed in the conditioned room (20±2°C-65%±4).

	RESULT	CLASS
Width	51.8N	1 Classified according to the Table-5
Length	85.3 N	

Table-4 Classification of Tensile Strenght

Class	*Tensile Strength*
6	>1000 N
5	>500 N
4	>250 N
3	>100 N
2	>60 N
1	>30N

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TEST RESULT

REPELLENCY TO LIQUIDS

Clause 4.12 Repellency to Liquids (EN ISO 6530:2005)

When tested in accordance with EN ISO 6530 for repellency to the liquid chemicals given in Table -9, the material shall be classified According to the levels performance in given Table-10 for each chemical tested.
Use those liquids against which protection is required, water is also cenvenient and safe liquid for general screening purposes.
Performed in the conditioned room (20±2°C-65%±4).
For each test liquid ,cut six test specimens of (360±2)mm by (235±5)mm from the sample.
Chemicals shall be of analytical purity grade.
Discharged the test liquid (10cm 3) within (10±1)s

Table-9 List of reference chemicals for absorption ,penetration and repellency testing

Chemical	*Concentration weight %*	*Temperature of chemical (±2°C)*
Sulfuric Acid (H2SO4)	30	20
Sodium Hydroxide (NaOH)	10	20
o-Xylene	Undiluted	20

Table 10- Classification of Repellency to liquids

Class	*Repellency Index (I_R)*
3	> 90 %
2	>80 %
1	>70 %

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Clause 4.13 Resistance to penetration by liquids (EN ISO 6530)

Table 11- Classification of Resistance to penetration by liquids

Class	*Penetration Index (Ip)*
3	< 1 %
2	< 5 %
1	<10 %

RESULT

Chemical	*Concentration weight %*	I_P	*Class*	I_R	*Class*
Sulfuric Acid (H2SO4)	30	< 1%	3	> 90%	3
Sodium Hydroxide (NaOH)	10	< 1 %	3	> 90%	3
o-Xylene	Undiluted	< 1%	1	> 80%	2

I_P:index of penetration
I_R: index of repellency
I_A: index of absorbtion

* Classification could not be made because the values in the table in the standard are not appropriate.

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TEST RESULT

SEAM STRENGTH-GRAB METHOD

Clause 5.5 Seam Strength ISO 13935-2: 2014
Jaw Speed: 50±5 mm/min, Gauge Length: 100 mm±1 mm.
Seam Type : 301. 100 % Polyester core-spun sewing-thread was used.
5kN. load was applied.
The average results are given for width and length direction of five samples.
Performed in the conditioned room(20±2°C-65%±4)

	Seam Strength (N)	Failure	Requirement
Width	109.8	FTJ	3 Classified according to the Table-13
Length	76.2	FTJ	

FTJ : Fabric Tear At The Jaw

Table 13- Classification of Seam Strength

CLASS	*Seam strength*
6	>500 N
5	>300 N
4	>125 N
3	>75 N
2	>50 N
1	>30 N

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TEST RESULT

PUNCTURE RESISTANCE

Clause 4.10.Puncture Resistance EN 863 (*)

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

The average results are given four samples.

SAMPLE	PUNCTURE RESISTANCE RESULT (N)	REQUIREMENT
1	24.9	2 Classified according to the Table-6
2	26.0	
3	29.3	
4	23.9	
Average Result	26.0	

RESULT **CLASS**

26.0 N

Table-4 Classification of Puncture Resistance
(Tablo-6)

Class	*Puncture Resistance*
6	*>250 N*
5	*>150 N*
4	*>100 N*
3	*>50 N*
2	*>10 N*
1	*>5N*

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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

SQR CERTIFICATION

Sertifika
CERTIFICATE

[redacted]

ISO 9001:2015

Kapsam/Scope

STERİL VE STERİL OLMAYAN TEK KULLANIMLIK ÜRÜNLERİN ÜRETİMİ VE DAĞITIMI (KATETER SETLERİ, HEMODİYALİZ GİRİŞ & ÇIKIŞ SETLERİ, CERRAHİ ÖRTÜLER, OPERASYON SETLERİ, TIBBİ ÖNLÜK VE CERRAHİ MASKELER)

MANUFACTURING AND DISTRIBUTION OF STERILE AND NON-STERILE SINGLE USE PRODUCTS (CATHETER SETS, HEMODIALYSIS CONNECTION & DISCONNECTION SETS, SURGICAL DRAPE AND OPERATION SETS, MEDICAL DRAPES, MEDICAL GOWNS, SURGICAL MASKS)

Bu sertifika ile yukarıda adı geçen kuruluşun Kalite Yönetim Sistemi gerekliliklerini karşıladığı tasdik olunur.

This is to certify that the above mentioned Company meets the requirement of Quality Management System.

Belge NO / Certification Number	: MTS-19032
İlk Kayıt Tarihi / Date of Initial Reg.	: 17.09.2020
Basım Tarihi / Date of Certificate	: 17.09.2020
Geçerlilik Tarihi / Date of Expiry	: 16.09.2021
Yeniden Belgelendirme Tarihi / Date of Recertification	: 16.09.2023

Operasyon Müdürü / Operation Manager

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

IAS ACCREDITED Management Systems Certification Body MSCB-136

SİGMACERT
ULUSLARARASI BELGELENDİRME EĞİTİM VE TEST HİZMETLERİ LTD. ŞTİ.

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TEST REPORT

REPORT NUMBER : TURT200077690
APPLICANT NAME : [redacted]
ADDRESS :
Attention : [redacted]
BUYER
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

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.

END OF TEST REPORT

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