MNA LABORATUVARLARI

Notified Body Number: 2841

AB Tip İnceleme Sertifikası
EU Type-Examination Certificate

Belge No / ***Certificate No*** : 91-21-01-R01

Belgelendirme Tarihi - Bir Sonraki Belge Tarihi /
Certification Date / Certificate Validity Date : 21.05.2021-07.05.2026

Belge Geçerlilik Tarihi ***/ Document Validity Period*** : 5 yıl / *5 years*

Firma Unvanı ve Adresi /
Company Name and Address : EN ECZA DEPOSU İLAÇ MEDİKAL ÖZEL SAĞLIK HİZMETLERİ İNŞAAT TAAHHÜT TİCARET A.Ş.
Factory: Saray Mah. Gıdacılar Cad. No: 18 Kahramankazan /ANKARA

Ürün Adı /Modeller / ***Product Name / Models*** : ENM-603

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-2021-00813

Ürün Tipi / ***Product Type:***

- EN 420+A1 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*****:** ENM-603 model ürünleri sentetik nitril kullanılarak imal edilmiştir./ *ENM-603 model products are manufactured using synthetic nitrile.*

Revizyon nedeni/ ***Reason for revision:*** Kapsam genişletilmiştir ve firma adresi revize edilmiştir./ *The scope has been expanded and company address has been revised.*

Volkan AKIN	***Okan AKEL***
21.05.2021	***21.05.2021***
Karar Verici / Approver	***Şirket Müdürü / General manager***

Notified Body Number: 2841

ATTACHMENTS (91-21-01-R01)

To certify the PPE product at Category III level, C2 or D module is accompanied by applying one of the conformity assessment methods along with the EU Type Examination (Module B).

Model : ENM-603

PPE SPECIFICATION	PERFORMANCE LEVELS
Dexterity	5
Material Resistance To Permeation By Chemicals	2 (Type B)
Phi-X174 Bacteriophage	Appropriate
Degradation (EN ISO 374-4:2019)	%40 NaOH: 3,75 % n-Heptane: 7,62 % %37 Formaldehyde : 8,81%

PPE produced as a single unit to fit an individual user, all the necessary instructions for manufacturing such PPE on the basis of the approved basic model:

MARKING

MANUFACTURER: EN ECZA DEPOSU İLAÇ MEDİKAL ÖZEL SAĞLIK HİZMETLERİ İNŞAAT TAAHHÜT TİCARET A.Ş.
PPE TYPE:

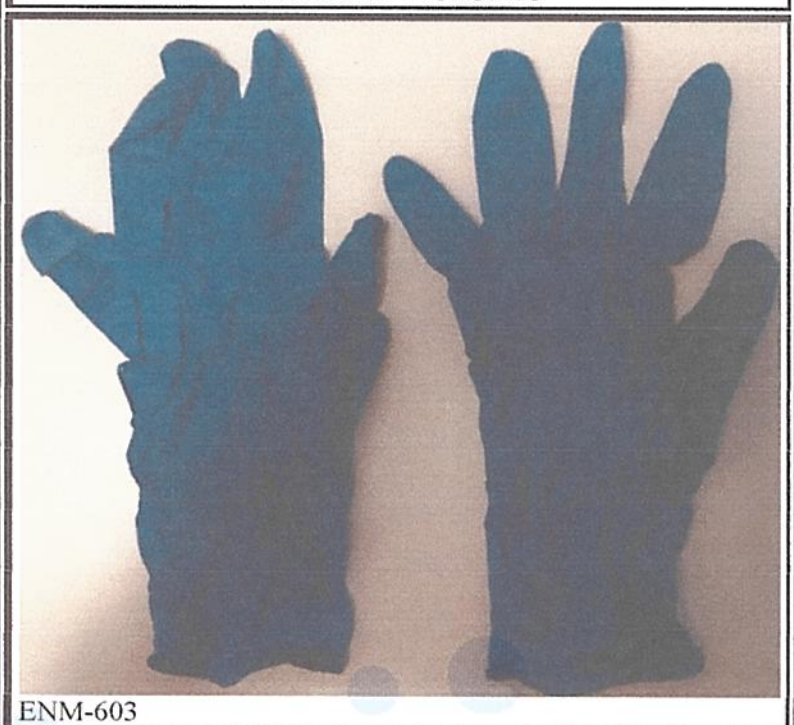
- EN 420+ A1 Protective gloves
- EN ISO 374-1 Protective Gloves Against Dangerous Chemicals And Micro-Organisms
- EN ISO 374-5 Protective Gloves Against Dangerous Chemicals And Micro-Organisms Part 5: Terminology and performance requirements for micro-organisms risks

PRODUCT SIZE / MODEL: ENM-603 (S, M, L, XL)
PICTOGRAM AND PERFORMANCE LEVELS:

	EN 420+A1	EN ISO 374-1/2016 Type B	EN ISO 374-5/2016
			
NB 2841		KJT	VIRUS

MNA LABORATUVARLARI SAN. TIC. LTD. ŞTİ declares that the above-mentioned product meets the requirements of the directive according to the EU Directive 2016/425, the safety of the product is covered by the conditions and use specified in this certificate and in the technical file.

ATTACHMENTS (91-21-01-R01)

PRODUCT PICTURES

ENM-603

DOCUMENTS IN THE TECHNICAL FILE
- Basic Health Safety Requirements - Risk Assessment - Test Reports - Technical Report

Report No : 91-21-01-R01

Report Date : 21.05.2021

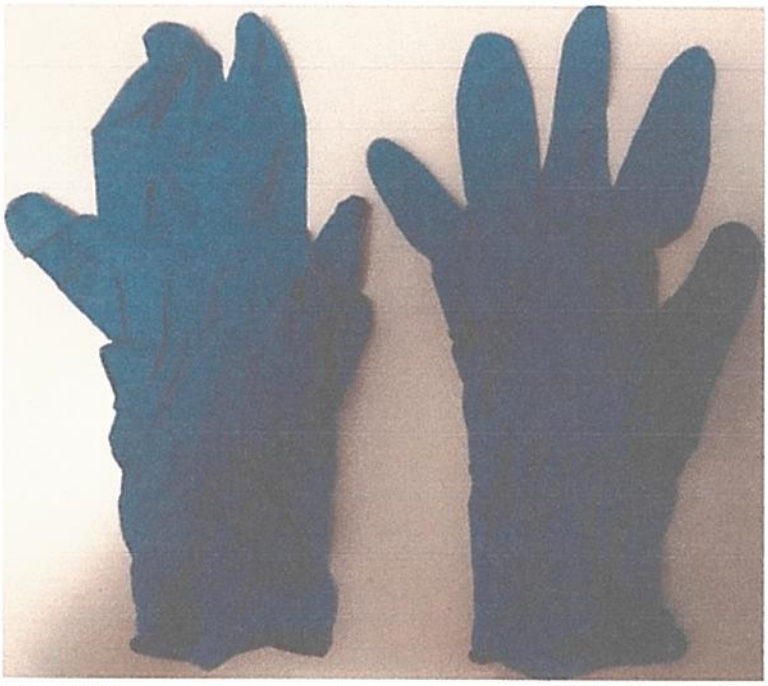
Application No : 91-21-01

1. **COMPANY INFORMATION:**
   EN ECZA DEPOSU İLAÇ MEDİKAL ÖZEL SAĞLIK HİZMETLERİ İNŞAAT TAAHHÜT TİCARET A.Ş.
   Saray Mah. Gıdacılar Cad. No: 18 Kahramankazan /ANKARA
   Tel: +90 324 357 56 44
   Fax: +90 324 357 58 44
   E-mail: info@enmedglobal.com

2. **PPE INFORMATION:**
   Disposable and non-sterile nitrile examination glove.

3. **PPE TYPE IDENTIFICATION**
   EN 420: 2003+A1:2009 Protective gloves
   EN ISO 374-1:2016 Protective Gloves Against Dangerous Chemicals And Micro-Organisms
   EN ISO 374-5:2016 Protective Gloves Against Dangerous Chemicals And Micro-Organisms Part 5: Terminology and performance requirements for micro-organisms risks

4. **PPE PICTURES**



ENM-603

5. **PPE DIMENSIONS:**
   ENM-603 model product has been found to be produced using S, M, L, XL 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 420: 2003+A1:2009.
- Protection levels and degrees are defined by the manufacturer.
- Suitable construction materials are determined by visual inspection according to EN 420: 2003+A1:2009 Article 4.1.
- pH content is determined according to EN 420: 2003+A1:2009 clause 4.3.2.
- The glove's ability has been tested and evaluated according to EN 420: 2003+A1:2009.
- The measurement of hand and glove has been done. It has been evaluated according to EN 420: 2003+A1:2009.
- The analysis of the glove has been made according to EN 420: 2003+A1:2009, EN ISO 374-2:2019 and EN ISO 374-1:2016. Protective gloves against hazardous chemicals and microorganisms have been evaluated according to EN ISO 374-1:2016.
- Determination of Organotin Compounds (DOT In-House Method: modified from EN ISO 16179), Phthalate Determination (ISO / TS 16181) are analyzed according to the standard.
- Analyzes against harmful chemicals have been performed and evaluated according to the REACH regulation.
- Gloves have been analyzed and evaluated according to the requirements of EN ISO 374-5:2016 standard against microbial risks.

8. ANALYSIS AND EVALUATIONS:

EN 420: 2003+A1:2009

ANALYSIS	PERFORMANCE LEVEL					RESULT	PERFORMANCE LEVEL	EVALUATION
	1	2	3	4	5			
pH	3.5<value<9.5					7,11	3.5<value<9.5	PASS
Dexterity	11 mm	9,5 mm	8 mm	6,5 mm	5 mm	5 mm	5	PASS
Organotin Compounds (DOT)	<1000 ppm					<10 ppm	<1000 ppm	PASS
Phthalates	<1000 ppm					<50 ppm	<1000 ppm	PASS

Size	Circumference (mm)	Length (mm)	RESULT		EVAULATION
			Circumference (mm)	Length (mm)	
9	229	192	209	192	*

* The product is produced according to special dimensions.

Size	Glove length (mm)	RESULT	EVAULATION
9	250	254	PASS

* The product is produced according to special dimensions.

EN ISO 374-1:2016, EN ISO 374-2:2019

ANALYSIS	PERFORMANCE LEVEL	RESULT	EVAULATION
Part 4: Determination of resistance to degradation by chemicals EN ISO 374-4:2019	There is no performance value. Only reporting is made.	%40 NaOH: 3,75 % n-Heptane: 7,62 % %37 Formaldehyde : 8,81%	-
Part 2: Determination of resistance to penetration (Air leak test) EN ISO 374-2:2019	No leak to be detected	No leak	PASS
Part 2: Determination of resistance to penetration (Water leak test) EN ISO 374-2:2019	No leak to be detected	No leak	PASS
Determination of material resistance to permeation by chemicals EN 16523-1:2015+A1:2018	2 (>30 min no leak. Sodium Hydroxide 40 %) (>30 min no leak. n-Heptane) (>30 min no leak. Formaldehyde 37%)	No leak	PASS

EN ISO 374-5:2016

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 ENM-603 model coded personal protective equipment; EN 420: 2003+A1:2009 Protective gloves, EN ISO 374-1:2016 Protective Gloves Against Dangerous Chemicals And Micro-Organisms, EN ISO 374-5:2016 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

Reason for revision :**The scope has been expanded and company information has been revised.**

CONTROLLER : **VOLKAN AKIN**

SING :

DATE : **21.05.2021**

Test
TS EN ISO/IEC 17025
AB-1183-T

AB-1183-T

M-2021-00813

06.05.2021

MNA LABORATORIES
TEST REPORT

Report No: M-2021-00813	Date: 06.05.2021	Page: 1 / 2	Rev:

Purpose of Analysis	:	SPECIAL REQUEST	**Brand**	:	ENMED
Sample Type	:	NITRILE GLOVE	**Model**	:	ENM 603
Sample Send Org.	:	EN ECZA DEPOSU İLAÇ MED.ÖZEL SAĞLIK HİZM.	**Sampler**	:	COSTUMER
Manufacturer Name	:	EN ECZA DEPOSU İLAÇ MED.ÖZEL SAĞLIK HİZM.			
Analysis Date	:	20.04.2021			
Sample Quantity	:	100 pieces			
Other informations	:				

No	Tests	Results		Limit Value	Method	Evaluation	Physical Condition
1	Finger Dexterity *	5 (mm)		5 mm	TS EN ISO 21420 Part 6.2	PERFORMANCE LEVEL:5	
2	Determination of Organotin Compounds (DOT) *	<10 (mg/kg)		<1000 ppm	In House Method SOP 05 Rev01 (Modified from ISO TS 16179)	PASS	
3	Determination of Phthalates	<50 (mg/kg)		<1000 ppm	ISO/TS 16181	PASS	
4	Penetration By Blood-Borne Pathogens(Bacteriophage)	0 (PFU/ml)		<1 PFU/ml	BS ISO 16604+ TS EN 14126 Part 4.1.4.1	PASS	
5	Determination of pH - Textile*	7,11		3.5 < Result < 9.5	TS EN ISO 3071	PASS	
6	Air Leak Test *	No leak		No leak to be	TS EN 374-2 Part 5.2	PASS	
7	Water Leak Test *	No leak		No leak to be	TS EN 374-2 Part 5.3	PASS	
8	Resistance To Degradation By Chemicals *	3,75 (%40 NaOH) (%)			TS EN 374-4		
9	Resistance To Permeation By Chemicals *	% 40 NaOH 30 min no leak. (ug/cm².min)		> 30 min	TS EN 16523-1	PERFORMANCE LEVEL:2	
10	Sizing and measurement of gloves*	254(mm)			TS EN ISO 21420 Part 6.1		
		Hand length	192(mm)		TS EN ISO 21420 Part 6.1		
		Circumference	209 (mm)		TS EN ISO 21420 Part 6.1		

SAMPLE PLACE

1. Line Sample place for finger dexterity: Size:9
10. Line Sample place for sizing and measurement of gloves: Size:9

Küçükbakkalköy Mahallesi Yenidogan Caddesi No: 21 Atasehir İstanbul
info@mnalab.com tel: 02165740708 faks: 02165751331

Test
TS EN ISO/IEC 17025
AB-1183-T

AB-1183-T
M-2021-00813
06.05.2021

MNA LABORATORIES
TEST REPORT

Report No: M-2021-00813	Date: 06.05.2021	Page: 2 / 2	Rev:

Purpose of Analysis	:	SPECIAL REQUEST	**Brand**	: ENMED
Sample Type	:	NITRILE GLOVE	**Model**	: ENM 603
Sample Send Org.	:	EN ECZA DEPOSU İLAÇ MED.ÖZEL SAĞLIK HİZM.	**Sampler**	:CUSTOMER
Manufacturer Name	:	EN ECZA DEPOSU İLAÇ MED.ÖZEL SAĞLIK HİZM.		
Analysis Date	:	20.04.2021		
Sample Quantity	:	100 pieces		
Other informations	:			

Operating as an experimental laboratory, MNA Laboratories have been accredited by TURKAK 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 pa ges, which are the supplementary part of this certificate.
10. Water Repellency Determination Hydrostatic Pressure Determination TS 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.
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 GERGİN
Sampling and Reporting Officer

Erhan ÜSTÜNEL
PPE Laboratory Responsible

Confirmed
6.05.2021
Volkan AKIN
Laboratory Manager

Küçükbakkalköy Mahallesi Yenidogan Caddesi No: 21 Atasehir İstanbul
info@mnalab.com tel: 02165740708 faks: 02165751331