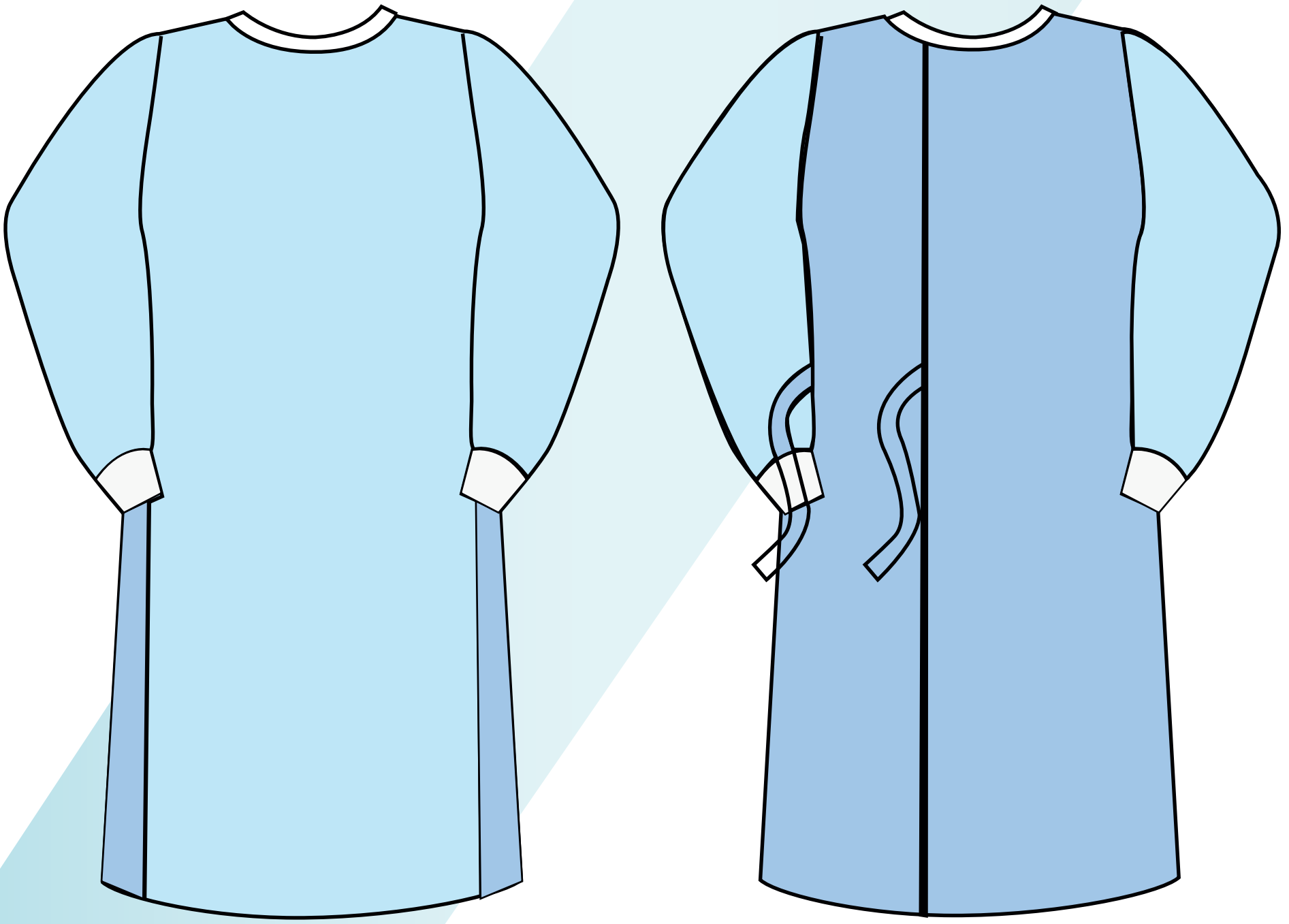
A&Z MED

Personal Protective Equipment

OLI-2028 Type 6

Disposable Laminated Surgical Gown



Personal Protective Equipment (PPE) Cat. III according to (EU) 2016/425

STANDARDS: EN 14126:2003/AC:2004 EN 13688:2013 EN 14325:2018 EN 13034:2005+A1:2009

ISO-9001:2015 ISO-13485:2016

CE 2163

.... LOT .....

A&ZMED

Personal Protective Equipment

OLI-2028

EN

AREA OF USE

Protective gown for limited protection against chemicals as well as against infectious agents analogous to the specified standards. Liquid-impermeable coating in the arm and front area. The coating material can be assumed to form a barrier against bacteria and viruses based on the results of the tests performed in accordance with EN 14126: 2003. In the case of exposure to hazardous biological substances that do not correspond to the degree of impermeability of the gown, bio-contamination of the user may occur. Please note the additionally provided product information.

CAUTION

Wearing chemical-protective clothing my cause thermal stress.
Please check for any damage before use!
Do not use damaged protective clothing!
Flammable material. Keep away from flame and heat sources!

PRECAUTIONS AND WARNINGS

1. Suitable for single use only. Dispose after use.
2. Change daily, i.e. use for max. 8 hours; in case of visible contamination change immediately!
3. Do not use if the packaging is damaged.
4. Do not use if irritation reactions or undesirable events occur.
5. To avoid danger of suffocation, keep this plastic bag away from babies and children. Do not use this plastic bag in cots, beds, prams or playpens. This bag is not a toy.

INSTRUCTIONS FOR USE

1. Open the packaging and take out the product.
2. Before using the gown, check the size and tightness of all sleeves.
3. Please turn inside out after use and then dispose of in the medical waste.
4. Storage conditions: In a well-ventilated, cool and dry warehouse, less than 80% relative humidity. Avoid exposure to direct sunlight and corrosive gases.

DE

ANWENDUNGSBEREICH

Schutzkittel für den eingeschränkten Schutz gegen Chemikalien sowie gegen Infektionserreger analog der genannten Normen. Flüssigkeitsundurchlässige Beschichtung im Arm- und Frontbereich. Gemäß den Prüfergebnissen nach EN 14126:2003 ist davon auszugehen, dass das beschichtete Material eine Barriere gegenüber Bakterien und Viren darstellt. Im Fall der Exposition gegenüber biologischen Gefahrenstoffen, die nicht dem Grad der Dichtigkeit des Schutzanzuges entsprechen, kann es zu einer Biokontamination des Trägers kommen.
Bitte beachten sie hierzu die zusätzlich bereitgestellten Produktinformationen

ACHTUNG

Das Tragen von Chemikalienschutzkleidung kann zu Hitzestress führen.
Vor der Verwendung auf Beschädigungen prüfen!
Beschädigte Schutzkleidung nicht verwenden!
Entzündbares Material. Von Flammen und Hitzequellen fernhalten!

VORSICHTSMAßNAHMEN UND WARNHINWEISE

1. Nur zum einmaligen Gebrauch geeignet. Nach Gebrauch zu entsorgen.
2. Täglicher Wechsel, d. h. max. für 8h verwenden; bei sichtbarer Kontamination sofort wechseln!
3. Nicht verwenden, wenn die Verpackung beschädigt ist.
4. Nicht mehr verwenden, wenn Reizreaktionen oder unerwünschte Ereignisse auftreten.
5. Um Erstickungsgefahr zu vermeiden, halten Sie diese Plastiktüte von Babys und Kindern fern. Verwenden Sie diese Plastiktüte nicht in Kinderbetten, Betten, Kinderwagen oder Laufställen. Diese Tüte ist kein Spielzeug.

GEBRAUCHSANWEISUNG

1. Öffnen Sie die Verpackung und nehmen Sie das Produkt heraus.
2. Vor dem Tragen dieses Kittels sollten Größe und Passform der Ärmel-Bündchen überprüft werden.
3. Bitte nach Gebrauch von innen nach außen stülpen (auf links drehen) und dann im medizinischen Abfall entsorgen.
4. Lagerbedingungen: In einem gut belüfteten, kühlen und trockenen Lagerhaus, weniger als 80% relative Luftfeuchtigkeit. Vermeiden Sie direkte Sonneneinstrahlung und den kontakt mit korrosiven Gasen.

FR

DOMAINE D'UTILISATION

Blouses d'isolation permettant une protection limitée contre les matières chimiques ainsi que les agents contagieux faisant l'objet des normes spécifiées. Revêtement étanche au niveau des bras et sur la partie avant de la blouse. D'après les résultats des tests effectués conformément à la norme EN 14126 : 2003, il est présumé que la matière dont la blouse est composée constitue une barrière contre les bactéries et les virus. En cas d'exposition de la blouse à des substances biologiques dangereuses, et contre lesquelles l'imperméabilité de celle-ci n'est pas garantie, l'utilisateur peut être biologiquement contaminé.

ATTENTION

Porter un vêtement de protection chimique peut provoquer un stress thermique.
Vérifiez la présence d'éventuels dommages avant toute utilisation!
N'utilisez en aucun cas un vêtement de protection endommagé!
Matière inflammable. Conserver à l'abri de la chaleur, des flammes nues ou autres sources d'inflammation.

PRÉCAUTIONS ET REMARQUES

1. Vêtement à usage unique. Jeter après utilisation.
2. Changer quotidiennement, usage limité à 8 heures maximum, en cas de contamination apparente changer immédiatement!
3. Ne pas utiliser si l'emballage est endommagé.
4. Ne plus utiliser en cas d'irritations ou autres effets indésirables.
5. Pour éviter tout risque de suffocation, ne pas laisser la pochette plastique à portée des enfants. Celle-ci ne doit pas être utilisée dans les lits pour enfants ou bébés, dans les poussettes ni dans les parcs de jeu pour enfants ou bébés. Cette pochette plastique n'est pas un jouet.

CONSIGNES D'UTILISATION

1. Ouvrir l'emballage et sortir le produit.
2. Avant de porter la blouse, contrôlez l'étanchéité de chacune des manches.
3. Après utilisation, tournez la blouse à l'envers, puis jetez-la dans les déchets médicaux.
4. Conditions de stockage : dans un dépôt frais et sec, bien aéré, et avec moins de 80% d'humidité.
À conserver à l'abri de la lumière directe et de tous gaz corrosifs.

ES

ÁREA DE USO

Batas que proporcionan protección limitada contra los químicos similares con estándares indicados y los agentes contagiosos. Recubrimiento impermeable de las mangas y de la parte delantera. La parte recubierta siempre debe colocarse hacia el interior. Según los resultados de las pruebas llevadas a cabo conforme a EN 14126: 2003, se puede certi¬car que el material utilizado en el recubrimiento establece una barrera contra los virus y bacterias. En caso de que el usuario esté expuesto a materias biológicamente peligrosas que no correspondan el grado de densidad, la biocontaminación se puede prever.

ATENCIÓN

La ropa de protección contra químicos puede causar estrés térmico.
Antes de usar comprobar defectos.
La ropa con defectos no se debe utilizar.
Material In amable. Mantener a distancia de seguridad del fuego y fuentes térmicas.

PRECAUCIONES Y ADVERTENCIAS

1. Uso único. Una vez utilizado, se debe desechar.
2. Se debe cambiar diariamente, es decir la duración de uso máximo es de 8 horas; en caso de haber contaminación palpable, se debe cambiar inmediatamente.
3. No se debe utilizar si el embalaje tiene defectos.
4. En caso de aparición de irritaciones y efectos adversos, no se debe utilizar más.
5. Para evitar el riesgo de asfixia, este embalaje de plástico debe ser mantenido lejos de los bebés y niños. Este embalaje de plástico no se debe utilizar en las cunas, camas, coches para bebés ni parques. Este embalaje no es un juguete.

INSTRUCCIONES DE USO

1. Abrir el embalaje para sacar el producto.
2. El tamaño y los puños deben revisarse antes de usar esta bata.
3. Después del uso, colocarlar del revés y desecharlo con otros desechos médicos. Condiciones de almacenamiento: en un almacén adecuadamente ventilado, fresco y seco, con menos del 80% de humedad relativa. Mantener lejos de la luz solar directa y gases corrosivos.

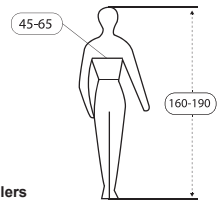
EN 13034:2005+A1:2009

Typ 6

EN 14126:2003

Typ 6-B

See additional User Guide
Siehe Informationen des Herstellers



Made in Turkey

Do not wash.	Do not dry clean.	Single use.
Do not iron.	Do not machine dry.	25°C 15°C
< 80%		NON STERILE

İBİŞLER TEKSTİL SAN. ve DIŞ TİC. A.Ş.
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www.ibisler.com info@ibisler.com

8 682742 370751

A&ZMED
Personal Protective Equipment

OLI-2028

MEASUREMENT CHART

MEASUREMENTS	STANDARD SIZE		
LENGHT FROM THE SHOULDER		128	
CHEST		67	
CHEST CIRCUMFERENCE		150	
BOTTOM		67	
BACK OVER LAPING		6	
SHOULDER		18	
SHOULDER RETURN		1	
ARMHOLE		26,5	
ARM LENGTH (WITHOUT RIB)		60	
BICEPS		27	
ARM LENGTH (WITHOUT RIB)		56	
RIB HIGHT		9	
ARM BOTTOM		7	
NECK OPENING		24	
BACK NECK DROP		3,5	
FRONT COLLAR DROP		10	
BELT FROM THE SHOULDER		51,5	
BELT HEIGHT		5	
BELT LENGTH		70	

TECHNICAL DATA SHEET

PRODUCT	%100 Polypropylene SS
COLOR	BLUE / WHITE
WEIGHT	40

MADE TEST	AVARAGE VALUE +/- %10	METHOD
TENSILE STRENGTH N / 5 cm (MD)	96,40	NWSP 110.1 R0(15)
TENSILE STRENGTH N / 5 cm (CD)	62,00	NWSP 110.1 R0(15)
ELONGATION % (MD)	100,50	NWSP 110.1 R0(15)
ELONGATION % (CD)	90,00	NWSP 110.1 R0(15)
WEIGHT (gr/m2)	40,00	NWSP 130.1 R0(15)
STRIKE THROUGH TIME (s)	0,00	NWSP 070.1 R0(15)
REWET (g)	0,00	NWSP 070.9 R1(15)

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UNIVERSAL

UNIVERSAL
CERTIFICATION

NB 2163

EU TYPE EXAMINATION CERTIFICATE

Certificate No: 2163-PPE-1341

İBİŞLER TEKSTİL SANAYİ VE DIŞ TİCARET A.Ş.
Orhangazi Mahallesi Tunç Caddesi No:[illegible]4358 Esenyurt ISTANBUL / TURKEY

It is certified that the manufacturer's technical file (Dated 25.08.2020) and the PPE product, described below, have been assessed and found to meet the applicable Essential Health and Safety Requirements in Annex II of Regulation (EU) 2016/425 based on the evaluation on technical documentation and relevant test reports.

Subcontracted Manufacturer Sites
Site 1: Fatsa OSB Mah. 101. Sokak No:11/A Fatsa ORDU / TURKEY

Identification of the Personal Protective Equipment
Brand Name: A&Z MED, **Model:** OLI-2028
Isolation gown, as a protective clothing for the part of body Type [PB]-6-B, manufactured from blue polypropylene non-woven fabric, inside bound seams, with back. The gown is available in 5 nominal sizes.

The following harmonised standards have been applied:

EN ISO 13688:2013, (General requirements for protective clothing)
EN 13034:2005+A1:2009, (Chemical protective clothing offering limited protective performance against liquid chemicals) Type PB [6], limited life clothing,
EN 14126:2003/AC:2004, (Protective clothing against infective agents) for Type PB [6]-B, limited life

Here by the manufacturer is allowed to use notified body number (2163) and can fix CE mark, as shown below, on the Category III product models given above, with the below requirements;

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9**.
- Ongoing successful performance in fulfilment of the requirements set out in Personal Protective **Equipment Regulation (EU) 2016/425** and harmonised standards, ensured by assessments based on **Annex V (Module C2) or Annex 8 (Module D)** of the regulation

This certificate is initially issued on **25/08/2020** and will be valid for 5 years from the issue date.

CE
2163

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

Verify the validity with the QR Code

EU DECLARATION OF CONFORMITY

MANUFACTURER

İBİŞLER TEKSTİL SANAYİ VE DIŞ TİCARET A.Ş.

Orhangazi Mahallesi Turgut Caddesi No:5 34358 Esenyurt ISTANBUL / TURKEY

Subcontracted Manufacturer Sites

Site 1: Fatsa Organize Sanayi Mah. 101. Sokak No:11/A Fatsa ORDU / TURKEY

Identification of the Personal Protective Equipment

Brand Name: A&Z MED, **Model:** OLI-2028

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The following harmonised standards have been applied:

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EN 14126:2003/AC:2004 (Protective clothing against infective agents) for Type PB [6]-B, limited life

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Issuing an appropriate EU Declaration of Conformity according to Personal Protective Equipment Regulation (EU) 2016/425 Annex 9.
On having successful performance in fulfilment of the requirements set out in Personal Protective Equipment Regulation (EU) 2016/425 and harmonised standards, ensured by assessments based on Annex 7 (Module C2) or Annex 8 (Module D) of the regulation

İlhan İBİŞ
General Manager
25/08/2020

CE
2163

BVCS
BRITISH VERITAS CERTIFICATION SERVICES

This is to Certify that

A&Z A&ZMED

İBİŞLER TEKSTİL SAN. VE DIŞ TİC. A.Ş.

ORHANGAZİ MAH. TUNÇ CAD. NO:5/B ESENYURT / İSTANBUL,TURKEY

Conforms to the Requirements of

ISO 9001:2015

Quality Management System

Tulum ve Medikal Maske Dikimi ve Satışı.

Jumpsuit and Medical Mask Sewing and Sale .

Certificate Number : Q.020.080.TR
Certification Period : 3 Years / 16.04.2023
Expiry Date : 17.04.2023
Certified Date : 17.04.2020

Approving Officer:

A. Otgun

MANAGEMENT SYSTEMS
ISO / IEC 17021-1:2015
NAC 007-MS

BRITISH VERITAS CERTIFICATION SERVICES
BVCS
CERTIVICATION
www.bvcscert.com

HMI Certification Training Ltd.
492 Bearwood Rd, Smethwick B66 4HB, Birmingham / West Midland - England
This certificate remains the property of HMI it is valitidy is subject to arrangement between the certificated client and HMI. For further detalis go to
www.bvcscert.com

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BRITISH VERITAS CERTIFICATION SERVICES

This is to Certify that

A&Z A&ZMED

İBİŞLER TEKSTİL SAN. VE DIŞ TİC. A.Ş.

ORHANGAZİ MAH. TUNÇ CAD. NO:5/B ESENYURT / İSTANBUL,TURKEY

Conforms to the Requirements of

ISO 13485:2016

Medical Device Quality Management System

Tulum , Medikal Önlük ve Medikal Maske Dikimi ve Satışı.

Jumpsuit,Medical Gowns and Medical Mask Sewing and Sale .

Certificate Number	: M.020.080.TR	**Expiry Date**	: 17.04.2023
Certification Period	: 3 Years / 16.04.2023	**Certified Date**	: 17.04.2020

Approving Officer:

A. Ozgun

BRITISH VERITAS CERTIFICATION SERVICES
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ANALYSIS REPORT

Report No. : **2016877E** Report Date : 12/08/2020

Applicant : UNIVERSAL SERTİFİKASYON VE GÖZETİM HİZMETLERİ TİCARET LTD.ŞTİ.

Address : Necip Fazıl Bulvarı Keyap Sitesi E2 Blok No:44/84 Yukarı Dudullu Ümraniye/İstanbul/Turkey

Sample : Apron Sample Code: 3304

Sample Package : Poly packing

Sample Amount : 5 adet

Sampling Point : -

Sampling Date : 21/07/2020

Sample Lot No. : -

Sample Carrying Conditions / Preservation Technique : -

Production Date : -

Packing Date : -

Expire Date : -

Producer Company : İbişler Tekstil Sanayi ve Dış Tic. A.Ş.

Sample Receiving Time : 21/07/2020 19:30:00

Analysis Beginning Time : 22/07/2020 14:00:00

Analysis Completion Time : 29/07/2020

Following analysis results were obtained from the specimen which was delivered to Çevre Laboratory by hand to hand

Parameters	Unit	Finding	Sınıf 1	Sınıf 2	Sınıf 3	LR Source	Method	Information
Sentetik Kanın Nüfuzuna Karşı Direnç								
The Average Thickness of the Material Tested	mm	0,21	-	-	-	-	ISO 16603	148
The Average Mass of the Material Tested	g	0,3131	-	-	-	-	ISO 16603	148
Test Spicemen 1: 0 kPa	-	Succeed	-	-	-	-	ISO 16603	149
Test Spicemen 1: 1,75 kPa	-	Succeed	-	-	-	-	ISO 16603	149
Test Spicemen 1: 3,5 kPa	-	Succeed	-	-	-	-	ISO 16603	149
Test Spicemen 1: 7 kPa	-	Succeed	-	-	-	-	ISO 16603	149
Test Spicemen 1: 14 kPa	-	Succeed	-	-	-	-	ISO 16603	149
Test Spicemen 1: 20 kPa	-	Succeed	-	-	-	-	ISO 16603	149
Test Spicemen Thickness 1	mm	0,22	-	-	-	-	ISO 16603	

Kübra HANCI AKAN
Microbiology Laboratory Responsible

Approved by
12/08/2020
Ömer Yasin BALIK
Laboratory Manager

Çevre Endüstriyel Analiz Laboratuvarı Hiz. Tic. A.Ş. Merkez Mahallesi Tatlıpınar Sokak No:13 Mart Plaza Kat:2/A Kağıthane / İstanbul
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ÇEVRE
ENDÜSTRİYEL ANALİZ
LABORATUVARI

ANALYSIS REPORT

Report No. : **2016877E** Report Date : 12/08/2020

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Parameters	Unit	Finding	Sınıf 1	Sınıf 2	Sınıf 3	LR Source	Method	Information
Test Specimen Mass 1	g	0,3611	-	-	-	-	ISO 16603	
Test Spicemen 2: 0 kPa	-	Succeed	-	-	-	-	ISO 16603	149
Test Spicemen 2: 1,75 kPa	-	Succeed	-	-	-	-	ISO 16603	149
Test Spicemen 2: 3,5 kPa	-	Succeed	-	-	-	-	ISO 16603	149
Test Spicemen 2: 7 kPa	-	Succeed	-	-	-	-	ISO 16603	149
Test Spicemen 2: 14 kPa	-	Succeed	-	-	-	-	ISO 16603	149
Test Spicemen 2: 20 kPa	-	Succeed	-	-	-	-	ISO 16603	149
Test Spicemen Thickness 2	mm	0,22	-	-	-	-	ISO 16603	
Test Specimen Mass 2	g	0,3652	-	-	-	-	ISO 16603	
Test Spicemen 3: 0 kPa	-	Succeed	-	-	-	-	ISO 16603	149
Test Spicemen 3: 1,75 kPa	-	Succeed	-	-	-	-	ISO 16603	149
Test Spicemen 3: 3,5 kPa	-	Succeed	-	-	-	-	ISO 16603	149
Test Spicemen 3: 7 kPa	-	Succeed	-	-	-	-	ISO 16603	149
Test Spicemen 3: 14 kPa	-	Fail	-	-	-	-	ISO 16603	149
Test Spicemen 3: 20 kPa	-	Fail	-	-	-	-	ISO 16603	149
Test Spicemen 3: The Time of Failure	dk	3	-	-	-	-	ISO 16603	
Test Spicemen 3: The Pressure of Failure	kPa	14	-	-	-	-	ISO 16603	
Test Spicemen Thickness 3	mm	0,18	-	-	-	-	ISO 16603	
Test Specimen Mass 3	g	0,2129	-	-	-	-	ISO 16603	
The Procedure Selected	-	D	-	-	-	-	ISO 16603	
Microbial Penetration - Dry Bacterium								
Microbial Penetration - Dry Bacterium	log cfu	1,7	2<-≤3	1<-≤2	≤1	-	ISO 22612	101, 150, 151
Test Spicemen 1 - Colony Count	cfu	72	-	-	-	-	-	
Test Spicemen 2 - Colony Count	cfu	85	-	-	-	-	-	
Test Spicemen 3 - Colony Count	cfu	60	-	-	-	-	-	
Test Spicemen 4 - Colony Count	cfu	>300	-	-	-	-	-	
Test Spicemen 5 - Colony Count	cfu	>300	-	-	-	-	-	

Kübra HANCI AKAN
Microbiology Laboratory Responsible

Approved by
12/08/2020
Ömer Yasin BALIK
Laboratory Manager

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ANALYSIS REPORT

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Parameters	Unit	Finding	Sınıf 1	Sınıf 2	Sınıf 3	LR Source	Method	Information
Test Spicemen 6 - Colony Count	cfu	>300	-	-	-	-	-	
Test Spicemen 7 - Colony Count	cfu	23	-	-	-	-	-	
Test Spicemen 8 - Colony Count	cfu	18	-	-	-	-	-	
Test Spicemen 9 - Colony Count	cfu	30	-	-	-	-	-	
Test Spicemen 10 - Colony Count	cfu	21	-	-	-	-	-	
Ortalama Koloni Sayısı	cfu	48	-	-	-	-	-	101
Negative Control Count 1	cfu	<1	-	-	-	-	-	
Negative Control Count 2	cfu	<1	-	-	-	-	-	
Talc Concentration	cfu/g	$3,8*10^8$	-	-	-	-	ISO 22612	
Microbial Penetration - Wet Bacterium								
Test Spicemen 1 - Colony Count	cfu	<1	-	-	-	-	ISO 22610	154
Test Spicemen 2 - Colony Count	cfu	<1	-	-	-	-	ISO 22610	154
Test Spicemen 3 - Colony Count	cfu	<1	-	-	-	-	ISO 22610	154
Test Spicemen 4 - Colony Count	cfu	266	-	-	-	-	ISO 22610	154
Test Spicemen 5 - Colony Count	cfu	200	-	-	-	-	ISO 22610	154
Test Spicemen 1 - Barrier Index	-	6	-	-	-	-	ISO 22610	154
Test Spicemen 2 - Barrier Index	-	6	-	-	-	-	ISO 22610	154
Test Spicemen 3 - Barrier Index	-	6	-	-	-	-	ISO 22610	154
Test Spicemen 4 - Barrier Index	-	2,76	-	-	-	-	ISO 22610	154
Test Spicemen 5 - Barrier Index	-	3,5	-	-	-	-	ISO 22610	154
Test Spicemen 1 - Percentage of Penetration	%	0	-	-	-	-	ISO 22610	154
Test Spicemen 2 - Percentage of Penetration	%	0	-	-	-	-	ISO 22610	154
Test Spicemen 3 - Percentage of Penetration	%	0	-	-	-	-	ISO 22610	154
Test Spicemen 4 - Percentage of Penetration	%	5,02	-	-	-	-	ISO 22610	154
Test Spicemen 5 - Percentage of Penetration	%	3,77	-	-	-	-	ISO 22610	154
Average Penetration Percentage	%	1,76	-	-	-	-	ISO 22610	32

Kübra HANCI AKAN
Microbiology Laboratory Responsible

Approved by
12/08/2020
Ömer Yasin BALIK
Laboratory Manager

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Following analysis results were obtained from the specimen which was delivered to Çevre Laboratory by hand to hand

Parameters	Unit	Finding	Sınıf 1	Sınıf 2	Sınıf 3	LR Source	Method	Information
Bacillus atrophaeus Concentration	spores/mL	$5,3*10^3$	-	-	-	-	ISO 22610	
Pathogen Penetration								
The Procedure Selected	-	D	-	-	-	-	ISO 16604	155
Hydrostatic Pressure - 1	kPa	20	-	-	-	-	ISO 16604	
Test Spicemen 1	-	Succeed	-	-	-	-	ISO 16604	157
Hydrostatic Pressure - 2	kPa	20	-	-	-	-	ISO 16604	
Test Spicemen 2	-	Succeed	-	-	-	-	ISO 16604	157
Hydrostatic Pressure - 3	kPa	7	-	-	-	-	ISO 16604	
Test Spicemen 3	-	Succeed	-	-	-	-	ISO 16604	157
Pre-test Bacteriophage Titer	pfu/mL	$3,3*10^8$	-	-	-	-	ISO 16604	
Post-test Bacteriophage Titer	pfu/mL	$2,7*10^8$	-	-	-	-	ISO 16604	
Negative Control	-	Succeed	-	-	-	-	ISO 16604	
Positive Control	-	Fail	-	-	-	-	ISO 16604	

Source of Limit Ranges : El ve Kol Koruması ve Can Yeleği Dahil Koruyucu Kıyafetler (EN 14126)

A: Acceptable NA: Not Acceptable

MU: Measurement Uncertainty

Method ISO : International Organization for Standardization

Information

101 : Test sample-1,2,3 is sampled from the front body, test sample-4,5,6 back body, test sample-7,8 right arm and test sample-9,10 left arm.
The average number of colonies in the relevant sample could not be included in the calculation, since the back body portion> 300 cfu appeared.

148 : Test sample-1 is sampled from the front body, test sample-2 right arm, test sample-3 back body. The thickness and mass given are the average of the results for these three samples.

149 : The retaining screen has 50% open area

150 : Test Conditions : 65±5 relative humidity and 20±2°C
ATCC 9372 Bacillus subtilis spores were used in the concentration of ethyl alcohol.
200 mm x 200 mm 12 test pieces used
The vibrator was operated in an air flow with a vibration frequency of 20800 per minute.
□
□

151 : EN 14126 standard provides Class 2 values according to Table 4.

154 : Test Conditions : 65±5 relative humidity and 20±2°C minimum 24 hours
The distance to the distance agar-to-brim is 3.0 mm.
25 cm x 25 cm 5 test pieces were used.
The tests were carried out from the outside of the sample.
ATCC 9372 Bacillus atrophaeus spore suspension was used.

Kübra HANCI AKAN
Microbiology Laboratory Responsible

Approved by
12/08/2020
Ömer Yasin BALIK
Laboratory Manager

Çevre Endüstriyel Analiz Laboratuvarı Hiz. Tic. A.Ş. Merkez Mahallesi Tatlıpınar Sokak No:13 Mart Plaza Kat:2/A Kağıthane / İstanbul
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ANALYSIS REPORT

Report No. **: 2016877E** Report Date **:** 12/08/2020

Incubator Control <4 cfu
Test Environment Control <25 cfu
□

155 : Test Conditions: Minimum 24 hours at 20±2°C and 65±5 % relative humidity
Sample size and number: 3 test samples in size 75x75mm
Name of test microorganism: ATCC 13706-B1 Escherichia coli bacteriophage Phi X174
PFU: Plate forming unit

157 : Test sample-2 were sampled from right arm.

157 : Test sample-3 were sampled from the back body part.

157 : Test sample-1 were sampled from the front body part.

32 : Test sample-1,2,3 is sampled from the front body, test sample-4,5,6 back body, test sample-7,8 right arm and test sample-9,10 left arm.

R1 : This report supersedes 30/07/2020 date 2016877E number of report which is invalid.

Note

1. When request, the conformit assessment is carried out in accordance with the legal regulations and standards or the decision rules which are agreed with the customer.
2. Descriptive information about the samples / sampling in the analysis report has been declared by the customer. Our laboratory is not responsible for the legal losses.
3. Analysis report covers samples/sampling that comes to the laboratory.
4. This report and results don't not be copied and printed partially or completely without permission of Cevre Industrial Analysis Laboratory for any commercial and advertising purposes.
5. This report shall not be used official purposes related to Enviromental Regulations.
6. The test report without sign is not valid.

End of Report

Kübra HANCI AKAN
Microbiology Laboratory Responsible

Approved by
12/08/2020
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ÇEVRE ENDÜSTRİYEL ANALİZ LABORATUVARI
ÇEVRE ENDÜSTRİYEL ANALİZ LABORATUVAR HİZM. TİC. A.Ş.

Microbial Penetration - Wet Bacteria Analysis Report Attachment (ISO 22610)

Sample No: 2016877E

Analysis Results

	Bacillus atrophaeus Spore Concentration (spore/mL)	X1 (cfu) 0-15 minute	X2 (cfu) 15-30 minute	X3 (cfu) 30-45 minute	X4 (cfu) 45-60 minute	X5 (cfu) 60-75 minute	Z (cfu)	Total Colony Count (cfu)	% Pn
Test Specimen - 1 (front bady part)	5300	0	0	0	0	0	67	0	0,00
Test Specimen - 2 (front bady part)		0	0	0	0	0	44	0	0,00
Test Specimen - 3 (right arm part)		0	0	0	0	0	76	0	0,00
Test Specimen - 4 (back bady part)		88	72	55	25	26	33	266	5,02
Test Specimen - 5 (back bady part)		62	29	38	41	30	61	200	3,77

X1: 1.plates colony count

X2: 2.plates colony count

X3: 3.plates colony count

X4: 4.plates colony count

X5: 5.plates colony count

Z: Number of plates in the reverse test sample

Pn: Percentage of penetration

Total Colony Count = X1+X2+X3+X4+X5

	T (cfu)	CUM1	CUM2	CUM3	CUM4	CUM5	Barrier İndex (EPP)	Donor (cfu)	Incubator Control (cfu)	Ambient Test Control (cfu)
Test Specimen - 1 (front bady part)	67	0,00	0,00	0,00	0,00	0,00	6,00	136	<4	<25
Test Specimen - 2 (front bady part)	44	0,00	0,00	0,00	0,00	0,00	6,00	105	<4	<25
Test Specimen - 3 (right arm part)	76	0,00	0,00	0,00	0,00	0,00	6,00	112	<4	<25
Test Specimen - 4 (back bady part)	299	0,29	0,54	0,72	0,80	0,89	2,76	89	<4	<25
Test Specimen - 5 (back bady part)	261	0,24	0,35	0,49	0,65	0,77	3,50	75	<4	<25

T = Z + X1 + X2 + X3 + X4 + X5

CUM1 = X1/T

CUM2 = (X2 + X1)/T

CUM3 = (X3 + X2 + X1)/T

CUM4 = (X4 + X3 + X2 + X1)/T

CUM5 = (X5 + X4 + X3 + X2 + X1)/T

Ömer Yasin BALIK
Laboratory Manager

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	
20025486-ing	
08-20	

Customer name:	UNIVERSAL SERTİFİKASYON VE GÖZETİM HİZMETLERİ TİCARET LTD.ŞTİ.
Address:	Yukarı Dudullu Mahallesi, KEYAP E2 No:84, 34775 Dudullu Organize Sanayi Bölgesi/Ümraniye/İstanbul
Buyer name:	İBİŞLER TEKSTİL SANAYİ VE DIŞ TİCARET ANONİM ŞİRKETİ
Contact Person:	SUAT KAÇMAZ
Order No:	
Article No:	
Name and identity of test item:	Blue surgical gown
The date of receipt of test item:	22.07.2020
Re-submitted/re-confirmation date:	-
Date of test:	22.07.2020-05.08.2020
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:	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.

Seal	*Date*	*Customer Representative*	*Head of Testing Laboratory*
TESTED BY EKOTEKS TESTEDİLMİŞTİR	05.08.2020	Servin YURT-SEVEN	Sevim A. RAZAK

REQUIRED TESTS	RESULT	COMMENTS
PHYSICAL PROPERTIES TESTS		
Abrasion	-	Class 5
Water Permeability	-	Class 5
Tear Strength	-	Class 2
Tensile Strength	-	Class 1
Repellency to Liquids	-	See test result
Resistance To Penetration By Liquids	-	Class 3
Seam Strength	-	Class 2
Surface Resistivity(1)	F	
Puncture Resistance	-	Class 1
Determination of resistance to damage by flexing	-	Class 5
MICROBIOLOGICAL TESTS		
Wet-Bacterial Penetration	-	Class 4

P: Pass
F: Fail
R: Refer to retailer technologist

Tests were classified according to BS EN 14325:2018
BS EN 14126 :2003 Protective clothing —Performance requirements and tests methods for protective clothing against infective agents
(1)Requirement was given by the vendor

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.

TEST RESULTS

Test Method : BS EN 14325:2018 (PROTECTIVE CLOTHING AGAINST CHEMICALS:TEST METHODS AND PERFORMANCE CLASSIFICATION OF CHEMICAL PROTECTIVE CLOTHING MATERIALS,SEAMS,JOINS AND ASSEMBLAGES (*)

ABRASION RESISTANCE AND LEAK TIGHTNESS

Clause 4.4.Abrasion Resistance (EN ISO 12947-2) ANNEX-B

Martindale Test Machine (47.5±2 rpm) with Lissajous Figure.
9 kPa pressure,
Performed in the conditioned room (20±2°C-65%±4).

RESULT	CLASS
No abrasion @ 1.000 revs	5 Classified according to the Table-1

Determination of the highest number of abrasion rubs which does not cause damage to the material and which shall be used for the performance classification.
The abrasion resistance of sample shall be Classified according to the levels of performance given in Table-1

Table-1 Classification of Abrasion Resistance

Class	*Number of rubs*
6	>2000
5	>1000
4	>400
3	>100
2	>40
1	>10

Clause 4.4.2.3 Hydrostatic head end –point determination (EN 20811)

If the average hydrostatic head exceeds 200mm,then the hydrostatic head method is applicable and the leak tightness shall be determined.

WATER PERMEABILITY ; EN ISO 20811:2018

Hydrostatic Head Tester, Textest marka Fx 3000 model
Temperature of water10.°C. Pressure increase ratio 10 mbar/dk.
Performed in the conditioned room (20±2°C-65%±4)

	RESULT	REQUIREMENT
Sample 1	1683 mm SS	>200 mmSS
Sample 2	1244.4 mm SS	
Sample 3	1458.6 mm SS	
Sample 4	1642.2mm SS	
Average	1507.1 mm SS	

TEST RESULT

TRAPEZOIDAL TEAR STRENGTH

Clause: 4.7.Trapezoidal Tear Resistance TS EN ISO 9073-4:2002(*)

Instron 5969 Speed:100±10 mm/min, Gauge length:5cm
The average results are given for width and length direction of five samples.
2 pre-tension applied
Performed in the conditioned room. (20±2°C - 65% ±4)

	RESULT	CLASS
Width	29.8 N	2 Classified according to the Table-4
Length	44.2 N	

Table-4 Classification of Trapezoidal Tear Resistance

Class	*Tear Strength*
6	>150 N
5	>100 N
4	>60 N
3	>40 N
2	>20 N
1	>10 N

Gen.f136-2/03

TENSILE STRENGTH

Clause 4.9.Tensile Strenght EN ISO 13934-1:2013

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 width and length direction of five samples.
Performed in the conditioned room (20±2°C-65%±4).

	RESULT	CLASS
Width	37.6 N	1 Classified according to the Table-5
Length	64.5 N	

Table-4 Classification of Tensile Strenght

Class	*Tensile Strength*
6	>1000 N
5	>500 N
4	>250 N
3	>100 N
2	>60 N
1	>30N

TEST RESULT
REPELLENCY TO LIQUIDS

Clause 4.12 Repellency to Liquids (EN ISO 6530:2005)

When tested in accordance with EN ISO 6530 for repellency to the liquid chemicals given in Table -9, the material shall be classified According to the levels performance in given Table-10 for each chemical tested.
Use those liquids against which protection is required, water is also cenvenient and safe liquid for general screening purposes.
Performed in the conditioned room (20±2°C-65%±4).

For each test liquid ,cut six test specimens of (360±2)mm by (235±5)mm from the sample.
Chemicals shall be of analytical purity grade.
Discharged the test liquid (10cm 3) within (10±1)s

Table-9 List of reference chemicals for absorption ,penetration and repellency testing

Chemical	*Concentration weight %*	*Temperature of chemical (±2°C)*
Sulfuric Acid (H2SO4)	30	20
Sodium Hydroxide (NaOH)	10	20
o-Xylene	Undiluted	20

Gen.f136-2/03

Table 10- Classification of Repellency to liquids

Class	*Repellency Index (I_R)*
3	> 90 %
2	>80 %
1	>70 %

Clause 4.13 Resistance to penetration by liquids (EN ISO 6530)

Table 11- Classification of Resistance to penetration by liquids

Class	*Penetration Index (Ip)*
3	< 1 %
2	< 5 %
1	<10 %

RESULT

Chemical	*Concentration weight %*	I_P	*Class*	I_R	*Class*
Sulfuric Acid (H2SO4)	30	0%	3	85.7 %	2
Sodium Hydroxide (NaOH)	10	0%	3	96.8 %	3
o-Xylene	Undiluted	0%	3	0.1 %	-

I_P: index of penetration
I_R: index of repellency
I_A: index of absorbtion

TEST RESULT

SEAM STRENGTH-GRAB METHOD

Clause 5.5 Seam Strength ISO 13935-2: 2014
Jaw Speed: 50±5 mm/min, Gauge Length: 100 mm±1 mm.
Seam Type : 301. 100 % Polyester core-spun sewing-thread was used.
5kN. Load was applied.
The average results are given for width and length direction of five samples.
Performed in the conditioned room(20±2°C-65%±4)

	Seam Strength (N)	Fail	CLASS
Shoulder seam	96.9 N	FTJ	2 Classified according to the Table-13
Sleeve	111.7 N	FTJ	
Armhole seam	82.3 N	FTJ	
Waist belt	70.5 N	FTJ	

FTS Fabric Tear At The Seam
FTJ : Fabric Tear At The Jaw

Table 13- Classification of Seam Strength

CLASS	*Seam strength*
6	>500 N
5	>300 N
4	>125 N
3	>75 N
2	>50 N
1	>30 N

TEST RESULT

SURFACE RESISTIVITY; EN 1149-1:2006(*)

Ohm meter (METRISO 3000) and ring probe were used.
Original sample was tested as the client's request

Pre-Treatment	-
Atmosphere for conditioning and testing	(23± 1)°C, (25± 5)%RH
Conditioning time	≥ 24 hours
Applied voltage	-
Number of samples tested	5

	RESULT	
Measurement	**Surface Resistivity**	**REQUIREMENT**
1.	7,5x $10^{12}\Omega$	
2.	10x $10^{12}\Omega$	
3.	25x $10^{12}\Omega$	
4.	13 x $10^{12}\Omega$	
5.	15x $10^{12}\Omega$	<2.5 x10^{9} **Ω**

TEST RESULT

PUNCTURE RESISTANCE

Clause 4.10.Puncture Resistance EN 863 (*)

RESULT	CLASS
5.2 N	1 Classified according to the Table-6

Table-4 Classification of Puncture Resistance
(Tablo-6)

Class	*Puncture Resistance*
6	>250 N
5	>150 N
4	>100 N
3	>50 N
2	>10 N
1	>5N

DETERMINATION OF RESISTANCE TO DAMAGE BY FLEXING METHOD C (CRUMPLE/FLEX) (*)

Test Metot : ISO 7854 :1995 Rubber- or plastics-coated fabrics -Determination of resistance to damage by flexing Method C (Crumple /Flex Test) (*)Clause 4.5
Two test pieces were prepared each 220 mm long x 190 mm widht
After cycle has finished examine the damage of samples and classified

RESULT	CLASS
>40 .000 cycles	Class 5 Classified according to the Table-2
No damage observed	

Table 2-Classification of flex cracking resistance

Class	Number of cycles
6	> 100 000
5	>40 000
4	> 15 000
3	> 5 000
2	> 2 500
1	> 1000

TEST RESULTS

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):	1-4x104 kob / ml
Incubation Conditions:	(36 ± 1) ° C 48 hours

RESULTS				
Breakthrough time, *t* min	**Number of Populating Bacteria (cfu)**		**Penetration Rate**	
15	X_1	0	R_{CUM1}	0
30	X_2	0	R_{CUM2}	0
45	X_3	0	R_{CUM3}	0
60	X_4	17	R_{CUM4}	0,04
75	X_5	42	R_{CUM5}	0,14
	Z	351		
	T	410		

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: X1 + X2 + X3 + X4 + X5 + Z
RCUM1 = X1/T
RCUM2 = (X2 + X1)/T
RCUM3 = (X3 + X2 + X1)/T
RCUM4 = (X4 + X3 + X2 + X1)/T
RCUM5 = (X5 + X4 + X3 + X2 + X1)/T

EVALUATION

Result	**Class (*)**
45 < ***t*** ≤ 60	*4*

(*) BS EN 14126:2003 Protective Clothing —Performance requirements and tests methods for protective clothing against infective agents

Class	**Breakthrough time, *t* min**
6	***t*** > 75
5	60 < ***t*** ≤ 75
4	45 < ***t*** ≤ 60
3	30 < ***t*** ≤ 45
2	15 < ***t*** ≤ 30
1	≤ 15 min