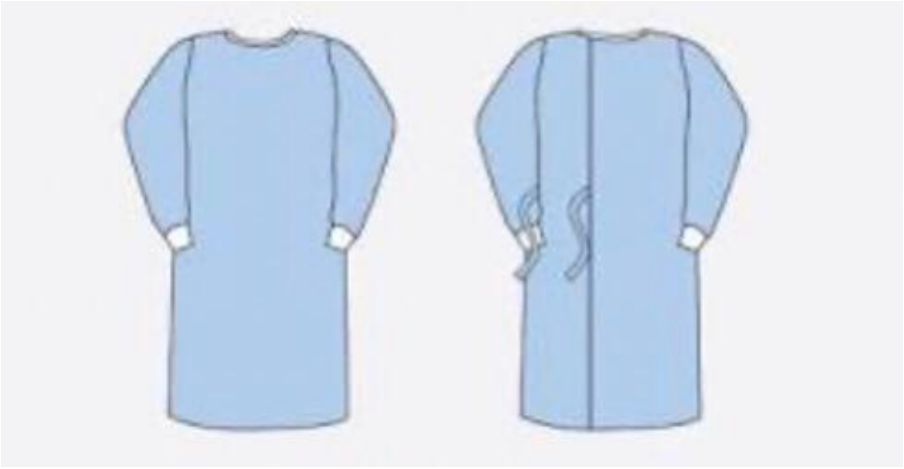
Conformity and Technical Report - #200420-01

Conformity and Technical Report - #200420-01 - BSM 5001

April 2020 - ©



This report includes the conformity and technical details of standard surgical gowns (Product ID BSM 5001) as of April 2020 produced in-house.

The company produces all of its goods in-house and currently exports to many countries including USA, Canada and EU.

OUR HEALTH MISSION

Our health mission is to supply the highest quality medical protective clothing while ensuring the highest customer satisfaction with continuous improvements and agile reliable product delivery.

We supply an extensive range of masks, aprons, scrubs, footwear and more, ideal for use in hospitals, clinics, GP surgeries, dental practices and other medical environments

BECAUSE WE CARE

The biggest threat in health care are pathogenic microorganisms – microorganisms can be transmitted with blood, body fluids, contaminated materials or medical instruments.

Medical protective clothing is essential equipment not only to protect medical professionals from pathogens, but also to protect patients from possible contamination by non-sterile garments.

STANDARD SURGICAL GOWNS

Produced in-house with CE - ISO 9001 - ISO 45001 and ISO 13485 certificates. The items can be shipped sterilized or non-sterilized depending on the requirements of the customer.

Material: 100% new pp non-woven or SMS non-woven

SMS Specifications: 3 layer structure, spunbond-meltblown-spunbond. Antistatic, breathable, low linting, Fluid repellent.

Weight: 36gsm - 43 gsm and 50 gsm

Applications: Surgical Gowns

Spunbond specifications: Hidrofobic, polipropleno non-woven fabric, one layer structure, 100% spunbond, Fluid repellent

Weight: 35 gsm

Applications: Patient and Visitor Gowns

Color: White - Blue - Green

Full length for maximum coverage. Latex free, sewn seams provide superior strength. Extra length on waist ties for easy securing in front. Additional ties at back of the neck and waist.

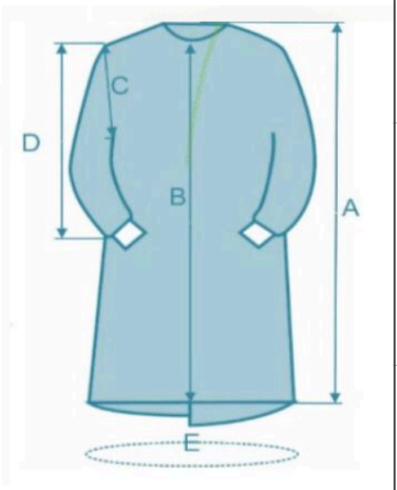
Type: Elastic wrist or with knitted cuff.

Sterilization method: EO Sterilization

Package Dimensions: 30x25x1,5 cm

Box Dimensions 60x40x40 / 100 pcs

Weight: Net 11 kg - Brut 11,50 kg

STANDARD SURGICAL GOWN	Available Sizes	Dimentions
	S	A 112 cm B 103 cm C 29 cm D 54 cm E 135 cm
	M	A 114 cm B 105 cm C 29 cm D 56 cm E 140 cm
	L	A 116cm B 107cm C 29cm D 58cm E 145cm
	XL	A 118cm B 109cm C 29cm D 60cm E 150cm
	2XL	A 120 cm B 111 cm C 29 cm D 62 cm E 155 cm

STANDARD SURGICAL GOWNS

ACTUAL PRODUCT IMAGE

STANDARD SURGICAL GOWNS

OUR CERTIFICATES

CERTIFICATE OF REGISTRATION

SYNDICATE OF INTERNATIONAL SYSTEM CERTIFICATIONS

CE

CE ATTESTATION OF CONFORMITY

Related Directives :
MEDICAL DEVICES 93/42/EEC---------TIBBİ CİHAZLAR DİREKTİFİ 93/42/EEC

Description of Product :
DISPOSABLE MEDICAL APRON
TEK KULLANIMLIK TIBBİ ÖNLÜK

Report Number /Rapor No :
M/TEC-4287 TEST VE KALİTE RAPORU

T rade Mar k

Regulations Applied acc. To Harmonized Standards:
EN14937, EN 61010-2-040, EN 61010-1, EN 60601-1-2 EMC, EN 60601-1

Manufactured by

Certificate No.: SISTURCE042020385
Issue Date (Original): 18.04.2020
Issue Date(Latest): 18.04.2020
Expiry Date: 17.04.2021

CE

This Certificate is issued under the following conditions:

1.It applies only to the above referenced models of the medical devices.
2.It does not imply that the SIS has performed any surveillance or control of their manufacture.
3.The manufacture is obligated to assure conformity of all in medical devices of the respective model to type assessed by the mean of this certificate.
4.The certificate remains valid until the manufacturing condition, the quality system or relevant legislation are changed .
5.After fulfilling of the relevant EU legislation requirements, the manufacture shall affix to each medical device, of the above referenced models, the CE-marketing according to this example:

Managing Director

Note: This certificate is valid only if produced with the continuation letter after the surveillance is carried out successfully.

The Organization's documentation and Implementation has been reviewed and found to comply with the relevant standard rules. This certificate of Registration is based on the evaluation of the mentioned scope given above. Organization is responsible for maintaining the responsibilities of the relevant standard rules. Any significant changes in the scope of the certification or standard referred above render this certificate invalid.

Corporate office(SIS):- Plot No. 1539, 2nd Floor, Sector-4,Gurgaon-122001, Haryana, India.
International office(SIS):- URB. Santa Ana Cal. German, Scherieber 276, San Isidro, Lima, Peru 15047.
Email us :-support@siscertifications.com, info@siscertifications.co.in. Call:- +91-9654721646
Web:- http://www.siscertifications.co.in, www.siscertifications.com
The status of this certificate can be verified on "http://www.siscertifications.co.in".

SIS CERT.

Issue No.: **01**

Certificate

Has been assessed and found to Comply with the Requirements of:
Denetlenmiş ve aşağıdaki standardın gerekliliklerine uygunluğu görülmüştür:

ISO 45001:2018

The Occupational Health and Safety Management System is applicable to:
İş Sağlığı Ve Güvenliği Yönetim Sistemi:

PRODUCTION AND SALES OF SHIRT, PROTECTIVE MASK, BONNET, OVERALLS, BODY BAG, PROTECTIVE WORK DRESS, SURGICAL APRON

GÖMLEK, KORUYUCU MASKE, BONE, TULUM, CESET TORBASI, KORUYUCU İŞ ELBİSESİ, CERRAHİ ÖNLÜK ÜRETİMİ VE SATIŞI

Certificate No: ISO/21128
Sertifika Numarası: ISO/21128

Date of Certification Audit: 10.04.2020
Denetim Tarihi: 10.04.2020

Date of Issue: 18.04.2020
Yayınlanma Tarihi: 18.04.2020

Date of Expiry: 17.04.2021
Son Geçerlilik Tarihi: 17.04.2021

1st Surveillance Audit : April 2021
1. Gözetim Denetim Tarihi : Nisan 2021
2nd Surveillance Audit : April 2022
2. Gözetim Denetim Tarihi : Nisan 2022

Qcs International Certifications Services Pvt. Ltd
Certificate of validity information E-mail: info@qcscert.com
mail to confirm

BIÇAKCILAR LABORATUVAR MEDİKAL A.Ş.

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Tel: +90 (212) 689 02 20 Fax: +90 (212) 689 02 29
http://www.bicakcilarlabmed.com.tr/
labinfo@bicakcilar.com

Talep no: TLP – 12-666 Request no	**HAVA GEÇİRGENLİK DENEY RAPORU** TEST REPORT FOR AIR PERMEANCE REPORT	00206.1303 rev01 31.07.2012
Teklif no: TLF – 12-175 Tender no		
Kabul Tarihi: 11.06.2012 Receiving Date		
Test başlangıç Tarihi: 12.06.2012 Test Initiation Date:		
Test Bitiş Tarihi: 13.06.2012 Test Final Date:		

❖ **MÜŞTERİ FİRMA- ADRES/** CUSTOMER-ADDRESS

❖ **TEST AMACI /** TEST TARGET

Numune ambalaj kağıtlarının hava geçirgenlik değerlerinin tespit edilmesi.
To determine the air permeance values for the packaging paper samples.

❖ **NUMUNEALMA METODU /** SAMPLING METHOD

Numuneler müşteri tarafından laboratuara gönderilmiştir.
Samples have been sent to the laboratory by the customer.
Numuneler standartta tanımlandığı şekilde, 10 cm x 10 cm boyutlarında kesilerek test edilmiştir.
Samples have been tested in accordance with the Standard method y cutting the samples as 10 cm x 10 cm dimensions.

❖ **METOD TANIMI /** METHOD DESCRIPTION

Hava Geçirgenlik Testi – BENDTSEN METODU
Air Permeance Test – BENDTSEN METHOD

❖ **REFERANS STANDART/** REFERENCE STANDARD

ISO 5636-3:1992

❖ **NUMUNE TANIMI – NUMUNE NO/** SAMPLE IDENTIFICATION – SAMPLE NO

Medikal Kraft Kağıt 50 x 100 mm
N12-0852

❖ **NUMUNE SAYISI/** SAMPLE QUANTITY

10 Adet

❖ **ÇEVRE ŞARTLARI/** TEST CONDITIONS

Sıcaklık/Temperature: 18-25 °C
Nem / Humidity: %30-60

❖ **TAŞERON BİLGİLERİ/** SUBCONTRACTOR INFORMATION

Taşeron kullanılmamıştır/Not used

❖ **ÖLÇÜM ANALİZ SONUÇLARI/** TEST RESULTS

Numune no	Test Edilen Numune	Ölçüm Sonucu ml/dk	(µm/(Pa.s)) cinsinden ölçüm sonucu	Aritmetik Ortalama	Standart Sapma
1	KAĞIT	900	10,17	914 ml/dk 10,32 µm/Pa.s	53,995 ml/dk 0,611 µm/Pa.s
2		850	9,60		
3		900	10,17		
4		880	9,94		
5		850	9,60		
6		900	10,17		
7		980	11,07		
8		1000	11,30		
9		980	11,07		
10		900	10,17		

❖ **LİMİTLER/** LİMİTS

EN 868-6: 2010 Packaging materials and systems for medical devices which are to be sterilized Part 6: Paper for the manufacture of packs for medical use for sterilization by ethylene oxide or irradiation- Requirements and test methods

Standardında tanımlı limit değerler: min. 0,2 □m/(Pa. s)

❖ **ÖLÇÜM BELİRSİZLİĞİ/** MEASUREMENT UNCERTAINITY

98,4 ml/dk

❖ **SAPMALAR/** DEVIATIONS

NA

❖ **ONAYLAR/** APPROVALS

	İsim/ Name	İmza/ Signature	Tarih/ Date
Testi Yapan/ Performed by:	Murat KAVAL KİMYA TEKN.		31.07.12
Kontrol Eden / Controlled by:	Hüseyin AYDIN KİMYA MÜH.		31.07.2012
Lab. Müdürü/ Lab. Manager:	Ülkü ÖKER Yük.KİMYA MÜH.		31.07.2012
Mühür/Seal:	BIÇAKCILAR LABORATUVAR MEDİKAL A.Ş.		

Test sonuçları bu test raporunda tanımlanan ve test edilen numuneler için geçerlidir.
Test results are valid only for the tested samples identified in this test report

NA: Uygulanamaz/Not applicable

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http://www.bicakcilarlabmed.com.tr/
labinfo@bicakcilar.com

Talep No: TLP-12-1415 Request No	**STERİLİTE DENEY RAPORU** **(ISO 11737-2)** STERILITY TEST REPORT	TÜRKAK Test TS EN ISO/IEC 17025 AB-0052-T
Teklif No:TLF-12-392 Tender No		AB-0052-T
Kabul Tarihi:22.11.2012 Receiving Date		00206.2884
Test Başlangıç Tarihi:23.11.2012 Test Initiation Date:		07.12.2012
Test Bitiş Tarihi:07.12.2012 Test Final Date:		

❖ **MÜŞTERİ FİRMA- ADRES/** CUSTOMER-ADDRESS

❖ **TEST AMACI /** TEST TARGET

Bu testin amacı test edilen numunelerin sterilliğinin araştırılmasıdır.
The purpose of this test to investigate the test samples sterility.

❖ **NUMUNEALMA METODU /** SAMPLING METHOD

Müşteri tarafından gönderilmiştir.
It was sent by the customer.

❖ **METOD TANIMI /** METHOD DESCRIPTION

Ürün sterilite testi LAF kabini altında direkt transfer metodu ile yapıldı.
Sterility test was performed under Laminar Air Flow by direct transfer method.

Test edilen ürün ya da SIP oranında kesilen numune, tüm numuneyi kapsayacak kadar TSB besiyeri ile dolu kavanozlara transfer edildi.
Sample or sample prepared as per SIP was transferred to the jar, filled with TSB growth medium enough to cover the sample.

Hazırlanan TSB kavanozları (30±2) °C'de inkübe edildi.
Prepared, TSB medium with product was incubated at (30±2)°C

Üreme yönünden, ürün içeren kavanozlar 14 gün boyunca kontrol edildi.
The jars containing the products were controlled for growth of microorganisms for 14 days.

❖ **REFERANS STANDART/** REFERENCE STANDARD

ISO 11737-2:2009 Sterilization of Medical devices- Microbiological methods

❖ **NUMUNE TANIMI – NUMUNE NO/** SAMPLE IDENTIFICATION – SAMPLE NO

Sudemed Markalı Sterilizasyon Rulosu İçindeki Spanç
N12-1854

❖ **NUMUNE SAYISI/** SAMPLE QUANTITY

1 Adet

❖ ÇEVRE ŞARTLARI/ TEST CONDITIONS

Sıcaklık/Temperature: 15-23 °C
Nem / Humidity: %35-60
Basınç Pressure: 0.02-0.08 inch H2O

❖ TAŞERON BİLGİLERİ/ SUBCONTRACTOR INFORMATION

Taşeron kullanılmamıştır / Not used

❖ NUMUNE ORANSAL PARÇASI/ SIP

NA

❖ TEST SONUÇLARI/ TEST RESULTS

	TSB için for TSB
Kontrol Edilen ürün sayısı Number of product controlled	1
Üreme görülen ürün sayısı ve gün Number and date of product growth observed	0

❖ LİMİTLER/ LİMİTS

Müşteri tarafından belirlenir
Shall be determined by the customer

❖ ÖLÇÜM BELİRSİZLİĞİ/ MEASUREMENT UNCERTAINITY

Yoktur / Not present

❖ SAPMALAR/ DEVIATIONS

NA

❖ ONAYLAR/ APPROVALS

	İsim/ Name	İmza/ Signature	Tarih/ Date
Testi Yapan/ Performed by:	Havva CAVA BİYOLOG		07.12.12
Uzman / Specialist:	Havva CAVA BİYOLOG		07.12.12
Lab. Müdürü / Lab. Manager	Ülkü ÖKER Yük.KİMYA MÜH		07.12.12
Mühür/Seal:	BIÇAKCILAR LABORATUVAR MEDİKAL A.Ş.		

Test sonuçları bu test raporunda tanımlanan ve test edilen numuneler için geçerlidir.
Test results are valid only for the tested samples identified in this test report
Bu rapor Bıçakcılar Laboratuarının yazılı onayı olmadan kısmen kopyalanamaz.
İmzasız ve mühürsüz raporlar geçersizdir.
This report shall not be reproduced other than in full except with the permission of Bıçakcılar Laboratory.
Testing reports without signature and seal are not valid

CERTIFICATE OF REGISTRATION

SYNDICATE OF INTERNATIONAL SYSTEM CERTIFICATIONS

This Certificate has been awarded to

In recognition of the organization's Management System
which complies with

ISO 9001:2015(QMS)

The scope of activities covered by this certificate is defined below

PRODUCTION AND SALES OF SHIRT, PROTECTIVE MASK, BONNET, OVERALLS, BODY BAG, PROTECTIVE WORK DRESS, SURGICAL APRON

GÖMLEK, KORUYUCU MASKE, BONE, TULUM, CESET TORBASI, KORUYUCU İŞ ELBİSESİ, CERRAHİ ÖNLÜK ÜRETİMİ VE SATIŞI

Certificate Number: **SISTURQ0420202037**
Date of Issue of Original Certificate: **18.04.2020**
Date of Issue of latest certificate: **18.04.2020**
Expiry Date: **17.04.2021**

Managing Director

Note: This certificate is valid only if produced with the continuation letter after the surveillance is carried out successfully.

The Organization's documentation and Implementation has been reviewed and found to comply with the relevant standard rules. This certificate of Registration is based on the evaluation of the mentioned scope given above. Organization is responsible for maintaining the responsibilities of the relevant standard rules. Any significant changes in the scope of the certification or standard referred above render this certificate invalid. This is an accredited certificate issued by SIS Certifications Pvt. Ltd. sanctioned for issue by International Accreditation Services , 3060 Saturn Street Suite 100 Brea, California 92821-1732, USA.

Corporate office(SIS):- Plot No. 1539, 2nd Floor, Sector-4,Gurgaon-122001, Haryana, India.
International office(SIS):- URB. Santa Ana Cal. German, Scherieber 276, San Isidro, Lima, Peru 15047.
Email us :-support@siscertifications.com, info@siscertifications.co.in. Call:- +91-9654721646
Web:- http://www.siscertifications.co.in, www.siscertifications.com
The status of this certificate can be verified on "http://www.siscertifications.co.in".

Issue No.: **01**

CERTIFICATE
of Registration

This is to Certify that the

Medical Devices – Quality Management System

has been independently assessed and is compliant
with the requirements of

ISO 13485:2016

This Certificate is applicable to the following product or service ranges:

PRODUCTION AND SALES OF SHIRT, PROTECTIVE MASK, BONNET, OVERALLS, BODY BAG, PROTECTIVE WORK DRESS, SURGICAL APRON

GÖMLEK, KORUYUCU MASKE, BONE, TULUM, CESET TORBASI, KORUYUCU İŞ ELBİSESİ, CERRAHİ ÖNLÜK ÜRETİMİ VE SATIŞI

:: Certificate No :: TR51935H

Date of initial registration	16 April 2020
Date of this Certificate	16 April 2020
Surveillance audit on or before	15 April 2021
Recertification Due / Certificate expiry	15 April 2023

This Certificate is property of Staunchly Management & System Services Ltd. and remains valid subject to satisfactory surveillance audits.

Director

STAUNCHLY MANAGEMENT & SYSTEM SERVICES LTD.
Suite 48, 88-90 Hatton Garden, London, EC1N 8PN.
Phone : +44 345 680 0199
Email : info@staunchlyservices.com Web : www.staunchlyservices.com

SMS/F109A/17/REV02

BIÇAKCILAR LABORATUVAR MEDİKAL A.Ş.

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labinfo@bicakcilar.com

DENEY RAPORU
TESTING REPORT

00206.1302
14.06.2012

ÖLÇÜM ANALİZ SONUÇLARI /TEST RESULTS

A-Kenarı	NUMUNE (N/15mm)	A-Kenarı	NUMUNE (N/15mm)
1	4,465	6	3,768
2	4,935	7	5,108
3	4,775	8	5,340
4	4,165	9	3,108
5	3,488	10	3,212
ORTALAMA =4,2364			

B-Kenarı	NUMUNE (N/15mm)	B-Kenarı	NUMUNE (N/15mm)
1	6,180	6	3,436
2	3,800	7	4,175
3	5,070	8	3,404
4	3,848	9	3,404
5	4,195	10	5,880
ORTALAMA =4,3342			

LİMİT DEĞERLER/ LIMITS

EN868–5: 2009 a uygun olarak yapışma dayanımı min.1,5N/15mm olmalıdır

ÖLÇÜM BELİRSİZLİĞİ/MEASUREMENT UNCERTAINTY

±0,04N

SAPMALAR/DEVIATIONS

NA

BIÇAKCILAR LABORATUVAR MEDİKAL A.Ş.

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DENEY RAPORU
TESTING REPORT

00206.1302
14.06.2012

	Testi Yapan Performed by	Onaylayan Approved by	
Görev/Position	Uzman Teknisyen	Validasyon Kıdemli Uzmanı Validation Experienced Specialist	Lab. Müdürü Lab. Manager
Ad/Soyad Name/Surname	Çilem ORHAN	Özenç EFE ÖZTÜRK	Ülkü ÖKER
İmza/Signature	14.06.12	(V) 14.06.12	(V) 14.06.12
Mühür/Seal	BIÇAKCILAR LABORATUVAR MEDİKAL A.Ş.		

Test sonuçları bu test raporunda tanımlanan ve test edilen numuneler için geçerlidir.
Bu rapor Bıçakcılar Laboratuarının yazılı onayı olmadan kısmen kopyalanamaz. İmzasız ve mühürsüz raporlar geçersizdir.

UYGUNLUK BEYANI	Belge No. M/TEC - 007 Rev. No. 0 Tarih: 01/ 01/ 2010

İşbu belge ile, aşağıda sıralanan ürünlerin

93/42/EEC Numaralı Tıbbi Cihazlar Yönetmeliğine

uygun olduğunu beyan ederiz.

Bu nedenle ürünler,

CE - uygunluk işaretinin

kullanılması ile ilgili tüm temel gerekli karşılamaktadır.

Sertifika No.: 022

Ürün Tipi:	**Sterilizasyon Ruloları ve Poşetleri Buhar Biyolojik İndikatör**
Sınıf:	**I**
Marka Adı:	**AXIS**

Karşılanan İlgili Uluslararası Standartlar
EN 867-5, EN 868-1&5, EN 11140-1, ISO 11607

İmalatçı:

İmza: —

Ürün Güvenliği :	ISO EN 13485

Geçerlilik Son Tarihi: 31.12.2014

BIÇAKCILAR LABORATUVAR MEDİKAL A.Ş.

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labinfo@bicakcilar.com

DENEY RAPORU
TESTING REPORT

00206.1302
14.06.2012

Talep no: TLP – 12-666 Request no	Teklif no: TLF-12-175 Tender no	Raporun Sayfa Sayısı : 2 Total page number
Test Adı: Yapışma Sağlamlık Kuvveti Kontrolü Test Name:	Test Başlangıç Tarihi: 12.06.2012 Test Initiation Date	Test Bitiş Tarihi: 13.06.2012 Completion Date

MÜŞTERİ BİLGİLERİ/SPONSOR INFORMATION

Müşteri Adı/ Customer Name	
Müşteri Adresi Customer Address	:

NUMUNE BİLGİLERİ/SAMPLE INFORMATION

Numune Tanımı Sample Identification	N12-0852 Medikal Kraft Kağıt
Miktar Quantity	10 Adet
Laboratuara ulaşma tarihi Sample receiving date	11.06.2012
Numune Alma Metodu Sampling Method	Numuneler müşteri tarafından laboratuara gönderilmiştir. Samples have been sent to the laboratory by the customer.

TEST BİLGİLERİ/TEST INFORMATION

Metod tanımı Method description	Herbir yapışma alanından, 15mm eninde ve cihaz aparatlarına uygun boyutta numune kesilir. Yapışma alanları numaralandırılırken ,herbir numune için altta kalan (CE işaretinin olduğu) kenar B olarak, karşısı ise A olarak tanımlanmıştır. Numune cihaz çeneleri arasına yerleştirilir ve 200mm/dk hızla çekilir.Maksimum kuvvet kaydedilir.
Referans standart no ve tarihi Standard number and date	EN868-5:2009 Annex D
Testin amacı Test target	Sıcaklıkla yapışabilir poşetlerin yapışma sağlamlık kuvvetinin belirlenmesi.
Malzemeler Materials	LF023 Gerilme Test Cihazı LF023-2 /5 Gerilme Test Cihazı Çeneleri
Ortam şartları Test conditions	Sıcaklık: 23+/-2 C° Nem : %40-%60 Rh
Şahit Numune Saklandı mı? Has witness sample been retained	Hayır
Varsa taşeron bilgileri: Subcontractor information	NA

BIÇAKCILAR LABORATUVAR MEDİKAL A.Ş.

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labinfo@bicakcilar.com

Talep no: TLP – 11-968 Request no	**PÜRÜZLÜLÜK DENEY RAPORU** TEST REPORT FOR ROUGHNESS	TÜRKAK Test TS EN ISO/IEC 17025 AB-0052-T
Teklif no: TLF -11-237 Tender no		AB-0052-T
Kabul Tarihi: 01.11.2011 Receiving Date		00036.12578
Test başlangıç Tarihi: 03.11.2011 Test Initiation Date:		03.11.2011
Test Bitiş Tarihi: 03.11.2011 Test Final Date:		

❖ **MÜŞTERİ FİRMA- ADRES/** CUSTOMER-ADDRESS

❖ **TEST AMACI** / TEST TARGET

Numune ambalaj kağıtlarının yüzey düzgünlük değerlerinin tespit edilmesi.
To determine the roughness values for the packaging paper samples.

❖ **NUMUNEALMA METODU** / SAMPLING METHOD

Numuneler müşteri tarafından laboratuara gönderilmiştir.
Samples have been sent to the laboratory by the customer.

Numuneler standartta tanımlandığı şekilde, 75 mm x 75 mm boyutlarında kesilerek test edilmiştir.
Samples have been tested in accordance with the Standard method y cutting the samples as 75 mm x 75 mm dimensions.

❖ **METOD TANIMI** / METHOD DESCRIPTION

Pürüzlülük Testi – BENDTSEN METODU
Roughness Test – BENDTSEN METHOD

❖ **REFERANS STANDART/** REFERENCE STANDARD

ISO 8791-2

❖ **NUMUNE TANIMI – NUMUNE NO/** SAMPLE IDENTIFICATION – SAMPLE NO

Sterilizasyon Rulosu
N11-1795

❖ **NUMUNE SAYISI/** SAMPLE QUANTITY

1 Rulo

❖ **ÇEVRE ŞARTLARI/** TEST CONDITIONS

Sıcaklık/Temperature: 21-25 °C
Nem / Humidity: %30-60

NA: Uygulanamaz/Not applicable

❖ TAŞERON BİLGİLERİ/ SUBCONTRACTOR INFORMATION

Taşeron kullanılmamıştır/Not used

❖ ÖLÇÜM ANALİZ SONUÇLARI/ TEST RESULTS

Numune no	Test Edilen Numune	Ölçüm Sonucu ml/dk	Aritmetik Ortalama	Standart Sapma
1	KAĞIT	380	376,5 ml/dk	14,53922 ml/dk
2		365		
3		370		
4		370		
5		380		
6		400		
7		360		
8		400		
9		360		
10		380		

❖ LİMİTLER/ LIMITS

EN 868-6: 1997 Packaging materials and systems for medical devices which are to be sterilized Part 6: Paper for the manufacture of packs for medical use for sterilization by ethylene oxide or irradiation- Requirements and test methods

Standardında tanımlı limit değerler: min.(50ml/dk)

max.(1200 ml/dk)

❖ ÖLÇÜM BELİRSİZLİĞİ/ MEASUREMENT UNCERTAINITY

45,5 ml/dk

❖ SAPMALAR/ DEVIATIONS

NA

❖ ONAYLAR/ APPROVALS

	İsim/ Name	İmza/ Signature	Tarih/ Date
Testi Yapan/ Performed by:	Murat KAVAL	.....	03.11.2011
Teknik Yönetici/ Technical Manager:	Melda AYDIN	.....	03.11.11
Lab. Müdürü / Lab. Manager	Ülkü ÖKER	.....	03.11.11
Mühür/Seal:	BIÇAKCILAR LABORATUVAR MEDİKAL A.Ş.		

Test sonuçları bu test raporunda tanımlanan ve test edilen numuneler için geçerlidir.
Test results are valid only for the tested samples identified in this test report

		DATE	19.03.2014
		DOC.NO	F32
		PAGE NO	1
		REV.NO	0
		REV.DATE	00.01.1900

TECHNICAL DATA SHEET

Product : Polypropylene

Product Description	: ENDLESS FILAMENTS MELTBLOWN, THERMALLY BONDED.
Raw Material	: 100 % PP
Application on Fabric	: SMS /HYDROPHOBIC
Treatment	:
Fabric Colour	: MEDICAL BLUE
Customer Name	:
Weight	: **40 GSM**
Width	:
Packing	: PE BAG WITH LABEL

PROPERTIES		TEST METHOD	UNIT	TARGET
WEIGHT		NWSP 130.1.R0 (15)	gsm	**40**
THICKNESS		NWSP 120.1.R0 (15)	mm	**0.36**
TENSILE STRENGTH	MD	NWSP 110.4.R0 (15)	N/5 cm	**108.0**
	CD			**50.0**
ELONGATION AT BREAK	MD	NWSP 110.4.R0 (15)	%	**136.0**
	CD			**119.5**
HYDROSTATIC HEAD		NWSP 080.6.R0(15)	mm	**400.0**

Tolerances For The Avarage Results

Weight	± 5 %
Thickness	± 10 %
Tensile Strenght	± 15 %
Elongation	± 15 %
Hydrostatic Head	± 15 %
Liquid Strike-Through Time	± 0,5 %
Air Permeability	± 20 %
Absorption	± 20 %

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

The product is wound onto cardboard cores and then wrapped in polyethylen film. Bar code labels with product code, description and lot details are applied to the outside of each pack and a small label is applied to each roll. Suitable sized rolls may be palletised and the pallet load cling-wrapped

Preperation Date	QUALITY CONTROL APPROVAL
06.04.2020	

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

EKOTEKS

TEST REPORT
DENEY RAPORU

20009637
03-20

Customer name:	
Address:	
Buyer name:	
Contact Person:	
Order No:	-
Article No:	SMS FABRIC
Name and identity of test item:	White non-woven fabric. (Claimed to be; 100 % PP , 30 gsm , Color Code: White)
The date of receipt of test item:	09.03.2020
Re-submitted/re-confirmation date:	-
Date of test:	09.03.2020-13.03.2020
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:	4

Seal	***Date***	***Customer Representative***	***Head of Testing Laboratory***
	13.03.2020	Hatice ACARALP	Sevim A. RAZAK 13.03.2020

EKOTEKS LABORATUVAR ve GÖZETİM HİZMETLERİ A.Ş.

20009637
03-20

REQUIRED TESTS	RESULT	COMMENTS
MICROBIOLOGICAL TEST		
Antibacterial Activity	P	
P: Pass F: Fail R: Refer to retailer technologist. Test results were evaluated according to EKOTEKS 70 (REF: 14683:2014) requirements		

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.f136-/03

TEST RESULT

BACTERİAL FİLTRATİON EFFİCİENCY (BFE)

Test Metod: EKOTEKS 70 (In-House Method-Bacterial Filtration Efficiency Testing /Ref: TS EN 14683:2019 Medical Face Masks,Requirements and Test Methods (*)

A specimen of the mask material is clamped between a impactor and an aerosol chamber. An aerosol of Staphylococcus aureus is introduced into the aerosol chamber and drawn through the mask material and the impactor under vacuum. The bacterial filtration efficiency of the mask is given by the number of colony forming units passing through the medical face mask material expressed as a percentage of the number of colony forming units present in the challenge aerosol.

Test Flow Rate	28,3 L/min
Test Flow Time	2 minute
Sample Sizes	5 piece (10x10 cm^2)
Microorganism	*Staphylococcus aureus* ATCC 6538
Bacterial concentration (cfu/ ml)	$5x10^5$ cfu/ ml
incubation conditions	24 hour, 35°C ± 2°C
Positive control average(C)	$3.0x10^3$ cfu/ ml

RESULTS		
Test Sample (T)	**Number of Bacteria (cfu/ml)**	**Bacterial Filtration Efficiency (% B)**
1	115	96.2 %
2	110	96.3 %
3	120	96.0 %
4	126	95.8 %
5	130	95.7 %

cfu: Colony-forming unit

B= (C-T) / C x 100

%B: Bacterial Filtration Efficiency
C: is the mean of the total plate counts for the two positive control runs
T: is the total plate count for the test specimen