

**CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL PLUS SUPERVISED
PRODUCT CHECKS AT RANDOM INTERVALS (MODULE C2)**

**MODÜL C2 - ÜRETİMİN DÂHİLÎ KONTROLÜ VE ÜRÜNÜN RASTGELE
ARALIKLARLA DENETİMLİ MUAYENESİNE DAYALI TİPE UYGUNLUK**

Belge No / Certificate No : 285-21-02-01
**Belgelendirme Tarihi - Bir Sonraki Belge Tarihi /
Certification Date / Certificate Validity Date** : 01.09.2022-01.09.2023
Belge Geçerlilik Tarihi / Document Validity Period : 1 yıl / 1 years
**Firma Unvanı ve Adresi /
Company Name and Address** : ESTAŞ EKSANTRİK SANAYİ VE TİCARET
ANONİM ŞİRKETİ
ŞEYH ŞAMİL OBS MAH. HALİS VERMEZOĞLU
CAD. NO:57 SİVAS
Marka / Model / Brand / Model : ESL-N00-1S, ESL-N00-1M, ESL-N00-1L
Direktifi / Directive : 2016/425 REGULATION
Modül/Kategori / Module / Category : C2 MODÜLÜ/ KATEGORİ III
MODULE C2 / CATEGORY III
**Teknik Değerlendirme Rapor No/
Technical Evaluation Report No** : 285-21-02-01

Ürün Tipi / Product Type:

- EN ISO 21420 Koruyucu Eldivenler / Protective gloves
- EN ISO 374-1 Tehlikeli Kimyasallara Ve Mikroorganizmalara Karşı Koruyucu Eldivenler (Performans Seviyeleri: Tip B) / Protective Gloves Against Dangerous Chemicals And Micro-Organisms (Performance Level: Type B)
- EN ISO 374-5 Tehlikeli Kimyasallara Ve Mikroorganizmalara Karşı Koruyucu Eldivenler - Bölüm 5: Mikroorganizmal riskler için terimler ve performans kuralları / Protective Gloves Against Dangerous Chemicals And Micro-Organisms Part 5: Terminology and performance requirements for micro-organisms risks

Ürünün Malzeme Bilgisi / Product Material Information: ESL-N00-1S, ESL-N00-1M, ESL-N00-1L model ürünleri sentetik nitril kullanılarak imal edilmiştir./ ESL-N00-1S, ESL-N00-1M, ESL-N00-1L model products are manufactured using synthetic nitrile.

Voİkan AKİN
01.09.2022

Karar Verici / Approver



Okan AKEL
01.09.2022

Şirket Müdürü / General Manager



**CONFORMITY TO TYPE BASED ON INTERNAL
PRODUCTION CONTROL PLUS SUPERVISED PRODUCT
CHECK AT RANDOM INTERVALS
(MODULE C2, ANNEX VII) (285-21-02-01)**

Report No : 285-21-02-01

Report Date : 01.09.2022

Application No : 285-21-02-01

1. COMPANY INFORMATION:

ESTAŞ EKSANTRİK SANAYİ VE TİCARET ANONİM ŞİRKETİ
ŞEYH ŞAMİL OBS MAH. HALİS VERMEZOĞLU CAD. NO:57 SİVAS

2. PPE INFORMATION:

Disposable and non-sterile synthetic nitrile glove.

3. PPE TYPE IDENTIFICATION

EN ISO 21420 Protective gloves

EN ISO 374-1 Protective Gloves Against Dangerous Chemicals And Micro-Organisms

EN ISO 374-5 Protective Gloves Against Dangerous Chemicals And Micro-Organisms Part 5: Terminology and performance requirements for micro-organisms risks

4. PPE PICTURES



ESL-N00-1S, ESL-N00-1M, ESL-N00-1L

5. PPE DIMENSIONS:

ESL-N00-1S, ESL-N00-1M, ESL-N00-1L model product has been found to be produced using S, M, L sizes.

6. PPE PRODUCT MATERIAL INFORMATION:

The product is made of synthetic nitrile.

7. ESSENTIAL HEALTH AND SAFETY REQUIREMENTS

- Visual examination has been made for ergonomics according to EN ISO 21420.
- Protection levels and degrees are defined by the manufacturer.
- Suitable construction materials are determined by visual inspection according to EN ISO 21420.
- pH content is determined according to EN ISO 21420.
- The glove's ability has been tested and evaluated according to EN ISO 21420.
- The measurement of hand and glove has been done. It has been evaluated according to EN ISO 21420.
- The analysis of the glove has been made according to EN ISO 21420 and EN ISO 374-1. Protective gloves against hazardous chemicals and microorganisms have been evaluated according to EN ISO 374-1.
- Analyzes against harmful chemicals have been performed and evaluated according to the REACH regulation.

**CONFORMITY TO TYPE BASED ON INTERNAL
PRODUCTION CONTROL PLUS SUPERVISED PRODUCT
CHECK AT RANDOM INTERVALS
(MODULE C2, ANNEX VII) (285-21-02-01)**

- Gloves have been analyzed and evaluated according to the requirements of EN ISO 374-5 standard against microbial risks.

**8. ANALYSIS AND EVALUATIONS:
EN ISO 21420**

ANALYSIS	PERFORMANCE LEVEL					RESULT	PERFORMANCE LEVEL	EVALUATION
	1	2	3	4	5			
pH	3.5<value<9.5					7,64	3.5<value<9.5	PASS
Dexterity	11 mm	9,5 mm	8 mm	6,5 mm	5 mm	5 mm	5	PASS
Dimethylformamide (DMFa)	<1000 ppm					<200 ppm	<1000 ppm	PASS
Polyaromatic hydrocarbons (PAHs)	<0,28 ppm					<0.1 ppm	<1 ppm	PASS

Size	Circumference (mm)	Length (mm)	RESULT		EVALUATION
			Circumference (mm)	Length (mm)	
9	152	160	215	195	*
10	178	171	228	198	*

* The product is produced according to special dimensions.

Size	Glove length (mm)	RESULT	EVALUATION
9	220	254	*
10	230	256	*

* The product is produced according to special dimensions.

EN ISO 374-1

ANALYSIS	PERFORMANCE LEVEL	RESULT	EVALUATION
Part 4: Determination of resistance to degradation by chemicals	There is no performance value. Only reporting is made.	34,6 % (37% Formaldehyde) 41,7 % (n-Heptane) 4,8 % (40 %NaOH)	-
Part 2: Determination of resistance to penetration (Air leak test)	No leak to be detected	No leak	PASS

**CONFORMITY TO TYPE BASED ON INTERNAL
PRODUCTION CONTROL PLUS SUPERVISED PRODUCT
CHECK AT RANDOM INTERVALS
(MODULE C2, ANNEX VII) (285-21-02-01)**

Part 2: Determination of resistance to penetration (Water leak test)	No leak to be detected	No leak	PASS
Determination of material resistance to permeation by chemicals	2 (>30 min no leak. Sodium Hydroxide 40 %)	No leak (%37 Formaldehyde) (n-Heptane) (40 %NaOH)	PASS

EN ISO 374-5

ANALYSIS	PERFORMANCE LEVEL	RESULT	EVAULATION
Clothing for protection against contact with blood and body fluids.	No leak to be detected according to ISO 16604 Procedure B.	No leak (0 PFU/ml)	PASS

9. DECISION PROPOSAL

Analysis and examinations ESL-N00-1S, ESL-N00-1M, ESL-N00-1L model coded personal protective equipment; EN ISO 21420 Protective gloves, EN ISO 374-1 Protective Gloves Against Dangerous Chemicals And Micro-Organisms, EN ISO 374-5 Protective Gloves Against Dangerous Chemicals And Micro-Organisms Part 5: Terminology and performance requirements for micro-organisms risks, Experiments and Marking standards are evaluated. It is recommended to be certified at the performance levels specified as a result of technical evaluations.

10. ATTACHMENTS

- Basic Health Safety Requirements
- Risk Assessment
- User Instruction
- Test Reports (M-2022-0666, 22070099)

CONTROLLER : VOLKAN AKIN**SIGNATURE :****DATE : 01.09.2022**

MNA LABORATORY ANALYSIS REPORT

AB-1183-T

M-2022-0666

08-22

Report Nu. : M-2022-0666	Date : 2022-08-31 09:53:49	Page : 1 / 5	Rev:
--------------------------	----------------------------	--------------	------

Purpose of Analysis	: Special request
Sample Send Org.	: ESTAŞ EKSANTRİK SANAYİ VE TİCARET A.Ş.
Address	: Şeyh Şamil OSB. Mah. Halis Vermezoğlu Cad. No:57 Merkez/Sivas
Sample Acceptance Date	: 2022-08-15 16:05:53
Analysis Date	: 2022-08-15 16:24:30
Sample Quantity	: 200 Pieces
Sample Description	: ESG-N00-1S, ESG-N00-1M, ESG-N00-1L ESL-N00-1S, ESL-N00-1M, ESL-N00-1L MMT-N00-1S, MMT-N00-1M, MMT-N00-1L ESG-N00-2S, ESG-N00-2M, ESG-N00-2L ESL-N00-2S, ESL-N00-2M, ESL-N00-2L MMT-N00-2S, MMT -N00-2M, MMT -N00-2L
Other informations	:

Determination of Gloved Finger Dexterity *

Tests	Analysis result	Limit Value	Method	Evaluation	Physical Condition
Determination of Gloved Finger Dexterity	5 mm for all sizes.	See the limits table.	TS EN ISO 21420 Part 6.2	Performance Level : 5	-

Limits	Level 1	Level 2	Level 3	Level 4	Level 5
Smallest diameter of pin fulfilling test conditions	11,0	9,5	8,0	6,5	5,0

Measurement of Glove Length *

Tests	Analysis result	Limit Value	Method	Evaluation	Physical Condition
Measurement of Glove Length	Check the table for results.	~	TS EN ISO 21420 Part 6.1	-	-

	Glove length (mm)	Hand length (mm)	Hand circumference (mm)	-
Size M	254	195	215	
Size L	256	198	228	

Textile-Determination of pH *

Tests	Analysis result	Limit Value	Method	Evaluation	Physical Condition
Textile-Determination	Check the table for	3,5<Result<9,5	TS EN ISO 3071	PASS	-

**MNA LABORATORY
ANALYSIS REPORT**

AB-1183-T

M-2022-0666

08-22

Report Nu. : M-2022-0666	Date : 2022-08-31 09:53:49	Page : 2 / 5	Rev:
of pH	results.		

Part of Sample	pH	Temperature (°C)
Protective Glove	7,64	23,0

Determination of Resistance to Penetration (Air Leak Test) *

Tests	Analysis result	Limit Value	Method	Evaluation	Physical Condition
Determination of Resistance to Penetration (Air Leak Test)	Check the table for results.	No leak to be detected.	TS EN 374-2 Part 5.2	PASS	-

	Sample
Result	No leak

Determination of Resistance to Penetration (Water Leak Test) *

Tests	Analysis result	Limit Value	Method	Evaluation	Physical Condition
Determination of Resistance to Penetration (Water Leak Test)	Check the table for results.	No leak to be detected.	TS EN 374-2 Part 5.3	PASS	-

	Sample
Result	No leak

Permeation by Liquid Chemical Under Conditions of Continuous Contact *

Tests	Analysis result	Limit Value	Method	Evaluation	Physical Condition
Permeation by Liquid Chemical Under Conditions of Continuous Contact	Check the table for results.	See the limits table.	TS EN 16523-1	Performance Level: 2	-

Limits	Level 1	Level 2	Level 3	Level 4	Level 5	Level 6
--------	---------	---------	---------	---------	---------	---------

MNA LABORATORY ANALYSIS REPORT

AB-1183-T

M-2022-0666

08-22

Report Nu. : M-2022-0666	Date : 2022-08-31 09:53:49	Page : 3 / 5	Rev:			
minute	> 10 min	> 30min ≤ 60min	> 60 min ≤ 120 min	> 120 min ≤ 240 min	> 240 min ≤ 480 min	> 480

Results	%40 NaOH	%37 Formaldehyde	Heptane
Sample 1	No leakage for 30mins under %40 NaOH	No leakage for 30mins under %37 Formaldehyde	No leakage for 30mins under Heptane
Sample 2	No leakage for 30mins under %40 NaOH	No leakage for 30mins under %37 Formaldehyde	No leakage for 30mins under Heptane
Sample 3	No leakage for 30mins under %40 NaOH	No leakage for 30mins under %37 Formaldehyde	No leakage for 30mins under Heptane

Determination of Resistance to Degradation by Chemicals *

Tests	Analysis result	Limit Value	Method	Evaluation	Physical Condition
Determination of Resistance to Degradation by Chemicals	Check the table for results.	There is no performance value.	TS EN 374-4	-	-

Chemical name	%40 NaOH	%37 Formaldehyde	Heptane
Result (%)	4,8	34,6	41,7
Standard deviation	1,0	0,3	0,8

Penetration By Blood-Borne Pathogens (Bacteriophage)

Tests	Analysis result	Limit Value	Method	Evaluation	Physical Condition
Penetration By Blood-Borne Pathogens (Bacteriophage)	Check the table for results.	See the limits table.	BS ISO 16604	PASS	-

Limits	Level 1	Level 2	Level 3	Level 4	Level 5	Level 6
	0 kPa	1,75 kPa	3,5 kPa	7 kPa	14 kPa	20 kPa

	PFU/ml
Sample 1	0 (14 kPa)
Sample 2	0 (14 kPa)

MNA LABORATORY ANALYSIS REPORT

AB-1183-T

M-2022-0666

08-22

Report Nu. : M-2022-0666	Date : 2022-08-31 09:53:49	Page : 4 / 5	Rev:
Sample 3		0 (14 kPa)	

Protective Gloves - The Determination of Dimethylformamide in Gloves

Tests	Analysis result	Limit Value	Method	Evaluation	Physical Condition
Protective Gloves - The Determination of Dimethylformamide in Gloves	Check the table for results.	<1000 ppm	En 16778	PASS	-

	ppm
Sample	<200

MNA LABORATORY ANALYSIS REPORT

AB-1183-T
M-2022-0666
08-22

Report Nu. : M-2022-0666	Date : 2022-08-31 09:53:49	Page : 5 / 5	Rev:
--------------------------	----------------------------	--------------	------

Operating as a test laboratory, MNA Laboratories is accredited by TÜRKAK according to AB-1183-T and TS EN ISO/IEC 17025:2017 standards has been done. A multilateral agreement with the European Accreditation Association (EA) on the recognition of the Turkish Accreditation Agency (TÜRKAK) test reports and It has signed a mutual recognition agreement with the International Laboratory Accreditation Association (ILAC).

*The analysis is within the scope of accreditation.

Note :

1. No part of this analysis report may be used alone or separately and may be partially copied or reproduced without the written permission of the laboratory. It cannot be reproduced, used by third parties or as a means of advertising.
2. Analysis results are valid for the sample sent and analyzed by the company/institution/individual to MNA Laboratories. represent the whole may not.
3. Unsigned and Unsealed reports are invalid.
4. This analysis report cannot be used in judicial-administrative proceedings and for advertising purposes.
5. Results are valid for the sample received.
6. A decision rule is a rule that determines how measurement uncertainty is to be taken into account when specifying compliance with a specified specification. TLM-052 Decision Rule According to the implementation instruction, the decision rule chosen in agreement with the customer will be applied if necessary.
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 ± 2 ° C temperature and 50 ± 4% relative humidity) are applied for ambient conditions.

Selin Gergin

Sample Acceptance and Reporting Officer

2022-08-23 13:52:38

Erhan Üstünel

Laboratory Responsible

2022-08-23 13:57:09

VOLKAN AKIN

Laboratory Manager

2022-08-23 13:33:27

**MASS**
MULTI SCIENCE**DENEY RAPORU**

AB-1454-T

22070099

07-22

Rapor No / Revizyon No: 22070099 / 0

Numune Kabul Tarihi: 5.07.2022

Rapor Yayın Tarihi: 7.07.2022

Sayfa: 1/3

MÜŞTERİ BİLGİLERİ

Başvuru Sahibi: MNA LABORATUVARLARI SAN. TİC. LTD. ŞTİ.
Adresi: Küçükbakkalköy Mah. Yenidoğan Cad. No:21 Ataşehir İSTANBUL
İlgili Kişi: Selin GERGİN
İletişim Bilgileri: 0545 538 70 61

NUMUNE BİLGİLERİ

Numune Tanımı: MAVİ PLASTİK MALZEME
Numune Miktarı: 1 Model
Marka:
Model Numarası: 537-538-539-540-541-542
Açıklama: Bu rapordaki test değerlendirmeleri, "Kimyasalların Kaydı, Değerlendirilmesi, İzni ve Kısıtlanması Hakkında Yönetmelik" ve standartlar ile yürürlükte olan diğer ilgili mevzuata göre yapılmıştır.

GENEL DEĞERLENDİRME GEÇER

Mühür

Numune Kabul ve Raportör

Laboratuvar Müdürü

Tarih



Dijital
olarak
imzalayan
TUNAHAN
EKER



Dijital
olarak
imzalayan
SELİN EKER

7.07.2022

Deney laboratuvarı olarak faaliyet gösteren Mass Laboratuvar ve Danışmanlık A.Ş. TÜRKAK'tan AB-1454-T dosya numarası ile TS EN ISO/IEC 17025 standardına göre akredite edilmiştir. Türk Akreditasyon Kurumu (TÜRKAK) deney raporlarının tanınırlığı konusunda Avrupa Akreditasyon Birliği (EA) ile çok taraflı Anlaşma ve Uluslararası Laboratuvar Akreditasyon Birliği (ILAC) ile karşılıklı olarak tanıma anlaşması imzalamıştır. Analiz sonuçları, metotları ve numune ile ilgili diğer bilgiler, müşteri tarafından "Analiz Talep Çizelgesi (Ç.01.PR.03)"nda belirtilen bilgiler doğrultusunda bu raporun ilgili sayfalarında verilmiştir. Test sonuçları, yukarıda belirtilen numune için geçerlidir. Numunenin ait olduğu lotu temsil etmeyebilir. Bu rapor, "Ürün Belgesi" yerine geçmez. Mass Laboratuvar ve Danışmanlık Hizmetleri A.Ş.'nin yazılı izni olmadan bu Analiz Raporu kısmen kopyalanamaz, çoğaltılamaz veya herhangi bir başka amaçla kullanılamaz. Numune alma işlemi tarafımızdan yapılmamıştır. İmzasız ve mühürlü Analiz Raporları geçersizdir. *S* işaretli analizler TÜRKAK tarafından TS EN ISO/IEC 17025'e göre akredite edilmiş kapsamımızda yer almaktadır. Testlerden arta kalan numuneler, rapor tarihinden itibaren 15 gün süre ile uygun koşullarda saklanır. Buna rağmen fiziksel, kimyasal, mikrobiyolojik olarak bozulan örnekler saklama süresine bakılmaksızın imha edilirler. Bu konuda müşteri hiçbir hak talep edemez. Bu raporda yer alan analiz sonuçları veya bu sonuçlara göre "Uygun/Uygun Değil (Pass/Fail)" değerlendirilmesi "Karar Kuralının Uygulanması Talimatı (PR.20/T.01)"na göre yapılmaktadır.



MASS
MULTI SCIENCE

MASS LABORATUVAR ve DANIŞMANLIK HİZMETLERİ A.Ş.

AB-1454-T

22070099

07-22

DENEY RAPORU

Rapor No / Revizyon No: 22070099 / 0

Sayfa Sayısı:

2/3

ÜRÜN FOTOĞRAFI



ÖZET TEST SONUÇLARI

	ANALİZ ADI	ANALİZ METODU	DEĞERLENDİRME
*	PAH - Poliaromatik Hidrokarbonların Tayini	PD CEN ISO TS 16190	GEÇER

ÜRÜN DETAYLARI

ÜRÜN	PARÇA NO	PARÇA TANIMI	ORTAK PARÇA
A	1	Mavi plastik malzeme	



MASS
MULTI SCIENCE

MASS LABORATUVAR ve DANIŞMANLIK HİZMETLERİ A.Ş.

AB-1454-T

22070099

07-22

DENEY RAPORU

Rapor No / Revizyon No: 22070099 / 0

Sayfa Sayısı:

3/3

TEST SONUÇLARI

Müşteri talebi doğrultusunda aşağıdaki analizler yapılmıştır.

Karar Kuralı : Müşteri, "Ölçüm belirsizliği dahil edilmeden" uygunluk beyanı verilmesini istediğini belirtmiştir.

* PAH - Poliaromatik Hidrokarbonların Tayini				
Test Metodu	PD CEN ISO TS 16190			
Test Başlangıç Tarihi:	5.07.2022		Test Bitiş Tarihi:	7.07.2022
Test Kısımları	Birim	Sonuç	Limit	Değerlendirme
1	mg/kg	< 0.28	1	GEÇER

Kontrol Edilen Parametreler:

Benzo(e)pyrene (Cas No: 192-97-2)

Benz[a]anthracene(Cas No: 56-55-3)

Benzo[a]pyrene (Cas No:50-32-8)

Dibenz[a,h]anthracene (Cas No: 53-70-3)

Raporlama Limiti : 0,28 mg/kg

Gaz Kromatografi-Kütle Spektroskopisi (GC-MS) cihazı ile tayin edilmiştir.

Benzo[j]fluoranthene (Cas No: 205-82-3)

Benzo[k]fluoranthene (Cas No: 207-08-9)

Chrysene (Cas No:218-01-9)

Benz[b]fluoranthene (Cas No: 205-99-2)

* Rapor Sonu *

MASS LABORATUVAR ve DANIŞMANLIK HİZMETLERİ A.Ş. | Sultaniye Mah. 350 Sk. Şelale Plaza 1/110 Esenyurt / İstanbul

Tel: 0(212) 909 03 80 | Web: www.masslab.com.tr | E-Mail: bilgi@masslab.com.tr