



# 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



## 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  
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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  
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General Manager



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



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

Markanın Tanımı Description of the Mark  
**TSE** veya/ör  veya/ör **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	08.09.2022
<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	ORGANİZE SANAYİ BÖLGESİ MAH. 19 NOLU CAD. NO:9 /9 MERKEZ KİLİS/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

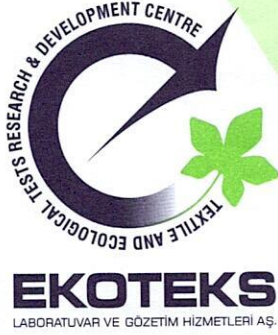
*e-imzalı/e-signed*

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





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



**TEST REPORT**  
DENEY RAPORU

AB-0583-T
21012425- ing
04-21

**Customer name:**

BAYTEKS TEKNİK TEKSTİL SAN. VE TİC. AŞ.

**Address:**

ORGANİZE SANAYİ BÖLG.19 NO'LU CAD.NO:11 MERKEZ/KİLİS

**Buyer name:**

-

**Contact Person:**

KADİR KARAGÜN

**Order No:**

REF:SD-04210-18/LOT:0000016139

**Article No:**

REINFORCED SURGICAL CLOTH(HIGH PERFORMANCE)

**Name and identity of test item:**

One sample blue surgical gown.(Claimed to be:4 Pieces Color:Medikal Blue)

**The date of receipt of test item:**

12.04.2021

**Re-submitted/re-confirmation  
date:**

-

**Date of test:**

12.04.2021-26.04.2021

**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:** 9

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.



**Date**  
26.04.2021

**Customer Representative**  
Yeşim ŞAHİN

**Head of Testing Laboratory**  
Sevim A. RAZAK  
26.04.2021

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AB-0583-T

21012425-  
ing

04-21

REQUIRED TESTS	RESULT	COMMENTS
<b>MICROBIOLOGICAL TEST</b>		
Microbial Cleanliness (Bioburden)	P	
Resistance to Bacterial Penetration-Wet Method	P	
Resistance to Microbial Penetration-Dry Method	P	
<b>PHYSICAL PROPERTIES TESTS</b>		
Tensile Strength / Dry	P	
Tensile Strength / Wet	P	
Bursting Strength / Dry	P	
Bursting Strength / Wet	P	
Water Permeability	P	
Blood Splash Resistance	P	
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(*) High 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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AB-0583-T

21012425-  
ing

04-21

## TEST RESULTS

### MICROBIAL CLEANLINESS (Bioburden) ; 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  $30 \pm 1$  °C for 72 hours, and 7 days at (20 to 25) °C for TSA and SDA plates respectively.  
Total microoragnisms counts are calculated.

	<u>RESULTS</u>	<u>REQUIREMENT</u>
Microbial cleanliness (cfu/100 cm <sup>2</sup> )	7 cfu/100 cm <sup>2</sup>	≤300 cfu/100 cm <sup>2</sup>

\*cfu= Colony forming unit.

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AB-0583-T

21012425-  
ing

04-21

## TEST RESULTS

### RESISTANCE TO BACTERIAL PENETRATION-WET METHOD ; BS EN ISO 22610: 2006

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.

Sample amount:	5 pieces 25x25cm <sup>2</sup>
Carrier Material:	30 µm thin, 25x25cm <sup>2</sup> Polyurethane Film
Coating Material:	25x25cm <sup>2</sup> HDPE Film
Microorganism:	Staphylococcus aureus ATCC 29213
Bacterial Concentration (kob / ml):	$5 \times 10^9$ kob/ml
Incubation Conditions:	( $36 \pm 1$ ) ° C 48 hours

RESULTS			
Number of Populating Bacteria (cfu)		Penetration Rate	
X <sub>1</sub>	0	RCUM1	0
X <sub>2</sub>	0	RCUM2	0
X <sub>3</sub>	0	RCUM3	0
X <sub>4</sub>	0	RCUM4	0
X <sub>5</sub>	0	RCUM5	0
Z	462		
T			462

X<sub>1</sub> ..... X<sub>5</sub>: Number of colonies growing in 5 parallel petri in the same sample  
Z: number of colonies growing in the sixth petri dish  
T: X<sub>1</sub> + X<sub>2</sub> + X<sub>3</sub> + X<sub>4</sub> + X<sub>5</sub> + Z

RCUM1 = X<sub>1</sub>/T  
RCUM2 = (X<sub>2</sub> + X<sub>1</sub>)/T  
RCUM3 = (X<sub>3</sub> + X<sub>2</sub> + X<sub>1</sub>)/T  
RCUM4 = (X<sub>4</sub> + X<sub>3</sub> + X<sub>2</sub> + X<sub>1</sub>)/T  
RCUM5 = (X<sub>5</sub> + X<sub>4</sub> + X<sub>3</sub> + X<sub>2</sub> + X<sub>1</sub>)/T

BARRIER INDEX (I <sub>B</sub> )		
I <sub>B</sub>	Result	Expected value (*)
I <sub>B</sub>	6	≥6

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



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AB-0583-T

21012425-  
ing

04-21

## TEST RESULTS

### RESISTANCE TO MICROBIAL PENETRATION-DRY METHOD; ISO 22612:2005

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  $0.5 \text{ g} \pm 0.1 \text{ g}$  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  $35^\circ \text{C}$  for 24 hours.

Sample amount: 6 pieces  $20 \times 20 \text{ cm}^2$   
Mikroorganism: *Bacillus subtilis* ATCC 9372  
Bacterial concentration (cfu/ml):  $1 \times 10^8 \text{ kob/ml}$   
Incubation conditions:  $35^\circ \text{C} / 24 \text{ hours}$

### RESULTS

#### Number of Populationg Bacteria (cfu)

1	0
2	0
3	0
4	0
5	0
6 (Control)	0
Total	0
Logarithm	-

### RESULT

Result (cfu/g)  
0 cfu/g

Expected Value  
 $\leq 300 \text{ cfu/g}$

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AB-0583-T

21012425-  
ing

04-21

## TEST RESULTS

### TENSILE STRENGTH; EN 29073-3:1996

Instron 5969 (Load: 5 kN), Strip Method.

Speed: 100 mm/min $\pm$ 10, Gauge length 200 mm.

Pre-load was not applied. Without wetting samples.

The average results are given for width and length direction of three samples

Performed in the conditioned room (20 $\pm$ 2°C-65% $\pm$ 4).

Dry ;

	<u>RESULT</u>	<u>REQUIREMENT</u>
Width	151.1 N	$\geq$ 20N (Dry)
Length	149.9 N	$\geq$ 20N (Dry)

### TENSILE STRENGTH; EN 29073-3:1996

Instron 5969 (Load: 5 kN), Strip Method.

Speed: 100 mm/min $\pm$ 10, Gauge length 200 mm.

Pre-load was not applied. Without wetting samples.

The average results are given for width and length direction of three samples

Performed in the conditioned room (20 $\pm$ 2°C-65% $\pm$ 4).

Wet;

	<u>RESULT</u>	<u>REQUIREMENT</u>
Width	149.3 N	$\geq$ 20N (Wet)
Length	154.6 N	$\geq$ 20N (Wet)

### BURSTING STRENGTH;; ISO 13938-1:1999

SDL ATLAS M229 tester. Test area: 30.5 mm diameter

The average results are given of 3 samples.

Performed in the conditioned room (20 $\pm$ 2°C-65% $\pm$ 4).

	<u>RESULT</u>	<u>REQUIREMENT</u>
Dry ;	310.6 kPa	$\geq$ 40 kPa (Dry)
Height at Burst*	10.4 mm	

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AB-0583-T

21012425-  
ing

04-21

## TEST RESULTS

### BURSTING STRENGTH;; ISO 13938-1:1999

SDL ATLAS M229 tester. Test area: 30.5 mm diameter  
The average results are given of 3 samples.  
Performed in the conditioned room ( $20\pm 2^{\circ}\text{C}$ - $65\%\pm 4$ ).

	<u>RESULT</u>	<u>REQUIREMENT</u>
Wet ;	332.0 kPa	$\geq 40$ kPa (Wet)
Height at Burst*	12.4 mm	

### WATER PERMEABILITY; ISO 811:2018

Hydrostatic Head Tester, Textest marka Fx 3000 model  
Temperature of water  $20^{\circ}\text{C}$ . Pressure increase ratio 10 mbar/min.  
Performed in the conditioned room ( $20\pm 2^{\circ}\text{C}$ - $65\%\pm 4$ )

	<u>RESULT</u>	<u>REQUIREMENT</u>
Sample 1	555.9 cm H <sub>2</sub> O	$\geq 100$ cm H <sub>2</sub> O
Sample 2	587.5 cm H <sub>2</sub> O	
Sample 3	562.0 cm H <sub>2</sub> O	
Sample 4	560.0 cm H <sub>2</sub> O	
Sample 5	578.3 cm H <sub>2</sub> O	
Average	568.7 cm H <sub>2</sub> O	

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AB-0583-T
21012425- ing
04-21

## TEST RESULTS

<b>DETERMINATION OF THE RESISTANCE TO PENETRATION BY BLOOD AND BODY FLUIDS-USING SYNTHETIC BLOOD; ISO 16603:2004</b>						
Textest, FX 3000-IV model + External Blood Cell						
Test samples were conditioned at $60 \pm 10\%$ relative humidity and $21 \pm 5^\circ \text{C}$ for at least 24 hours before testing.						
<b>Test Procedure Applied:</b>		A procedure B procedure (Only extensible or elastomeric materials)				
Pressure (kPa)	Time (Min.)	Test Result			Overall Result	
		Test 1	Test 2	Test 3		
0	5	PASS	PASS	PASS	PASS	
14	1	PASS	PASS	PASS		
0	4	PASS	PASS	PASS		
The time of failure (sn)		-	-	-		
Thickness of material tested (mm):		0.61	0.61	0.61		
Weight of material tested (g/m <sup>2</sup> ):		0.88	0.88	0.88		

Gen.F136-2/03

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AB-0583-T

21012425-  
ing

04-21

## TEST RESULTS

### LINT AND OTHER PARTICLES GENERATION FROM NONWOVEN; ISO 9073-10: 2003

5 samples in longitudinal direction (separate for inner and outer surface) are tested. The samples are placed in the Gelbo Flex device, which makes twisting and compression movements, in a clean room in Class 5 category according to ISO 14644-1. Lint and particles detached from the sample are counted with counter device and classified to size range.

SOLAIR 3100 particles measuring device

Min. measuring size: 0,3 µm,

Maks. measuring size: 25 µm

Air Flow: : 28,3 ± 1,4 L/dk

Working mode: 30 sec x 10 consecutive periods

<u>SAMPLE (INNER SURFACE)</u>		<u>SAMPLE (OUTER SURFACE)</u>	
Total linting :	86	Total linting :	26
Standard deviation :	50	Standard deviation :	20
Coefficient of variation :	%58	Coefficient of variation :	%78
Coefficient of linting (CL):	2	Coefficient of linting (CL):	1
<u>SAMPLE (TOTAL)</u>			
<u>Total linting :</u>	112		
Coefficient of linting (CL)*	2		

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



**TÜBİTAK  
BURSA TEST AND ANALYSIS LABORATORY**

AB-0494-T
MT20210576
04-21

Page 1 / 2

**TEST REPORT**

**Customer Name/Address** :TÜRK STANDARTLARI ENSTİTÜSÜ GAZİANTEP BELGELENDİRME  
MÜDÜRLÜĞÜ / 2. Organize Sanayi Bölgesi Hacı 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 to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) for the recognition of test reports.

Date  
14/04/2021

e-signature

Anıl ÇETİNOĞLU

Person in Charge of Laboratories

e-signature

Sedat AKTAŞ

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"

**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		
		<u>Dry Sample</u>	<u>Wet Sample</u>
<b>Bursting Strength</b> <b>(A) EN ISO 13938-1</b>	<b>Bursting Strength</b>	146 kPa	137 kPa
	CV(%)	% 5,1	% 7,3
	<b>Bursting Height</b>	14 mm	14 mm
	CV(%)	% 1,4	% 2,9
	<b>Bursting Time</b>	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<sup>2</sup>
- 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.