



INTERNATIONAL CERTIFICATION

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# Sertifika

**OLEY TIBBİ ÜRÜNLER VE MEDİKAL MALZEMELER  
SAN. TİC. LTD. ŞTİ.**

kuruluşunun,

PARSELLER MAH. MENEKŞE CD. FEYYAZ SK. N.2-2/1-2/2-2/4  
ÜMRANIYE/İSTANBUL

adresinde,

**TEK KULLANIMLIK STERİL OLMAYAN CERRAHİ ÖNLÜK, CERRAHİ BONE, CERRAHİ MASKE,  
CERRAHİ TULUM ÜRETİMİ, SATIŞI, İTHALATI VE İHRACATI**

**MANUFACTURE, SALES, IMPORT AND EXPORT OF DISPOSABLE NON STERILE SURGICAL  
GOWN, SURGICAL CAP, SURGICAL MASK, SURGICAL OVERALLS**

kapsamında,

## ISO 13485:2016

**Medikal Cihazlar-Kalite Yönetim Sistemi**

Uygulanmayan Maddeler; 7.3, 7.5.3, 7.5.4, 7.5.5, 7.5.7, 7.5.9.2, 8.3.4  
şartlarını sağladığı kanıtlanmıştır.

Sertifika No : C-US-20813271  
Belgelendirme Tarihi : 13.06.2020  
Düzenleme Tarihi : 13.06.2020  
Geçerlilik Tarihi : 12.06.2021  
Belge Periyodu : 3 Yıl



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TGS  
International Certification

Bu sertifikanın geçerliliği, TGS belgelendirme kurallarına uyulması ve yılda en az bir defa yapılacak olan gözetim tetkiklerinin olumlu sonuçlanmasına bağlıdır. Sertifikanın geçerliliği [www.tgsbelgelendirme.com](http://www.tgsbelgelendirme.com) adresinden kontrol edilebilmektedir.

**TGS ULUSLARARASI BELGELENDİRME TEKNİK KONTROL VE GÖZETİM HİZMETLERİ LTD. ŞTİ.**

Şerifali Mh. Tavukçuyolu Cd. No:256/4 Ümraniye/İSTANBUL

Tel: +90 216 327 09 77(Pbx) Fax: +90 216 546 05 70

[info@tgsbelgelendirme.com](mailto:info@tgsbelgelendirme.com) / [www.tgsbelgelendirme.com](http://www.tgsbelgelendirme.com) / [www.tgscert.com](http://www.tgscert.com)



INTERNATIONAL CERTIFICATION



# Sertifika

**OLEY TIBBİ ÜRÜNLER VE MEDİKAL MALZEMELER  
SAN. TİC. LTD. ŞTİ.**

kuruluşunun,

PARSELLER MAH. MENEKŞE CD. FEYYAZ SK. N.2-2/1-2/2-2/4 ÜMRANIYE/İSTANBUL

adresinde,

**KİŞİSEL KORUYUCU EKİPMANLARIN RADYASYON KORUYUCU ÖNLÜK, AKSESUAR VE  
EKİPMANLARIN, ELEKTROMANYETİK KORUYUCU EKİPMANLARIN VE AKSESUARLARIN, AYAK VE DİZ  
KORUYUCU ÜRÜNLERİNİN ÜRETİMİ, SATIŞI, İTHALATI VE İHRACATI**

**MANUFACTURE, SALES, IMPORT AND EXPORT OF PERSONAL PROTECTIVE EQUIPMENTS, RADIATION  
PROTECTIVE APRONS, ACCESSORIES AND EQUIPMENTS, ELECTROMAGNETIC PROTECTIVE  
EQUIPMENTS AND ACCESSORIES, PROTECTIVE COVERALLS, SHOE AND KNEE COVER**

kapsamında,

## ISO 45001:2018

### İş Sağlığı ve Güvenliği Yönetim Sistemi

şartlarını sağladığı kanıtlanmıştır.



TGS  
International Certification

Sertifika No : S-NA-20813271  
Belgelendirme Tarihi : 13.06.2020  
Düzenleme Tarihi : 13.06.2020  
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**TGS ULUSLARARASI BELGELENDİRME TEKNİK KONTROL VE GÖZETİM HİZMETLERİ LTD. ŞTİ.**

Şerifali Mh. Tavukçuyolu Cd. No:256/4 Ümraniye/İSTANBUL  
Tel: +90 216 327 09 77(Pbx) Fax: +90 216 546 05 70

[info@tgsbelgelendirme.com](mailto:info@tgsbelgelendirme.com) / [www.tgsbelgelendirme.com](http://www.tgsbelgelendirme.com) / [www.tgscert.com](http://www.tgscert.com)

# AT UYGUNLUK BEYANI EC DECLARATION OF CONFORMITY



## İMALATÇI/MANUFACTURER:

Oley Tıbbi Ürünler Medikal Mlz. San. Tic. Ltd Şti.

**Address/Address:** Parseller Mh. Menekşe Cd. Feyyaz Sk. No:2/3 Ümraniye İstanbul TURKEY

**Web:** www.oleytibbiurunler.com

**Ürün Tanımı:** Tip 3/4-b Tip 5/6-b Koruyucu Tulum

**Product Description:** Type 3/4-b Type 5/6-b Protective Coverall

**Tip Model Adı:** OLEY2311

**Type Model Name:** OLEY2311

**Marka:** OLEY

**Brand:** OLEY

**Belge No/Certificate No:** 90-20-01

**Belgelendirme Tarihi/ Certification date:** 09.12.2020

**Belge Geçerlilik Tarihi/ Certification Validty date:** 09.12.2025

**Direktif:** 2016/425 KKD Yönetmeliği

**Directive :** 2016/425 PPE Directive Related

## Test Standartları/Test Standards:

**EN ISO 13688** Koruyucu Giyecekler- Genel Özellikler / Protective Clothing - General Requirements

**EN 13034+ A1** Sıvı Kimyasallara Karşı Koruyucu Giysi (Tip 6-B)/ Protective Clothing Against Liquid Chemicals (Type 6-B)

**EN ISO 13982-1** Katı Parçacıklara Karşı Koruyucu Giysi (Tip 5-B) / Protective Clothing Against Solid Particules (Type 5-B)

**EN 14605+A1** Koruyucu Giyecekler - Sıvı Kimyasal Maddelere Karşı (Tip3-B, Tip 4-B) / Protective Clothing Against Liquid Chemicals (Type 3-B, Type 4-B)

**EN 14126** Koruyucu Giyecekler - Patojen Organizmalara Karşı / Protective Clothing Performance Requirements and Test Methods For Protective Clothing Against Infective Agents

Üretici firma, Oley Tıbbi Ürünler Medikal Mlz. San. Tic. Ltd Şti. Address: Parseller Mh. Menekşe Cd. Feyyaz Sk. No:2/3 Ümraniye İstanbul TURKEY, aşağıda belirtilen ürünün 2016/425 sayılı Yönetmeliğin (AB) düzenlemelerine, temel gereksinimlerine (Ek II) ve uyumlaştırılmış standartlara ve yönetmelik (AB) gerekliliklerine uygun olduğunu kendi sorumluluğu altında beyan eder.

The manufacturer, Oley Tıbbi Ürünler Medikal Mlz. San. Tic. Ltd Şti. Address: Parseller Mh. Menekşe Cd. Feyyaz Sk. No:2/3 Ümraniye İstanbul TURKEY declares under their sole responsibility, that the product mentioned below complies with the regulations, essential requirements (Annex IX) and harmonised standards of Regulation (EU) 2016/425.

KKD Yönetmeliği (AB) 2016/425 Ek IX uyarınca uygunluk değerlendirmesi: Kategori III

Conformity assessment according to Annex IX of PPE-Regulation(EU) 2016/425: Category III

AB tip incelemesi (Modül B) gerçekleştirilmiş ve AB Tip İnceleme Sertifikası 90-20-01, Onaylanmış Kuruluş MNA 2841 tarafından test raporu MNA M-2020-0567 ya istinaden. Türe Uygunluk, Dahili üretim kontrolü artı Onaylanmış Kuruluş MNA 2841 gözetiminde rastgele aralıklarla denetlenen ürün kontrolleri (Modül C2).

The EU type examination (Module B) was carried out and the EU Type Examination Certificate 90-20-01 was issued by the Notified Body MNA 2841 based on MNA M-2020-0567 . The Conformity to Type based on internal production control plus supervised product checks at random intervals (Module C2) under the supervision of the Notified Body MNA 2841.

Şenay Şentürk  
General Manager  
İstanbul-TURKEY  
09.12.2020

**OLEY TIBBİ ÜRÜNLER VE MEDİKAL  
MLZ. SAN. TİC. LTD. ŞTİ.**  
Parseller Mh. Menekşe Cd. Feyyaz Sk.  
No: 2-2/1-2/2-2/4 Ümraniye - İSTANBUL  
ALEMDAŞ V.D. : 641 031 6213  
www.oleytibbiurunler.com



## AB Tip İnceleme Sertifikası EU Type-Examination Certificate

**Belge No / Certificate No** : 90-20-01  
**Belgelendirme Tarihi - Bir Sonraki Belge Tarihi /  
Certification Date / Certificate Validity Date** : 09.12.2020-09.12.2025  
**Belge Geçerlilik Tarihi / Document Validity Period** : 5 yıl / 5 years  
**Firma Unvanı ve Adresi /  
Company Name and Address** : OLEY TIBBİ ÜRÜNLER VE MEDİKAL MALZEMELER  
SAN. TİC. LTD. ŞTİ.  
Parseller Mah. Menekşe Cad. Feyyaz Sok. No: 2 Ümraniye/  
İSTANBUL/TÜRKİYE  
**Ürün Adı/Modeller / Product Name / Models** : OLEY 2311  
**Direktifi / Directive** : 2016/425 REGULATION  
**Modülü/Kategori / Module / Category** : B MODÜLÜ/ KATEGORİ III  
MODULE B / CATEGORY III  
**Test Rapor No/ları / Test Report No** : MNA M-2020-00567  
**Ürün Tipi / Product Type:**

- EN ISO 13688 Koruyucu giyecekler - Genel özellikler / Protective clothing - General requirements
- EN 13034+ A1 Sıvı Kimyasallara Karşı Koruyucu Giysi (Tip 6-B) / Protective Clothing Against Liquid Chemicals (Type 6-B)
- EN ISO 13982-1 Katı Parçacıklara Karşı Koruyucu Giysi (Tip 5-B) / Protective Clothing For Use Against Solid Particulates (Type 5-B)
- EN 14605+A1 Koruyucu Giyecekler - Sıvı Kimyasal Maddelere Karşı (Tip 3-B, Tip 4-B) / Protective clothing against liquid chemicals (Type 3-B, Type 4-B)
- EN 14126 Koruyucu Giyecekler - Patojen Organizmalara Karşı / Protective Clothing - Performance Requirements And Tests Methods For Protective Clothing Against Infective Agents

**Ürünün Malzeme Bilgisi / Product Material Information:** OLEY 2311 model ürünleri kaplamalı kumaş kullanılarak imal edilmiştir. / OLEY 2311 model products are manufactured using coated fabric.

**Volkan AKIN**  
09.12.2020  
Karar Verici / Approver



**Okan AKEL**  
09.12.2020  
Şirket Müdürü / General manager



MNA Laboratuvarları San. Tic.Ltd .Şti  
Adres: Küçükbakkalköy Mahallesi Yenidoğan Cad.No:21 Ataşehir/ İstanbul  
Tel: 0216 574 07 08 Faks: 0216 575 13 31 [www.mnalab.com](http://www.mnalab.com)

U-Form-002/Rev.04/12.03.2020



**MNA LABORATORIES  
TEST REPORT**

Report No: M-2020-00567	Date: 09.12.2020	Page: 1 / 8	Rev:
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<b>Purpose of Analysis</b>	: SPECIAL REQUEST	<b>Brand</b>	:
<b>Sample Type</b>	: PROTECTIVE CLOTHING	<b>Model</b>	: OLEY 2311
<b>Sample Send Org.</b>	: OLEY TIBBİ URUNL.VE MEDİ.MLZ SAN.TİC.LTD.ŞTİ.	<b>Sampler</b>	: CUSTOMER
<b>Manufacturer Name</b>	: OLEY TIBBİ URUNL.VE MEDİ.MLZ SAN.TİC.LTD.ŞTİ.		
<b>Analysis Date</b>	: 27.11.2020		
<b>Sample Quantity</b>	: 41 pieces		
<b>Other informations</b>	:		

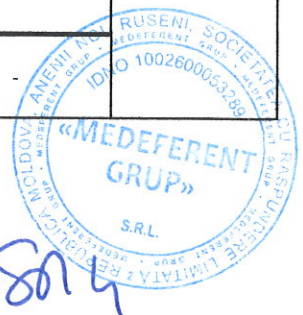
No	Tests	Results	Limit Value	Method	Evaluation	Physical Condition
1	Abrasion Resistance	10 (Cycle)	>10 Cycle	BS EN 14325 Part 4.4	PERFORMANC E LEVEL:1	
2		10 (Cycle)	>10 Cycle	BS EN 14325 Part 4.4		
3		10 (Cycle)	>10 Cycle	BS EN 14325 Part 4.4		
4		10 (Cycle)	>10 Cycle	BS EN 14325 Part 4.4		
5	Tear Resistance- Trapezoidal	41,79(Newton)	>20 N	EN ISO 9073-4+ BS EN 14325 Part 4.7	PERFORMANC E LEVEL:2	
6		34,02(Newton)	>20 N	EN ISO 9073-4+ BS EN 14325 Part 4.7		
7		43,10(Newton)	>20 N	EN ISO 9073-4+ BS EN 14325 Part 4.7		
8		39,19(Newton)	>20 N	EN ISO 9073-4+ BS EN 14325 Part 4.7		
9		44,66(Newton)	>20 N	EN ISO 9073-4+ BS EN 14325 Part 4.7		
10		121,54 (Newton)	>20 N	EN ISO 9073-4+ BS EN 14325 Part 4.7		
11		127,40 (Newton)	>20 N	EN ISO 9073-4+ BS EN 14325 Part 4.7		
12		121,32 (Newton)	>20 N	EN ISO 9073-4+ BS EN 14325 Part 4.7		
13		127,30 (Newton)	>20 N	EN ISO 9073-4+ BS EN 14325 Part 4.7		
14		141,59 (Newton)	>20 N	EN ISO 9073-4+ BS EN 14325 Part 4.7		
15	Puncture Resistance	7,99(Newton)	>5 N	EN 863+ BS EN 14325 Part 4.10	PERFORMANC E LEVEL:1	
16		7,23 (Newton)	>5 N	EN 863+ BS EN 14325 Part 4.10		
17		8,10(Newton)	>5 N	EN 863+ BS EN 14325 Part 4.10		

## MNA LABORATORIES TEST REPORT

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<b>Sample Type</b>	: PROTECTIVE CLOTHING	<b>Model</b>	: OLEY 2311
<b>Sample Send Org.</b>	: OLEY TIBBİ URUNL.VE MEDİ.MLZ SAN.TİC.LTD.ŞTİ.	<b>Sampler</b>	: CUSTOMER
<b>Manufacturer Name</b>	: OLEY TIBBİ URUNL.VE MEDİ.MLZ SAN.TİC.LTD.ŞTİ.		
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<b>Other informations</b>	:		

18	Puncture Resistance	6,80 (Newton)	>5 N	EN 863+ BS EN 14325 Part 4.10	PERFORMANC E LEVEL:1	
19	Flex Cracking Resistance	500 (Cycle)	>500 Cycle	EN ISO 7854+ BS EN 14325 Part 4.5	PERFORMANC E LEVEL:1	
20	Penetration by Liquids-Sulphuric Acid	Penetration	0,8 (%)	<1 %	EN ISO 6530+ BS EN 14325 Part 4.12,13	PERFORMANC E LEVEL:3
		Repellency	97,6 (%)	>90 %	EN ISO 6530+ BS EN 14325 Part 4.12,13	
		Absorption	- (%)		EN ISO 6530+ BS EN 14325 Part 4.12,13	-
21	Penetration by Liquids-Sodium Hydroxide	Penetration	0,4 (%)	< 1%	EN ISO 6530+ BS EN 14325 Part 4.12,13	PERFORMANC E LEVEL:3
		Repellency	98,8 (%)	>90 %	EN ISO 6530+ BS EN 14325 Part 4.12,13	
		Absorption	- (%)		EN ISO 6530+ BS EN 14325 Part 4.12,13	-
22	Wet Bacterial Penetration(1. sample)	1. plate	3 (Colony)		ISO 22610:2018 + TS EN 14126 Part 4.1.4.2	
		2. plate	5 (Colony)		ISO 22610:2018 + TS EN 14126 Part 4.1.4.2	
		3. plate	6 (Colony)		ISO 22610:2018 + TS EN 14126 Part 4.1.4.2	
		4. plate	4 (Colony)		ISO 22610:2018 + TS EN 14126 Part 4.1.4.2	
		5. plate	3 (Colony)		ISO 22610:2018 + TS EN 14126 Part 4.1.4.2	
		6. plate	- (Colony)		ISO 22610:2018 + TS EN 14126 Part 4.1.4.2	
		% Penetration	0,18 (%)		ISO 22610:2018 + TS EN 14126 Part 4.1.4.2	



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## MNA LABORATORIES TEST REPORT

Report No: M-2020-00567	Date: 09.12.2020	Page: 3 / 8	Rev:
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<b>Purpose of Analysis</b>	: SPECIAL REQUEST	<b>Brand</b>	:
<b>Sample Type</b>	: PROTECTIVE CLOTHING	<b>Model</b>	: OLEY 2311
<b>Sample Send Org.</b>	: OLEY TIBBİ URUNL.VE MEDİ.MLZ SAN.TİC.LTD.ŞTİ.	<b>Sampler</b>	: CUSTOMER
<b>Manufacturer Name</b>	: OLEY TIBBİ URUNL.VE MEDİ.MLZ SAN.TİC.LTD.ŞTİ.		
<b>Analysis Date</b>	: 27.11.2020		
<b>Sample Quantity</b>	: 41 pieces		
<b>Other informations</b>	:		

Sample No	Sample Description	Plate No	Colony Count	Standard	Result
23	Wet Bacterial Penetration(2. sample)	1. plate	3 (Colony)	ISO 22610:2018 + TS EN 14126 Part 4.1.4.2	
		2. plate	5 (Colony)	ISO 22610:2018 + TS EN 14126 Part 4.1.4.2	
		3. plate	5 (Colony)	ISO 22610:2018 + TS EN 14126 Part 4.1.4.2	
		4. plate	4 (Colony)	ISO 22610:2018 + TS EN 14126 Part 4.1.4.2	
		5. plate	3 (Colony)	ISO 22610:2018 + TS EN 14126 Part 4.1.4.2	
		6. plate	- (Colony)	ISO 22610:2018 + TS EN 14126 Part 4.1.4.2	
		% Penetration	0,17 (%)	ISO 22610:2018 + TS EN 14126 Part 4.1.4.2	-
24	Wet Bacterial Penetration(3. sample)	1. plate	3 (Colony)	ISO 22610:2018 + TS EN 14126 Part 4.1.4.2	
		2. plate	5 (Colony)	ISO 22610:2018 + TS EN 14126 Part 4.1.4.2	
		3. plate	4 (Colony)	ISO 22610:2018 + TS EN 14126 Part 4.1.4.2	
		4. plate	5 (Colony)	ISO 22610:2018 + TS EN 14126 Part 4.1.4.2	
		5. plate	2 (Colony)	ISO 22610:2018 + TS EN 14126 Part 4.1.4.2	
		6. plate	- (Colony)	ISO 22610:2018 + TS EN 14126 Part 4.1.4.2	



## MNA LABORATORIES TEST REPORT

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<b>Purpose of Analysis</b>	: SPECIAL REQUEST	<b>Brand</b>	:
<b>Sample Type</b>	: PROTECTIVE CLOTHING	<b>Model</b>	: OLEY 2311
<b>Sample Send Org.</b>	: OLEY TIBBİ URUNL.VE MEDİ.MLZ SAN.TİC.LTD.ŞTİ.	<b>Sampler</b>	: CUSTOMER
<b>Manufacturer Name</b>	: OLEY TIBBİ URUNL.VE MEDİ.MLZ SAN.TİC.LTD.ŞTİ.		
<b>Analysis Date</b>	: 27.11.2020		
<b>Sample Quantity</b>	: 41 pieces		
<b>Other informations</b>	:		

24	Wet Bacterial Penetration(3. sample)	%Penetration	0,16 (%)		ISO 22610:2018 + TS EN 14126 Part4.1.4.2	-
25	Wet Bacterial Penetration(4. sample)	1. plate	2 (Colony)		ISO 22610:2018 + TS EN 14126 Part4.1.4.2	
		2. plate	4 (Colony)		ISO 22610:2018 + TS EN 14126 Part4.1.4.2	
		3. plate	6 (Colony)		ISO 22610:2018 + TS EN 14126 Part4.1.4.2	
		4. plate	5 (Colony)		ISO 22610:2018 + TS EN 14126 Part4.1.4.2	
		5. plate	4 (Colony)		ISO 22610:2018 + TS EN 14126 Part4.1.4.2	
		6. plate	-(Colony)		ISO 22610:2018 + TS EN 14126 Part4.1.4.2	
		%Penetration	0,18 (%)		ISO 22610:2018 + TS EN 14126 Part4.1.4.2	
26	Wet Bacterial Penetration(5. sample)	1. plate	5 (Colony)		ISO 22610:2018 + TS EN 14126 Part4.1.4.2	
		2. plate	5 (Colony)		ISO 22610:2018 + TS EN 14126 Part4.1.4.2	
		3. plate	2 (Colony)		ISO 22610:2018 + TS EN 14126 Part4.1.4.2	
		4. plate	3 (Colony)		ISO 22610:2018 + TS EN 14126 Part4.1.4.2	
		5. plate	5 (Colony)		ISO 22610:2018 + TS EN 14126 Part4.1.4.2	



## MNA LABORATORIES TEST REPORT

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<b>Purpose of Analysis</b>	: SPECIAL REQUEST	<b>Brand</b>	:
<b>Sample Type</b>	: PROTECTIVE CLOTHING	<b>Model</b>	: OLEY 2311
<b>Sample Send Org.</b>	: OLEY TIBBİ URUNL.VE MEDİ.MLZ SAN.TİC.LTD.ŞTİ.	<b>Sampler</b>	: CUSTOMER
<b>Manufacturer Name</b>	: OLEY TIBBİ URUNL.VE MEDİ.MLZ SAN.TİC.LTD.ŞTİ.		
<b>Analysis Date</b>	: 27.11.2020		
<b>Sample Quantity</b>	: 41 pieces		
<b>Other informations</b>	:		

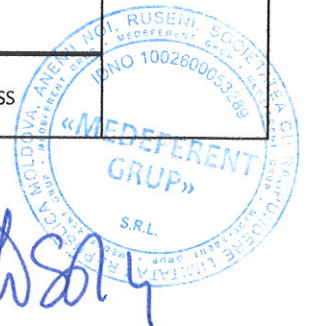
26	Wet Bacterial Penetration(5. sample)	6. plate	- (Colony)		ISO 22610:2018 + TS EN 14126 Part 4.1.4.2	
		% Penetration	0,17 (%)		ISO 22610:2018 + TS EN 14126 Part 4.1.4.2	
		Total Penetration %	0,17 (%)	≤ 15 min	ISO 22610:2018 + TS EN 14126 Part 4.1.4.2	PERFORMANC E LEVEL:1
27	Seam Strength	59,00(Newton)		>50 N	EN ISO 13935-2	PERFORMANC E LEVEL:2
28		58,05(Newton)		>50 N	EN ISO 13935-2	
29		67,12(Newton)		>50 N	EN ISO 13935-2	
30		72,56(Newton)		>50 N	EN ISO 13935-2	
31		72,96(Newton)		>50 N	EN ISO 13935-2	
32		67,91(Newton)		>50 N	EN ISO 13935-2	
33		59,38(Newton)		>50 N	EN ISO 13935-2	
34		61,83(Newton)		>50 N	EN ISO 13935-2	
35		64,34(Newton)		>50 N	EN ISO 13935-2	
36	Tensile Strength	41,78(Newton)		>30 N	ISO 13934-1	PERFORMANC E LEVEL:1
37		42,32(Newton)		>30 N	ISO 13934-1	
38		38,80(Newton)		>30 N	ISO 13934-1	
39		38,99(Newton)		>30 N	ISO 13934-1	
40		37,23(Newton)		>30 N	ISO 13934-1	

**MNA LABORATORIES  
 TEST REPORT**

Report No: M-2020-00567	Date: 09.12.2020	Page: 6 / 8	Rev:
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<b>Purpose of Analysis</b>	: SPECIAL REQUEST	<b>Brand</b>	:
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<b>Sample Send Org.</b>	: OLEY TIBBİ URUNL.VE MEDİ.MLZ SAN.TİC.LTD.ŞTİ.	<b>Sampler</b>	: CUSTOMER
<b>Manufacturer Name</b>	: OLEY TIBBİ URUNL.VE MEDİ.MLZ SAN.TİC.LTD.ŞTİ.		
<b>Analysis Date</b>	: 27.11.2020		
<b>Sample Quantity</b>	: 41 pieces		
<b>Other informations</b>	:		

41	Tensile Strength	119,98 (Newton)	>30 N	ISO 13934-1	PERFORMANC E LEVEL:1	
42		114,96 (Newton)	>30 N	ISO 13934-1		
43		113,45 (Newton)	>30 N	ISO 13934-1		
44		116,72 (Newton)	>30 N	ISO 13934-1		
45		129,95 (Newton)	>30 N	ISO 13934-1		
46	General Size Designation	Chest	122 (cm)	84-96 cm	EN ISO 13688	PASS
		Height	190 (cm)	158-170 cm	EN ISO 13688	
47		Chest	123 (cm)	84-96 cm	EN ISO 13688	PASS
		Height	195 (cm)	158-170 cm	EN ISO 13688	
48		Chest	124 (cm)	84-96 cm	EN ISO 13688	PASS
		Height	196 (cm)	158-170 cm	EN ISO 13688	
49		Chest	128 (cm)	84-96 cm	EN ISO 13688	PASS
		Height	197 (cm)	158-170 cm	EN ISO 13688	
50		Chest	130 (cm)	84-96 cm	EN ISO 13688	PASS




**MNA LABORATORIES  
TEST REPORT**

Report No: M-2020-00567	Date: 09.12.2020	Page: 7 / 8	Rev:
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<b>Purpose of Analysis</b>	: SPECIAL REQUEST	<b>Brand</b>	:
<b>Sample Type</b>	: PROTECTIVE CLOTHING	<b>Model</b>	: OLEY 2311
<b>Sample Send Org.</b>	: OLEY TIBBİ URUNL.VE MEDİ.MLZ SAN.TİC.LTD.ŞTİ.	<b>Sampler</b>	: CUSTOMER
<b>Manufacturer Name</b>	: OLEY TIBBİ URUNL.VE MEDİ.MLZ SAN.TİC.LTD.ŞTİ.		
<b>Analysis Date</b>	: 27.11.2020		
<b>Sample Quantity</b>	: 41 pieces		
<b>Other informations</b>	:		

50	General Size Designation	Height	198 (cm)	158-170 cm	EN ISO 13688	PASS
51	Penetration by spray of liquids (Spray Test)	0 (cm <sup>2</sup> )		3 times the maximum calibration stain	BS EN ISO 17491-4	PASS
52	Dry Microbial Penetration	2,06 (log cfu)		2 < log cfu ≤ 3	BS EN ISO 22612+ TS EN 14126 Part 4.1.4.4	PERFORMANC E LEVEL:1
53	Penetration By Blood-Borne Pathogens(Bacteriophage)	0 (PFU/ml)		3,5 kPa	BS ISO 16604+ TS EN 14126 Part 4.1.4.1	PERFORMANC E LEVEL:3
54		0 (PFU/ml)		3,5 kPa	BS ISO 16604+ TS EN 14126 Part 4.1.4.1	
55		0 (PFU/ml)		3,5 kPa	BS ISO 16604+ TS EN 14126 Part 4.1.4.1	
56	Total Inward Leakage	Ljmn,82/90:17,8 Ls,8/10:14,2 (%)		Ljmn,82/90≤30 Ls,8/10≤15	ISO 13982-2	PASS
57	Permeation	%40 NaOH 30 min no leak (ug/cm <sup>2</sup> .dk)		>30 min	ISO 6529	PERFORMANC E LEVEL:2
58	Penetration by jet of liquids (Jet Test)	0 (cm <sup>2</sup> )		3 times the maximum calibration stain	EN ISO 17491-3	PASS
59	Determination of pH - Textile*	6,95		3.5 < Result < 9.5	EN 420 + A1 Part 4.3.2 TS EN ISO 3071	PASS

**SAMPLE PLACE**

46. Line Sample place for General Size Designation : Size:S  
 47. Line Sample place for General Size Designation : Size:M  
 48. Line Sample place for General Size Designation : Size:L  
 49. Line Sample place for General Size Designation : Size:XL  
 50. Line Sample place for General Size Designation: Size:XXL  
 50. Line Sample place for General Size Designation: Size:XXL



**MNA LABORATORIES  
TEST REPORT**

Report No: M-2020-00567	Date: 09.12.2020	Page: 8 / 8	Rev:
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<b>Purpose of Analysis</b>	: SPECIAL REQUEST	<b>Brand</b>	:
<b>Sample Type</b>	: PROTECTIVE CLOTHING	<b>Model</b>	: OLEY 2311
<b>Sample Send Org.</b>	: OLEY TIBBİ URUNL.VE MEDİ.MLZ SAN.TİC.LTD.ŞTİ.	<b>Sampler</b>	: CUSTOMER
<b>Manufacturer Name</b>	: OLEY TIBBİ URUNL.VE MEDİ.MLZ SAN.TİC.LTD.ŞTİ.		
<b>Analysis Date</b>	: 27.11.2020		
<b>Sample Quantity</b>	: 41 pieces		
<b>Other informations</b>	:		

Operating as an experimental laboratory, MNA Laboratories have been accredited by TÜRKAK with AB-1183-T and TS\_EN\_ISO / IEC\_17025: 2017 standard. Turkish Accreditation Agency (TÜRKAK) signed a multilateral agreement with the European Accreditation Association (EA) on the recognition of test reports and a mutual recognition agreement with the International Laboratory Accreditation Association (ILAC).

\* Analysis is under accreditation.

**Note :**

1. No part of this analysis report can be used alone or separately, and may not be partially copied or reproduced, used to third parties and as a means of advertising without the written permission of the laboratory.
2. Analysis results are valid for the above mentioned sample sent by MNA Laboratory company / institution / person. It may not represent the whole.
3. Unsigned and unsealed reports are invalid.
4. This analysis report cannot be used in judicial-administrative procedures and for advertising purposes.
5. Results are valid for the sample as received.
6. The decision rule is the rule that determines how measurement uncertainty is taken into account when specifying the PASS density to a specified specification. According to the TLM-052 Decision Rule Implementation instruction, the Decision Rule Implementation Method selected in agreement with CUSTOMER is clearly stated in the report.
7. Limit Values are determined by taking from analysis methods.
8. The laboratory is not responsible if the information provided by the CUSTOMER affects the validity of the results.
9. Test and / or measurement results, expanded measurement uncertainties (if any) and test methods are given in the following pages, which are the supplementary part of this certificate.
10. Water Repellency Determination Hydrostatic Pressure Determination T S ISO 811 (Hydrostatic Pressure Tester E / N: 53) Analysis, Seam Strength EN ISO 13965-2 (Strength Test Device E / N: 50) Analysis and resistance to liquid chemical permeation TS EN 659 -A1 Part 3.18 (Liquid Chemical Transfer Device E / N: 107) Analysis is carried out in the conditioning room and ISO 139 PART 3.2

conditions ( $23 \pm 2$  ° C temperature and  $50 \pm 4$  % relative humidity) are applied for ambient conditions.

11. List of phthalates analyzed is below.

Di-iso-nonyl phthalate (DINP), CAS number: 28553-12-0 or 68515-48-0

Di- (2-ethylhexyl) phthalate (DEHP), CAS number: 117-81-7

Di-n-octyl phthalate (DNOP), CAS number: 117-84-0

Di-iso-decyl phthalate (DIDP), CAS number: 26761-40-0 or 68515-49-1

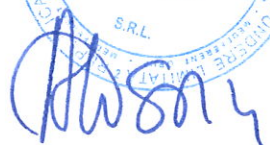
Butyl benzyl phthalate (BBP), CAS number: 85-68-7

Di-butyl phthalate (DBP), CAS number: 84-74-2

Selin GERGIN  
Sampling and Reporting  
Officer

Erhan ÜSTÜNEL  
PPE Laboratory Responsible

Confirmed  
09.12.2020  
Volkan AKIN  
Laboratory Manager



# CERTIFICATE

## The company

**BAYTEKS TEKNIK TEKSTIL SAN. VE TIC. A.S.**  
Organize Sanayi Bölgesi 19 Nolu Cadde No. 9  
79000 Merkez - Kilis, TURKEY

is granted authorisation according to STANDARD 100 by OEKO-TEX® to use the STANDARD 100 by OEKO-TEX® mark, based on our test report 19.0.01029



## for the following articles:

**Nonwoven spunbonded, melt blown and their composite structures produced from white and masterbatch (pigment dyestuff) dyed polypropylene and polypropylene/polyethylene (reprocessing of own waste), with and without PE lamination (in colour white and blue) and additives including UV stabiliser.**


The results of the inspection made according to STANDARD 100 by OEKO-TEX®, Appendix 4, **product class II** have shown that the above mentioned goods meet the human-ecological requirements of the STANDARD 100 by OEKO-TEX® presently established in Appendix 4 for products with direct contact to skin.

The certified articles fulfil requirements of Annex XVII of REACH (incl. the use of azo colourants, nickel release, etc.), the American requirement regarding total content of lead in children's articles (CPSIA; with the exception of accessories made from glass) and of the Chinese standard GB 18401:2010 (labelling requirements were not verified).

The holder of the certificate, who has issued a conformity declaration according to ISO 17050-1, is under an obligation to use the STANDARD 100 by OEKO-TEX® mark only in conjunction with products that conform with the sample initially tested. The conformity is verified by audits.

**The certificate 06.MO.41419 is valid until 31.03.2021**

Boennigheim, 28.01.2020

  
Dipl.-Ing. (FH) Ivonne Schramm  
Head of Certification Body OEKO-TEX®



To who is in concern,

**Declaration letter**

*Under Certificate 06.MO.41419, Standard 100 for raw materials for coveralls, include test standards:*

*Provide protection according to EN 14126, ISO 16604, be impermeable to water and organic liquids (including in the form of aerosols), and provide protection against penetration of blood and body fluids using the ISO 16603 method.*

23.03.2021

Şenay ŞENTÜRK  
General Manager

OLEY TIBBİ URUNLER MEDİKAL  
MLZ SAN TIC LTD STI  
Parseller Mh. Menekse Cd. Feyyaz Sk. No:2/3 Umraniye İstanbul 34773 TURKEY  
No: 0090 216 611 93 33  
ALEX 0415 216 641193  
www.oleytibbiurunler.com



**OLEY TIBBİ URUNLER MEDİKAL MLZ SAN TIC LTD STI**

Address: Parseller Mh. Menekse Cd. Feyyaz Sk. No:2/3 Umraniye İstanbul 34773 TURKEY

Ph: 0090 216 611 93 33 Fax:0090 216 611 93 22 www.oleytibbiurunler.com info@oleytibbiurunler.com





*Handwritten signature*





**Liquid Protection**

Type 6 - Light Liquid Splashes  
(EN 13034:2005 + A1:2009)



**Liquid Protection**

Type 4 - Liquid Spray  
(EN 14605:2005 + A1:2009)



**Dust Protection**

Type 5 - Solid Airborne Particulates  
EN ISO 13982-1:2004



**Anti-static**

Anti-static coating\* on both sides  
(EN 1149-5:2008)



**Nuclear**

Radioactive particulates Class 2  
(EN 1073-2:2002 except EN863 puncture)



**Biohazard**

Types 4-B, 5-B & 6-B - Infective Agents  
(EN 14126:2003 except ISO 16604)

\* All apparel must be suitably grounded for anti-static treatment to be effective.  
Does not offer protection against radiation.



Limited use



Do not dry



Do not wash



Do not dry-clean



Do not bleach



Do not iron



Flammable



Breathable Fabric PP+PE



**Personal Protective Coverall**  
**Persönlicher Schutzoverall**

S     M     L     XL  
 2XL     3XL     4XL     5XL



**1** STCK.  
**PCS.**



*Handwritten signature*



# PROTECTIVE COVERALLS TECHNICAL DATE SHEET

Protective Coverall designed to help protect against liquid chemicals (Type 3 - Type 4) hazardous dust (Type 5), certain light liquid splashes (Type 6)

Three panel hood design on coveralls for compatibility with complementary PPE

Seamless shoulder and sleeve tops for fewer entry points for contaminants and increased comfort

Elasticized waist and ankles and knit or elastic cuffs on all models for increased comfort and mobility

Two-way zipper for on/off convenience

Model: OLEY0909

Model: OLEY2311

Sewn from Laminated Non-Woven Fabric with High Quality, Light Weight and Easy to Wear. Made of Soft, Sturdy, Breathable and Waterproof Fabric.

To Increase Protection Against Less Dangerous Chemicals and Dusts; Two-layer, Hooded and Covered Zipper is used with Laminated Fabric. Made from 57 gsm laminated material.

EN ISO 13688 Protective Clothing - General Requirements

EN 13034+ A1 Protective Clothing Against Liquid Chemicals (Type 6-B)

EN ISO 13982-1 Protective Clothing Against Solid Particules (Type 5-B)

EN 14605+A1 Protective Clothing Against Liquid Chemicals (Type 3-B, Type 4-B)

EN 14126 Protective Clothing Performance Requirements and Test Methods For Protective Clothing Against Infective Agents





**Liquid Protection**

Type 6 - Light Liquid Splashes  
(EN 13034:2005 + A1:2009)



**Liquid Protection**

Type 4 - Liquid Spray  
(EN 14605:2005 + A1:2009)



**Dust Protection**

Type 5 - Solid Airborne Particulates  
EN ISO 13982-1:2004



**Anti-static**

Anti-static coating\* on both sides  
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Types 4-B, 5-B & 6-B - Infective Agents  
(EN 14126:2003 except ISO 16604)



\* All apparel must be suitably grounded for anti-static treatment to be effective.  
Does not offer protection against radiation.



Breathable Fabric PP+PE



Limited use



Do not dry



Do not wash



Do not dry-clean



Do not bleach



Do not iron



Flammable



### COVERALLS SIZE CHART

Size	Chest	Length
M-L	92-108 cm	170-180 cm
L-XL	108-116 cm	180-190 cm
XL-XXL	116-124 cm	190-195 cm
3XL-4XL	124-135 cm	190-195 cm

Personal Protective Coverall  
Persönlicher Schutzoverall

- S
- M
- L
- XL
- 2XL
- 3XL
- 4XL
- 5XL



1 STCK.  
PCS.



### Label Example

PROTECTIVE COVERALLS  
OLEY0909 / OLEY2311



8 6 8 2 4 5 0 8 2 0 3 9 5  
 Production Date: :11/2020  
 Expiry Date: :11/2025  
 LOT No :202101/02  
 Size :2XL



Manufacturer: Oley Tıbbi Ürünler Medikal Mlz. San. Tic. Ltd Şti

Address: Parseller Mh. Menekşe Cd. Feyyaz Sk. No:2/3  
Ümraniye İstanbul TÜRKİYE www.oleytibbiurunler.com  
info@oleytibbiurunler.com



### Packing List

1 Master Box can carry 50 pcs.(From L size to 3XL Size)  
Box Dimensions are 60\*40\*40 cm  
1 box is 9,32 kg

-Packing List may change based on sizes, please indicate the sizes

