Digitally signed by Granaci Boris
Date: 2022.10.07 11:39:19 EEST
Reason: MoldSign Signature
Location: Moldova

DECLARATION OF CONFORMITY

MANUFACTURER: BAYTEKS TEKNİK TEKSTİL SAN. VE TİC. A.Ş

Organize Sanayi Bölgesi 19 Nolu Cad. No:9 MERKEZ/KİLİS
Tel: 0342 337 30 30
Fax: 0342 337 30 35

PRODUCTS : **Sterile Gowns, Drapes and Sets**

NOTIFIED BODY : **KİWA BELGELENDİRME HİZMETLERİ A.Ş.**
ITOSB 9.CADDE NO:15 TEPEÖREN TUZLA - İSTANBUL - TÜRKİYE

ID NO : **1984**

CERTIFICATION NO:

CLASSIFICATION : Class IS Rule 1 MDD 93/42/ECC Annex IX

EXECUTED ANNEX : MDD 93/42/ECC (For all versions).

ANNEX V Conformity Assessment Route.

APPLIED STANDARDS: EN ISO 13485:2012, ISO 14971:2012, EN ISO 11135:2014, EN 556-1:2001/AC:2006, EN ISO 15223-1:2012, EN ISO 11737-1:2006, EN ISO 11737-2:2009, EN ISO 14644, EN ISO 10993-1:2009/AC:2010, EN ISO 10993-7:2008/AC:2009, EN 13795:2011+A1:2013, EN 1041:2008+A1:2013, EN ISO 11607-1:2009+A1:2014, EN ISO 11607-2:2006+A1:2014, EN ISO 19011:2011, BS EN 62366-1:2015

APPLICATION : The directive for our product is the Council Directive 93/42 / EEC for all versions of medical devices.The Manufacturer of the product, Bayteks Teknik Tekstil San. And Tic. A.Ş, is responsible for the requirements of this council directive. Our products are not medical devices that contains human blood derivatives, animal products, animal skin, tissues, or blood derivatives or phthalates.

STERILE PRODUCTS

	PRODUCT NAME	REF.CODE	GMDN CODE
1	STANDARD SURGICAL GOWN	SG-0001-01	35778
2	STANDARD SURGICAL GOWN	SG-0001-02	35778
3	STANDARD SURGICAL GOWN	SG-0001-03	35778
4	STANDARD SURGICAL GOWN	SG-0001-04	35778
5	STANDARD SURGICAL GOWN	SG-0001-05	35778
6	REINFORCED SURGICAL GOWN	SG-0002-01	35778
7	REINFORCED SURGICAL GOWN	SG-0002-02	35778
8	REINFORCED SURGICAL GOWN	SG-0002-03	35778
9	REINFORCED SURGICAL GOWN	SG-0002-04	35778
10	REINFORCED SURGICAL GOWN	SG-0002-05	35778
11	STANDARD SURGICAL GOWN	SG-0007-01	35778
12	STANDARD SURGICAL GOWN	SG-0007-02	35778
13	STANDARD SURGICAL GOWN	SG-0007-03	35778

14	STANDARD SURGICAL GOWN	SG-0007-04	35778
15	STANDARD SURGICAL GOWN	SG-0007-05	35778
16	REINFORCED SURGICAL GOWN	SG-0008-01	35778
17	REINFORCED SURGICAL GOWN	SG-0008-02	35778
18	REINFORCED SURGICAL GOWN	SG-0008-03	35778
19	REINFORCED SURGICAL GOWN	SG-0008-04	35778
20	REINFORCED SURGICAL GOWN	SG-0008-05	35778
21	BACK TABLE COVER	SD-0300-01	47783
22	BASIC SURGERY DRAPE	SD-0301-01	47783
23	FOOT DRAPE	SD-0302-01	47783
24	SIDE DRAPE	SD-0303-01	47783
25	ANESTHESIA DRAPE	SD-0304-01	47783
26	ANGIOGRAPHY DRAPE	SD-0305-01	47783
27	ANGIOGRAPHY DRAPE WITH	SD-0305-02	47783
28	FEMORAL RADIAL ANGIOGRAPHY DRAPE WITH TRANSPARENT PANELS	SD-0306-01	47783
29	ARTHROSCOPY DRAPE WITH POUCH	SD-0307-01	47783
30	HIP DRAPE WITH ELASTIC FENESTRATION	SD-0308-01	47783
31	VERTICAL IZOLATION DRAPE TRANSPARENT +PE	SD-0309-01	47783
32	OPHTALMIC DRAPE WITH DOUBLE POUCH	SD-0310-01	47783
33	OPHTHALMIC DRAPE WITH SINGLE POUCH	SD-0311-01	47783
34	BASIC SURGERY DRAPES	SD-0312-01	47783
35	HAND SURGERY DRAPE WITH ELASTIC FENESTRATION	SD-0313-01	47783
36	ARTHROSCOPY DRAPE	SD-0314-01	47783
37	SUB- EXTREMITY DRAPE	SD-0315-01	47783
38	UPPER- EXTREMITY DRAPE	SD-0316-01	47783
39	GYNAECOLOGY DRAPE	SD-0317-01	47783
40	GYNAECOLOGY DRAPE WITH POUCH	SD-0318-01	47783
41	O.P.U DRAPE FENESTRATED	SD-0319-01	47783
42	UNDER BUT- TOCKS DRAPE WITH POUCH	SD-0320-01	47783
43	UNDER BUT- TOCKS DRAPE	SD-0320-02	47783
44	E.N.T DRAPE	SD-0321-01	47783
45	HEAD DRAPE (TURBAN)	SD-0322-01	47783
46	CYRANIOTOMY DRAPE	SD-0323-01	47783
47	CARPAL TUNNEL DRAPE	SD-0324-01	47783
48	SPINAL VERTEBRA DRAPE	SD-0325-01	47783
49	SHUNT DRAPE	SD-0326-01	47783
50	FENESTRATED DRAPE	SD-0329-01	47783
51	CARDIOVASCULAR DRAPE	SD-0331-01	47783
52	LAPAROSCOPIC ABDEMINAL PERINEAL DRAPE	SD-0333-01	47783
53	LAPAROSCOPIC PELVISCOPY DRAPE	SD-0334-01	47783
54	LAPARATOMY DRAPE WITH INCISE FILM	SD-0335-01	47783

55	LAPAROTOMY DRAPE WITH INCISE FILM AND POUCH	SD-0336-01	47783
56	TUR DRAPE WITH POUCH	SD-0337-01	47783
57	PERCUTANEOUS DRAPE	SD-0338-01	47783
58	UROLOGY DRAPE	SD-0339-01	47783
59	CYSTOSCOPY DRAPE	SD-0340-01	47783
60	MAYO STAND COVER	SD-0341-01	47783
61	CESAREAN DRAPE	SD-0342-01	47783
62	LITOTOMIC GYNAECOLOGY DRAPE WITH POUCH	SD-0343-01	47783
63	LITOTOMIC GYNAECOLOGY DRAPE	SD-0344-01	47783
64	THORAX DRAPE WITH INCISE FILM	SD-0345-01	47783
65	THYROID DRAPE	SD-0346-01	47783
66	U-SPLIT PERINEUM DRAPE	SD-0347-01	47783
67	U - SPLIT HIP DRAPE	SD-0348-01	47783
68	U-SPLIT DRAPE +PE	SD-0349-01	47783
69	U - SPLIT SHOULDER ARTHROSCOPY DRAPE WITH POUCH	SD-0350-01	47783
70	BY-PASS DRAPE	SD-0351-01	47783
71	ABDOMINAL DRAPE	SD-0354-01	47783
72	TRANSPARENT PE ADHESIVE DRAPE	SD-0355-01	47783
73	GYNAECOLOGY SPLIT DRAPE	SD-0356-01	47783
74	ARM DRAPE	SD-0357-01	47783
75	LAPAROSCOPY DRAPE	SD-0361-01	47783
76	BABY DRAPE	SU-2107-01	47783
77	LEG COVER	SU-2118-04	47783
78	CARPAL TUNNEL PACK	SP-1001-01	47783
79	HEAD PACK	SP-1002-01	47783
80	LAMINECTOMY PACK	SP-1003-01	47783
81	CRANIOTOMY PACK	SP-1004-01	47783
82	SHUNT PACK	SP-1005-01	47783
83	OPERATION PACK	SP-1007-01	47783
84	GENERAL SURGERY PACK	SP-1008-01	47783

The products listed in the list above and their contents are classified Class 1 Sterile products. These products ,their content, and their accessories do not take part in any other class.We herewith declare that the above mentioned products conforms general requirements of the Council Directive 93/42/EEC for all versions of Medical Device Directive .

Applied Directives

Medical Device Directive MDD 93/42/EEC (incl. 2007/47/EC) ANNEX V ALL VERSIONS.

DATE OF ISSUE : 12.02.2018
REV. NO. :
SIGNATURE –STAMP :

NAME- SURNAME : MUSTAFA GÜLER
POSITION : FOREIGN TRADE MANAGER

BAYTEKS
TEKNİK TEKSTİL SAN. ve TİC. A.Ş.
MRK: Org. San. Böl. 19 Nolu Cad. No.9 Merkez/KİLİS
Tel: 0.342 337 3030 Fax: 0.342 337 3035
Mersis No.: 0159 0038 749 0017 Tic.Sic.No.3976
KİLİS V.D.: 159 003 8749 www.bayteks.com

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

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

Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1317789**

Certificate Holder:

BAYTEKS TEKNİK TEKSTİL SAN. VE TİC. A.Ş.
ORGANİZE SANAYİ BÖLGESİ 19 NO'LU CAD. NO:9
79000 MERKEZ – KİLİS / TURKEY

Scope: Design, production, processing and sales of non-woven surface fabric

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid from 2020-03-18 until 2023-03-17.
First certification 2014

2020-01-23

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln

www.tuv.com

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

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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

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*	08.09.2022
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*	ORGANİZE SANAYİ BÖLGESİ MAH. 19 NOLU CAD. NO:9 /9 MERKEZ KİLİS/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

e-imzalı/e-signed

31.08.2021

Belgelendirme Merkezi Başkanı Adına
RIZA BUĞRA ALP GİRAY OKUMUŞ

GAZİANTEP BELGELENDİRME MÜDÜRÜ

*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 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

https://evrakkontrol.tse.org.tr/BelgeDogrulama.aspx?p=led9vuzh adresinden belgenin doğruluğunu ve geçerliliğini sorgulayınız.

TEST REPORT

Customer Name/Address :TÜRK STANDARTLARI ENSTİTÜSÜ GAZİANTEP BELGELENDİRME MÜDÜRLÜĞÜ / 2. Organize Sanayi Bölgesi Haci Sani Konukkoğlu Bulvarı No: 9 / Başpınar / GAZİANTEP

T/F:(342) 337-95-03/ / (342) 337-95-08

Order Date/No :24/02/2021 Tarihli ve 2137871 Sayılı Yazı

Sample Description : Inspection Number:2137871 2 m2 Surgical Gown Fabric (Bayteks Tekstil)
Sample Receipt Date :12/04/2021 **Sample Delivered by**: Cargo Delivery

Number of Pages: 2

Remarks : Sampling and identification of the sample was done by the customer. By the request of the customer, Turkish version of the same date and numbered report was also created.

*TÜBİTAK Bursa Test and Analysis Laboratory accredited by TÜRKAK under registration number AB-0494-T for General Requirements for the Competence of Testing and Calibration Laboratories TS EN ISO/IEC 17025 as test laboratory.
*Test results,methods measurement uncertainty (if applicable, given in 95% confidence interval) and other information are given on the following pages which are part of this report.
*This report and results can not be used for the purpose of advertising by the requesting client.
*This report has been given as a full content and can not be copied by sections. This report can not be reproduced without prior written approval of TÜBİTAK BUTAL.
*In case the information provided by the customer, TÜBİTAK BUTAL will not be responsible for this information.
*In case of sampling by customer the results in this report refer only to samples tested
*In case of sampling by customer, the sampling uncertainty were not included to the uncertainty budget.
*Test marked with (A) refers the test within the scope of TS EN ISO / IEC 17025 accreditation and marked with (D) refers the test provided by external sources.
*Testing reports without e-signature are not valid.
Turkish Accreditation Agency (TURKAK) is a signatory to the European co-operation for Accreditation (EA) Multilateral Agreement (MLA) and tothe International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) for the recognition of test reports.

Date
14/04/2021

e-signature	*e-signature*
Anıl ÇETİNOĞLU	Sedat AKTAŞ
Person in Charge of Laboratories	Director

This document has been signed by e-signature.
The document can be verified via the link " https://butalonlinetest.tubitak.gov.tr/butalOnline " using the code “NW33423789'03B”

Gaziakdemir Mah. Merinos Cad. No. 11, 16190, Osmangazi, BURSA/TURKE
T. +90 224 233 94 40 F. +90 224 233 94 45 - +90 224 234 57 06
www.butal.tubitak.gov.tr e-mail: butal@tubitak.gov.tr

Test Date : **12- 14/ 04/ 2021**

Sample Description : **Inspection Number:2137871 2 m2 Surgical Gown Fabric (Bayteks Tekstil)**

Test Name and Test Method	Test Result		
		Dry Sample	**Wet Sample**
Bursting Strength	**Bursting Strength**	146 kPa	137 kPa
(A) EN ISO 13938-1	CV(%)	% 5,1	% 7,3
	Bursting Height	14 mm	14 mm
	CV(%)	% 1,4	% 2,9
	Bursting Time	19,7 s	19,9 s
	CV(%)	% 3,2	% 3,2

Test Conditions

a) Version of applied standard: EN ISO 13938-1: 2019

b) Applied method: Hydraulic Diaphragm Method

c) Test Device: SDL Autoburst

d) Test Diameter: 30,5 mm, Test Area: 7,3 cm^2

e) Number of Test specimen: 5

f) Test conditions according to ISO 139 (20±2°C, %65±4 Relative Humidity)

Note

Before wet tests, the test pieces were immersed in 1 liter distilled water for one hour.

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
21007884-ING
03-21

Customer name:	BAYTEKS TEKSTİL SAN. VE TİC. A.Ş.
Address:	ORGANİZE SAN.BÖLG. 19 NOLU CAD. NO:9 MERKEZ/KİLİS
Buyer name:	TSE GAZİANTEP BELGELENDİRME MÜDÜRLÜĞÜ/İBRAHİM AÇAR
Contact Person:	KADİR KARAGÜL
Order No:	-
Article No:	-
Name and identity of test item:	Blue non-woven surgical gown
The date of receipt of test item:	01.03.2021
Re-submitted/re-confirmation date:	-
Date of test:	01.03.2021-11.03.2021
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:	6

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***
	11.03.2021	Zahide TAPAN	Sevim A. RAZAK 11.03.2021

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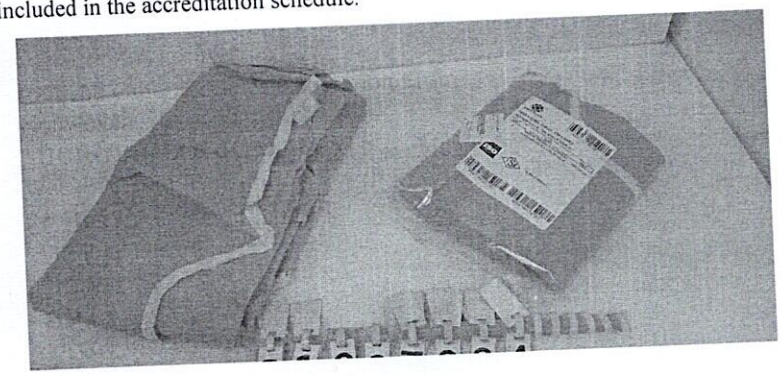
Testing reports without signature and seal are not valid.

REQUIRED TESTS	RESULT	COMMENTS
PHYSICAL PROPERTIES		
Water Permeability	P	
Lint and Other Particles Generation From Nonwoven	P	
MICROBIOLOGICAL TESTS		
Wet- Bacterial Penetration	P	
Dry-Bacterial Penetration	P	
Microbial Cleanliness (Bioburden)	P	

P: Pass
F: Fail
R: Refer to retailer technologist.
Test results were evaluated according to EN 13795-1:2019 Standard Performance Properties 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 %. 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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Testing reports without signature and seal are not valid.

AB-0583-T
21007884-ING
03-21

TEST RESULTS

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	54,1 cm H_2O	≥ 20 cm H_2O
Sample 2	56,2 cm H_2O	
Sample 3	53,7 cm H_2O	
Sample 4	63,7 cm H_2O	
Sample 5	60,1 cm H_2O	
Average	57,5 cm H_2O	

Gen.f136-2/03

MICROBIAL CLEANLINESS (Bioburden)

Test Metod: Ref: EN ISO 11737-1:2018 /TS 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/ 100 cm^2)	14 cfu/100 cm^2	≤300 cfu/100 cm^2

***cfu= Colony forming unit.**

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):	$5x10^3$ kob / ml
Incubation Conditions:	(36 ± 1) ° C 48 hours

RESULTS			
Number of Populating Bacteria (cfu)		**Penetration Rate**	
X_1	45	R_{CUM1}	0,04
X_2	59	R_{CUM2}	0,09
X_3	93	R_{CUM3}	0,17
X_4	124	R_{CUM4}	0,28
X_5	135	R_{CUM5}	0,40
Z	659		
T	1115		

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	4,99	≥2,8

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

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TEST RESULT

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	0
2	0
3	0
4	0
5	0
6 (Control)	0
Total	0
Logarithm	-

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

RESULT	
Result (cfu/g)	**Expected Value**
0 cfu/g	≤300 cfu/g

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AB-0583-T
21007884-ING
03-21

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 :8 Standard deviation : 5 Coefficient of variation : 62% Coefficient of linting (CL) :1	Total linting :44 Standard deviation :35 Coefficient of variation : 81% Coefficient of linting (CL) : 2
SAMPLE, MATERIAL (TOTAL)	
Total linting 51 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.
both standard performance and high performance testing.

Gen.f136-2/03

BAYTEKS
BAYTEKS TEKSTİL SAN. VE TİC. A.Ş.

DATE	19.03.2021
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REV.NO	0

TECHNICAL DATA SHEET

Product : Polypropylene

Product Description	: ENDLESS FILAMENTS MELTBLOWN , THERMALLY BONDED.
Raw Material	: 100 % PP
Application on Fabrıc	: SMS/HYDROPHOBIC
Treatment	:
Fabrıc Colour	: MEDICAL BLUE
Customer Name	:
Weight	: **43 GSM**
Width	:
Packing	: PE BAG WITH LABEL

PROPERTIES	TEST METHOD	UNIT	TARGET
WEIGHT	NWSP 130.1.R0 (15)	gsm	**43**
THICKNESS	NWSP 120.1.R0 (15)	mm	**0,33**
TENSILE STRENGTH MD	NWSP 110.4.R0 (15)	N/5 cm	**115,0**
TENSILE STRENGTH CD			**55,0**
ELONGATION AT BREAK MD	NWSP 110.4.R0 (15)	%	**145,0**
ELONGATION AT BREAK CD			**133,0**
HYDROSTATIC HEAD	NWSP 080.6.R0(15)	mm	**430,0**
AIR PERMEABILITY	NWSP 070.1.R0 (15)	l/m²/s(200 pa)	
ABSORPTION WATER	NWSP 010.4.R0 (15)	H_2O/cm^2	**150,0**

Tolerances For The Avarage Results

Weight	± 5 %
Thickness	± 10 %
Tensile Strenght	± 15 %
Elongation	± 15 %
Hydrostatic Head	± 15 %
Air Permeability	± 20 %
Absorption	± 5 H_2O/cm^2

Roll Tolerance

Length : - 0 / +5% against target / ordered lenght

Width : Up to 150 cm in width = -0mm/+5mm Over 150 cm in width = - 0mm/+10

Splice : Maxium five splices per roll

BAYTEKS
TEKNİK TEKSTİL SAN. ve TİC. A.Ş.
Merkez: Başpınar (Organize) OSB Mah. O.S.B. 2. BOLGE
83207 Nolu Cad. No.2 Şehitkamil/GAZİANTEP
Fabrika: Org. San. Böl. 19 Nolu Cadde No.9 Merkez/NİLÜFER
Mersis No.: 0159 0038 7490 0017 Tic. Sic. No.: 54557
Gazikent Vergi Dairesi Vergi No.: 159 003 8749