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  veya/or TSE

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İPTAL EDİLEN BELGE NUMARASI (Varsa) *INDICATION OF SUPERSEDED LICENCE (if any)*	030701-TSE-01/03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

BELGE KAPSAMI
SCOPE OF LICENCE

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

Digitally signed by Granaci Boris
Date: 2023.09.13 15:15:34 EEST
Reason: MoldSign Signature
Location: Moldova

e-imzalı/e-signed

06.09.2022

Belgelendirme Merkezi Başkanı Adına
HÜSAMETTİN ERBİLGİN

GAZİANTEP BELGELENDİRME MÜDÜR V.

*TSE GAZİANTEP BELGELENDİRME MÜDÜRLÜĞÜ * Adres: 2.Organize Sanayi Bölgesi Hacı Sani Konukoğlu 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 LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş.
Esenyurt Firuzköy Bulvarı No:29 34325 Avcılar
İstanbul/ TÜRKİYE

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

EKOTEKS

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***	***Customer Representative***	***Head of Testing Laboratory***
	12.10.2020	Hatice ACARALP	Sevim A. RAZAK 12.10.2020

EKOTEKS LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş.

AB-0583-T
20035727 -ing
10-20

REQUIRED TESTS	RESULT	COMMENTS
PHYSICAL PROPERTIES		
Tensile Strength **/ Dry**	P	
Tensile Strength **/ Wet**	P	
Bursting Strength **/ Dry**	P	
Bursting Strength **/ Wet**	P	
Water Permeability	P	
MICROBIOLOGICAL TESTS		
Microbial Cleanliness (Bioburden)	P	
Wet-Bacterial Penetration	P	
Dry-Bacterial Penetration	P	

P: Pass
F: Fail
R: Refer to retailer technologist.
(1)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.

AB-0583-T
20035727 -ing
10-20

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 ;

	RESULT	**REQUIREMENT**
Weft	72.5 N	≥ 20N (Dry)
Warp	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 ;

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

	RESULT	**REQUIREMENT**
Dry ;	201.4 kPa	≥ 40 kPa (Dry)
Height at Burst*	14.9 mm	

AB-0583-T
20035727 -ing
10-20

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 ;	190.2 kPa	≥ 40 kPa (Wet)
Height at Burst*	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)

	RESULT	**REQUIREMENT**
Sample 1	147.0 cmSS	≥ 100cmSS
Sample 2	150.0 cmSS	
Sample 3	157.2 cmSS	
Sample 4	163.3 cmSS	
Sample 5	160.1 cmSS	
Average	158.6 cmSS	

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 ± 1 ° C for 72 hours, growth microorganisms are counted on the agar.

	RESULTS	**REQUIREMENT**
Microbial cleanliness (cfu/g)	32 cfu/g	≤300 cfu/g Type I and Type II mask

EKOTEKS LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş.

AB-0583-T
20035727 -ing
10-20

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 ± 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):	2x104 kob / ml
Incubation Conditions:	(36 ± 1) ° C 48 hours

RESULTS			
Number of Populating Bacteria (cfu)		**Penetration Rate**	
X_1	**0**	R_{CUM1}	0
X_2	**0**	R_{CUM2}	0
X_3	**0**	R_{CUM3}	0
X_4	**0**	R_{CUM4}	0
X_5	**0**	R_{CUM5}	0
Z	**459**		
T	459		

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

$R_{CUM1} = X1/T$
$R_{CUM2} = (X2 + X1)/T$
$R_{CUM3} = (X3 + X2 + X1)/T$
$R_{CUM4} = (X4 + X3 + X2 + X1)/T$
$R_{CUM5} = (X5 + X4 + X3 + X2 + X1)/T$

BARRIER INDEX (I_B)		
	Result	**Expected value (*)**
I_B	6	≥2,8

$I_B = 6 – (CUM1 + CUM2 + CUM3 + CUM4 + CUM5)$

** EN 13795-1:2019 Surgical gowns and drapes - Requirements and test methods are evaluated according to Table-1.*

EKOTEKS LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş.

AB-0583-T
20035727 -ing
10-20

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	1	
4	3	
5	2	
6 (Control)	0	
Total	9	
Logarithm	0.95	
** EN 13795-1:2019 Surgical gowns and drapes - Requirements and test methods are evaluated according to Table-1.*		
RESULT		
Result (cfu/g)		**Expected Value**
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
www.kiwa.com.tr

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

Genel Müdür

TÜRKAK BDS NO
YS-2DA4-42C1

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
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.

TÜRKAK BDS NO
YS-2DA4-42C1

Last Modified: 01 February 2021 - R 02

EKOTEKS LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş.
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

TESTED BY Seal EKOTEKS TESTEDİL

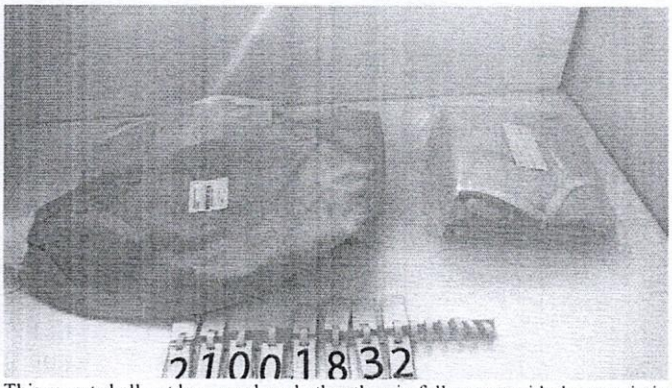
Date	***Customer Representative***	***Head of Testing Laboratory***
25.01.2021	Yeşim ŞAHİN	Sevim A. RAZAK 25.01.2021

21001832
01-21

REQUIRED TESTS	RESULT	COMMENTS
PHYSICAL PROPERTIES TESTS		
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.



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 Standard deviation : 4 Coefficient of variation : 18% Coefficient of linting (CL) : 1	Total linting : 16 Standard deviation : 7 Coefficient of variation : 46% 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.

Gen.f136-2/03

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

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

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

www.tuv.com

DAkkS Deutsche Akkreditierungsstelle D-ZM-16031-01-00

TÜVRheinland®
Precisely Right.