

AB Tip İnceleme Sertifikası EU Type-Examination Certificate

Belge No / Certificate No	: 92-20-05
Belgelendirme Tarihi - Bir Sonraki Belge Tarihi / Certification Date / Certificate Validity Date	: 20.01.2021-20.01.2026
Belge Geçerlilik Tarihi / Document Validity Period	: 5 yıl / 5 years
Firma Ünvanı ve Adresi / Company Name and Address	: FAGO MEDİKAL SAN. VE TİC. LTD. ŞTİ. 15 Temmuz Mah. Cami Yolu Cad. No:106 / Z1 Bağcılar/ İSTANBUL
Ürün Adı /Modeller / Product Name / Models	: FAMEX FM1006
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-2020-00592
Ürün Tipi / Product Type:	
- EN ISO 13688:2013 Koruyucu giyecekler - Genel özellikler / Protective clothing - General requirements	
- EN 13034:2005+A1:2009 Sıvı Kimyasallara Karşı Koruyucu Giysi (Tip 6-B) / Protective Clothing Against Liquid Chemicals (Type 6-B)	
- EN ISO 13982-1: 2004+A1:2010 Katı Parçacıklara Karşı Koruyucu Giysi (Tip 5-B)/ Protective Clothing For Use Against Solid Particulates (Type 5-B)	
- EN 14126:2003 Koruyucu Giyecekler - Patojen Organizmalara Karşı / Protective Clothing - Performance Requirements And Tests Methods For Protective Clothing Against Infective Agents	

Ürünün Malzeme Bilgisi / Product Material Information: FAMEX FM1006 model ürünleri kaplamalı kumaş kullanılarak imal edilmiştir./ FAMEX FM1006 model products are manufactured using coated fabric.

Volkan AKIN
20.01.2021

Karar Verici / Approver

Okan AKEL
20.01.2021

Şirket Müdürü / General manager



ATTACHMENTS (92-20-05)

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 : FAMEX FM1006

PPE SPECIFICATION	PERFORMANCE LEVELS
Classification	Type 5-B, Type 6-B
Abrasion Resistance	1
Tear Resistance (Trapezoidal)	2
Tensile Strength	1
Puncture Resistance	1
Liquid Repellency	NaOH: 3, H ₂ SO ₄ : 3
Resistance To Penetration By Liquid	NaOH: 3, H ₂ SO ₄ : 3
Flex Cracking Resistance	1
Seam Strength	2
Wet Bacterial Penetration	1
Dry Microbial Penetration	1
Phi-X174 Bacteriophage	3

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: FAGO MEDİKAL SAN. VE TİC. LTD. ŞTİ.

PPE TYPE:

- EN ISO 13688:2013 Protective clothing - General requirements
- EN 14126:2003 Protective clothing - Performance requirements and tests methods for protective clothing against infective agents
- EN 13034:2005+A1:2009 Protective Clothing Against Liquid Chemicals (Type 6-B)
- EN ISO 13982-1: 2004+A1: 2010 Protective Clothing For Use Against Solid Particulates (Type 5-B)

MODEL: FAMEX FM1006 **PRODUCT SIZE:** S, M, L, XL, 2XL, 3XL, 4XL

PICTOGRAM AND PERFORMANCE LEVELS:

EN ISO 13688:2013

EN ISO 13982-1: 2004+A1: 2010 (Type 5-B)

EN 14126:2003

EN 13034:2005+A1:2009 (Type 6-B)



NB 2841

“Flammable material. Keep away from fire.”

“Do not re-use”

Type 5-B, Type 6-B

MNA Laboratuvarları Şan. Tic.Ltd .Şti

Adres: Küçükbakkalköy Mahallesi Yenidoğan Cad.No:21 Ataşehir/ İstanbul

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U-Form-002/Rev.04/12.03.2020

ATTACHMENTS (92-20-05)

MNA LABORATORIES 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.

**DOCUMENTS IN THE TECHNICAL FILE**

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