



**TÜRK STANDARDLARI ENSTİTÜSÜ**  
**TÜRK STANDARDLARINA UYGUNLUK BELGESİ**  
**TURKISH STANDARDS INSTITUTION**  
**CERTIFICATE OF CONFORMITY TO TURKISH STANDARDS**

Markanın Tanımı Description of the Mark  
TSE veya or TSE veya or TSE

<b>BELGE NUMARASI</b> REFERENCE NUMBER OF LICENCE	030701-TSE-01/04
<b>BELGENİN İLK VERİLİŞ TARİHİ</b> DATE OF FIRST ISSUE OF LICENCE	08.09.2015
<b>BELGENİN SON GEÇERLİLİK TARİHİ</b> LICENCE VALID UNTIL	08.09.2023
<b>BELGE SAHİBİ KURULUŞUN ADI</b> NAME OF THE LICENCE HOLDER	BAYTEKS TEKNİK TEKSTİL SANAYİ VE TİCARET ANONİM ŞİRKETİ
<b>BELGE SAHİBİ KURULUŞUN ADRESİ</b> ADDRESS OF THE LICENCE HOLDER	BAŞPINAR(ORGANİZE)OSB MAH. O.S.B. 4.BÖLGE 83404 NOLU CAD. NO:15 /0 ŞEHİTKAMİL GAZİANTEP/TÜRKİYE
<b>ÜRETİM YERİ ADI</b> NAME OF THE MANUFACTURING PLACE	BAYTEKS TEKNİK TEKSTİL SANAYİ VE TİCARET ANONİM ŞİRKETİ
<b>ÜRETİM YERİ ADRESİ</b> ADDRESS OF THE MANUFACTURING PLACE	ORGANİZE SAN. BÖL. 19 NOLU CAD.NO:9 KİLİS / TÜRKİYE
<b>İPTAL EDİLEN BELGE NUMARASI (Varsa)</b> INDICATION OF SUPERSEDED LICENCE (if any)	030701-TSE-01/03
<b>TESCİLLİ TİCARİ MARKASI</b> REGISTERED TRADE MARK	BAYMED
<b>İLGİLİ TÜRK STANDARDI</b> RELATED TURKISH STANDARD	TS EN 13795-1 / 30.09.2019
<b>BELGE KAPSAMI</b> SCOPE OF LICENCE	

Cerrahi önlükler, standard performans, tek kullanımlık  
Cerrahi örtüler, standard performans, tek kullanımlık

*e-imzalı/e-signed*

06.09.2022

Belgelendirme Merkezi Başkanı Adına  
HÜSAMETTİN ERBİLGİN

GAZİANTEP BELGELENDİRME MÜDÜR V.

\*Bu belge, belgelendirilen ürünün, üretim yerinin Enstitümüzün belirlediği şartları karşıladığını da gösterir.

\*Bu belge, hiç bir suretle tahrif edilemez, kısmen veya okunmasını zorlaştıracak şekilde çoğaltılamaz, kazıntı ve silinti yapılamaz.

\*TSE GAZİANTEP BELGELENDİRME MÜDÜRLÜĞÜ \* Adres: 2.Organize Sanayi Bölgesi Hacı Sani Konukoglu Bulvarı No:9 Başpınar 27120 Şehitkamil GAZİANTEP \* Telefon: 0 342 337 95 03 (Pbx) \* Faks: 0 342 337 95 08

\*TSE BELGELENDİRME MERKEZ BAŞKANLIĞI: Adres: Necatibey Cad. No:112 06100 Bakanlıklar/ANKARA – Telefon: 0 312 416 64 81 / 416 64 27, Faks:0 312 416 66 17 E-posta :bmb@tse.org.tr , web : www.tse.org.tr





**EKOTEKS**

**EKOTEKS LABORATUVAR ve GÖZETİM  
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*

AB-0583-T

20035727  
-ing

10-20

**Customer name:** BAYTEKS TEKNİK TEKSTİL SAN. VE TİC. A.Ş  
**Address:** -  
**Buyer name:** ORGANİZE SAN. MAH. 19 NOLU CAD. NO:11 MERKEZ /KİLİS  
**Contact Person:** KADİR KARAGÜN  
**Order No:** REF:SG-01222-05 LOT:50815  
**Article No:** PROTECTED SURGICAL APRON  
**Name and identity of test item:** Coated medical blue surgical gown.  
**The date of receipt of test item:** 29.09.2020  
**Re-submitted/re-confirmation date:** -  
**Date of test:** 29.09.2020-12.10.2020  
**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:** 7

*The Turkish Accreditation Agency (TURKAK) is signatory to the multilateral agreements of the European co-operation for the Accreditation (EA) and of the International Laboratory Accreditation (ILAC) for the Mutual recognition of test reports.*

*EKOTEKS LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş. accredited by TÜRKAK under registration number [AB-0583-T] for ISO 17025:2017 as test laboratory.*

*The test and/or measurement results, the uncertainties (if applicable) with confidence probability and test methods are given on the following pages which are part of this report.*

**Seal**

**Date**  
12.10.2020

**Customer Representative**  
Hatice ACARALP

**Head of Testing Laboratory**  
Sevim A. RAZAK

12.10.2020

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**EKOTEKS LABORATUVAR ve GÖZETİM  
HİZMETLERİ A.Ş.**

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REQUIRED TESTS	RESULT	COMMENTS
<b>PHYSICAL PROPERTIES</b>		
Tensile Strength / <b>Dry</b>	P	
Tensile Strength / <b>Wet</b>	P	
Bursting Strength / <b>Dry</b>	P	
Bursting Strength / <b>Wet</b>	P	
Water Permeability	P	
<b>MICROBIOLOGICAL TESTS</b>		
Microbial Cleanliness (Bioburden)	P	
Wet-Bacterial Penetration	P	
Dry-Bacterial Penetration	P	
P: Pass F: Fail R: Refer to retailer technologist. ( <sup>1</sup> )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**

**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 ;**

	<u>RESULT</u>	<u>REQUIREMENT</u>
<b>Weft</b>	72.5 N	≥ 20N (Dry)
<b>Warp</b>	162.8 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 ;**

	<u>RESULT</u>	<u>REQUIREMENT</u>
<b>Weft</b>	75.1 N	≥ 20N (Wet)
<b>Warp</b>	160.1 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<sup>3</sup>/min.  
The average results are given of five samples.  
Performed in the conditioned room (20±2°C-65%±4).

	<u>RESULT</u>	<u>REQUIREMENT</u>
<b>Dry ;</b>	201.4 kPa	≥ 40 kPa (Dry)
<b>Height at Burst*</b>	14.9 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**

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

	<b><u>RESULT</u></b>	<b><u>REQUIREMENT</u></b>
<b>Wet ;</b>	190.2 kPa	≥ 40 kPa (Wet)
<b>Height at Burst*</b>	13.8 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)

	<b><u>RESULT</u></b>	<b><u>REQUIREMENT</u></b>
<b>Sample 1</b>	147.0 cmSS	≥ 100cmSS
<b>Sample 2</b>	150.0 cmSS	
<b>Sample 3</b>	157.2 cmSS	
<b>Sample 4</b>	163.3 cmSS	
<b>Sample 5</b>	160.1 cmSS	
<b>Average</b>	158.6 cmSS	

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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 Metod:** Ref: EN ISO 11737-1:2018 (\*)

The sample is put in extraciton liquid after shaking well, inoculated on the agar.  
After incubation at  $30 \pm 1$  ° C for 72 hours, growth microorganisms are counted on the agar.

	<b><u>RESULTS</u></b>	<b><u>REQUIREMENT</u></b>
<b>Microbial cleanliness (cfu/g)</b>	32 cfu/g	$\leq 300$ cfu/g Type I and Type II mask

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## TEST RESULT

**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 ( $3N \pm 0.02$ ). 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.

<b>Sample amount:</b>	5 pieces 25x25cm2
<b>Carrier Material:</b>	30 µm thin, 25x25cm2 Polyurethane Film
<b>Coating Material:</b>	25x25cm2 HDPE Film
<b>Microorganism:</b>	Staphylococcus aureus ATCC 29213
<b>Bacterial Concentration (kob / ml):</b>	2x104 kob / ml
<b>Incubation Conditions:</b>	(36 ± 1) ° C 48 hours

RESULTS			
Number of Populating Bacteria (cfu)		Penetration Rate	
<b>X<sub>1</sub></b>	<b>0</b>	<b>R<sub>CUM1</sub></b>	<b>0</b>
<b>X<sub>2</sub></b>	<b>0</b>	<b>R<sub>CUM2</sub></b>	<b>0</b>
<b>X<sub>3</sub></b>	<b>0</b>	<b>R<sub>CUM3</sub></b>	<b>0</b>
<b>X<sub>4</sub></b>	<b>0</b>	<b>R<sub>CUM4</sub></b>	<b>0</b>
<b>X<sub>5</sub></b>	<b>0</b>	<b>R<sub>CUM5</sub></b>	<b>0</b>
<b>Z</b>	<b>459</b>		
<b>T</b>		<b>459</b>	
<p><i>X<sub>1</sub> ..... X<sub>5</sub>: Number of colonies growing in 5 parallel petri in the same sample</i>  <i>Z: number of colonies growing in the sixth petri dish</i>  <i>T: X<sub>1</sub> + X<sub>2</sub> + X<sub>3</sub> + X<sub>4</sub> + X<sub>5</sub> + Z</i></p> <p><i>R<sub>CUM1</sub> = X<sub>1</sub>/T</i>  <i>R<sub>CUM2</sub> = (X<sub>2</sub> + X<sub>1</sub>)/T</i>  <i>R<sub>CUM3</sub> = (X<sub>3</sub> + X<sub>2</sub> + X<sub>1</sub>)/T</i>  <i>R<sub>CUM4</sub> = (X<sub>4</sub> + X<sub>3</sub> + X<sub>2</sub> + X<sub>1</sub>)/T</i>  <i>R<sub>CUM5</sub> = (X<sub>5</sub> + X<sub>4</sub> + X<sub>3</sub> + X<sub>2</sub> + X<sub>1</sub>)/T</i></p>			
BARRIER INDEX (I <sub>B</sub> )			
	Result	Expected value (*)	
<b>I<sub>B</sub></b>	<b>6</b>	<b>≥2,8</b>	
<p><i>I<sub>B</sub> = 6 – (CUM1 + CUM2 + CUM3 + CUM4 + CUM5)</i></p> <p><i>* EN 13795-1:2019 Surgical gowns and drapes - Requirements and test methods are evaluated according to Table-1.</i></p>			

**EKOTEKS LABORATUVAR ve GÖZETİM  
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**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.

<b>Sample amount:</b>	6 pieces 20x20 cm <sup>2</sup>	
<b>Mikroorganism:</b>	<i>Bacillus subtilis</i> ATCC 9372	
<b>Bacterial concentration (cfu/ml):</b>	1x10 <sup>8</sup>	
<b>Incubation conditions:</b>	35°C / 24 hours	
<b>RESULTS</b>		
<b>Number of Populationg Bacteria (cfu)</b>		
1		1
2		2
3		1
4		3
5		2
<b>6 (Control)</b>		0
<b>Total</b>		9
<b>Logarithm</b>		0.95
* EN 13795-1:2019 Surgical gowns and drapes - Requirements and test methods are evaluated according to Table-1.		
<b>RESULT</b>		
<b>Result (cfu/g)</b>		<b>Expected Value</b>
9 kob/gr		≤300kob/gr





CERTIFICATE



## BAYTEKS TEKNİK TEKSTİL SANAYİ VE TİCARET A.Ş.

ORGANİZE SANAYİ BÖLGESİ 19 NOLU CAD. NO: 11 MERKEZ - KİLİS - TÜRKİYE

TEK KULLANIMLIK STERİL VE NON-STERİL CERRAHİ ÖNLÜKLERİ, ÖRTÜLERİ VE SET  
ÜRETİMİ, DEPOLAMASI, DAĞITIMI VE SATIŞI

kapsamında

### EN ISO 13485:2016

Uluslararası Tıbbi Cihazlar Kalite Yönetim Sistemi Standardına uygun bir yönetim  
sistemi kurmuştur.

*"Standardın aşağıda verilen maddeleri hariç tutulmuştur"*

*"7.5.3" "7.5.4" "7.5.9.2"*

Sertifika No : M 10892  
İlk Belgelendirme Tarihi : 12 Ocak 2018  
Sertifika Tarihi : 01 Şubat 2021  
Son Geçerlilik Tarihi : 31 Ocak 2024

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  
[info@kiwa.com.tr](mailto:info@kiwa.com.tr)  
[www.kiwa.com.tr](http://www.kiwa.com.tr)

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

Genel Müdür



Sertifika Son Güncelleme Tarihi : 01 Şubat 2021 - R 02



CERTIFICATE



## BAYTEKS TEKNİK TEKSTİL SANAYİ VE TİCARET A.Ş.

ORGANİZE SANAYİ BÖLGESİ 19 NOLU CAD. NO: 11 MERKEZ - KİLİS - TURKEY

**PRODUCTION, STORAGE, DISTRIBUTION AND SALES OF DISPOSABLE STERILE  
AND NON STERILE SURGICAL GOWNS, DRAPES AND SETS**

with a scope of

### EN ISO 13485:2016

Has established a management system in accordance  
with international Medical Devices Quality Management System Standard

*"Following elements of the standard are excluded"*

*"7.5.3" "7.5.4" "7.5.9.2"*

Certificate No	: M 10892
Initial Certification Date	: 12 January 2018
Certification Date	: 01 February 2021
Expiration Date	: 31 January 2024

Kiwa Belgelendirme Hizmetleri A.Ş.  
ITOSB 9. Cadde No. 15 Tepeören Tuzla  
Istanbul / Turkey

Tel: + 90 216 593 25 75  
Faks: + 90 216 593 25 74  
[info@kiwa.com.tr](mailto:info@kiwa.com.tr)  
[www.kiwa.com.tr](http://www.kiwa.com.tr)

General Manager



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



**EKOTEKS LABORATUVAR ve GÖZETİM  
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Esenyurt Firuzköy Bulvarı No:29 34325 Avcılar  
İstanbul/ TÜRKİYE

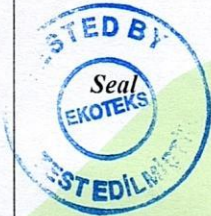
21001832

01-21

**TEST REPORT**  
*DENEY RAPORU*

**Customer name:** BAYTEKS TEKNİK TEKSTİL SAN. TİC. AŞ.  
**Address:** ORGANİZE SANAYİ BÖLGESİ 19 NO'LU CADDE NO:11  
MERKEZ/KİLİS  
**Buyer name:** -  
**Contact Person:** KADİR KARAGÜN  
**Order No:** REF:SG-01222-05/LOT:50815  
**Article No:** PROTECTED SURGICAL GOWN  
**Name and identity of test item:** Blue non-woven gown. (Claimed to be;MEDICAL BLUE)  
**The date of receipt of test item:** 18.01.2021  
**Re-submitted/re-confirmation date:** -  
**Date of test:** 18.01.2021-25.01.2021  
**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:** 3

Gen.f136-2/03



**Date**  
25.01.2021

**Customer Representative**  
Yeşim ŞAHİN

**Head of Testing Laboratory**  
Sevim A. RAZAK  
25.01.2021

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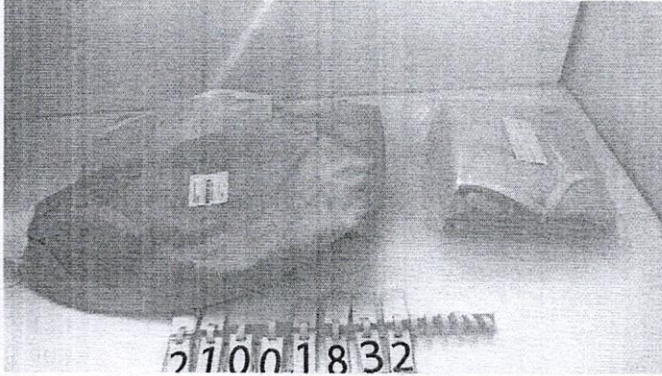
EKOTEKS LABORATUVAR ve GÖZETİM  
HİZMETLERİ A.Ş.

21001832

01-21

REQUIRED TESTS	RESULT	COMMENTS
<b>PHYSICAL PROPERTIES TESTS</b>		
Lint and Other Particles Generation From Nonwoven	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 %. The declaration of conformity was given in accordance with the Simple Acceptance Decision Rule. Tests marked (\*) in this report are not included in the accreditation schedule.



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Gen. fl136-2/03

## TEST RESULTS

### LINT AND OTHER PARTICLES GENERATION FROM NONWOWEN;

**Test Metod:** ISO 9073-10: 2003 (\*)

5 test samples that in cross direction are maintained to twisting and compression action with Gelbo Flex for inner and outer surface in a clean room condition (according to ISO 14644-1 Class 5).

Lint and particles detached from the sample are counted with counter device and classified to size range.

Min. measuring size of SOLAIR 3100 particles measuring device: 0,3 µm.

Max. measuring size of SOLAIR 3100 particles measuring device: 25 µm.

Air flow: 28,3 ± 1,4 L/min

Working mode: 30 s x 10 consecutive periods

SAMPLE, INNER SURFACE (3 µm - 25 µm)		SAMPLE, OUTER SURFACE (3 µm - 25 µm)	
Total linting	: 23	Total linting	: 16
Standard deviation	: 4	Standard deviation	: 7
Coefficient of variation	: 18%	Coefficient of variation	: 46%
Coefficient of linting (CL):	1	Coefficient of linting (CL)	: 1
SAMPLE, MATERIAL (TOTAL)			
Total linting	:39		
Coefficient of linting (CL)*	:2		

\*According to EN ISO EN ISO 13795-1:2019, Coefficient of linting (CL) (log 10) should be ≤4 for analysis of critical product area and less critical product area of both standard performance and high performance testing.



# CERTIFICATE

## EC Certificate

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

Certificate Number: 1984-MDD-18-479

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:**

**BAYTEKS TEKNİK TEKSTİL  
SANAYİ VE TİCARET ANONİM ŞİRKETİ**

Organize Sanayi Bölgesi 19 nolu Cad. No:9 Merkez / Kilis - Turkey

**Products:** Sterile Disposable Surgical Gown, Sterile Disposable Surgical Drapes, Sterile Disposable Surgical Packs

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

**Report Number:** M.5035.03  
**Date of first issue:** 12 January 2018  
**Date of last issue:** 16 September 2020  
**Revision Number:** 03  
**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.

Kiwa Belgelendirme Hizmetleri A.Ş. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number: 1984

Muhteşem Gökhan Yücel  
Head of Notified Body

16 September 2020, Istanbul, Turkey

# Certificate

Standard **ISO 14001:2015**

Certificate Registr. No. **01 104 2115858**

Certificate Holder: **BAYTEKS TEKNİK TEKSTİL SANAYİ VE TİCARET A.Ş.**  
ORGANİZE SANAYİ BÖLGESİ 19 NO'LU CAD. NO:9  
79000 MERKEZ / KİLİS  
Turkey

Scope: Non-woven fabric production, storage, marketing and sales

Proof has been furnished by means of an audit that the requirements of ISO 14001:2015 are met.

Validity: The certificate is valid from 2021-08-23 until 2024-08-22.  
First certification 2021

2021-08-23

  
TÜV Rheinland Cert GmbH  
Am Grauen Stein · 51105 Köln