

# 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**  
21.05.2021

**Karar Verici / Approver**



**Okan AKEL**  
21.05.2021

**Şirket Müdürü / General manager**







**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			
<b>MANUFACTURER:</b> EN ECZA DEPOSU İLAÇ MEDİKAL ÖZEL SAĞLIK HİZMETLERİ İNŞAAT TAAHHÜT TİCARET A.Ş.			
<b>PPE TYPE:</b>			
<ul style="list-style-type: none"><li>- EN 420+ A1 Protective gloves</li><li>- EN ISO 374-1 Protective Gloves Against Dangerous Chemicals And Micro-Organisms</li><li>- EN ISO 374-5 Protective Gloves Against Dangerous Chemicals And Micro-Organisms Part 5: Terminology and performance requirements for micro-organisms risks</li></ul>			
<b>PRODUCT SIZE / MODEL:</b> ENM-603 (S, M, L, XL)			
<b>PICTOGRAM AND PERFORMANCE LEVELS:</b>			
	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.

## PRODUCT PICTURES



ENM-603

## DOCUMENTS IN THE TECHNICAL FILE

- Basic Health Safety Requirements
- Risk Assessment
- Test Reports
- Technical Report