



# CERTIFICATE

## MEDİKAL OLUŞUM SAN. VE TİC. LTD. ŞTİ.

DAĞYAKA MAH. 2038 CAD. NO:4/20/2  
KAHRAMANKAZAN / ANKARA / TÜRKİYE

*Has been assessed and found to Comply with the Requirements of:  
Denetlenmiş ve aşağıdaki standardın gerekliliklerine uygunluğu görülmüştür:*

### ISO 13485:2016

*Medical Devices -Quality Management System is applicable to:  
Tıbbi Cihazlar Kalite Yönetim Sistemi*

**DESIGN, PRODUCTION AND SALES OF MEDICAL DISINFECTANTS AND  
CHEMICALS AND AUXILIARY MATERIALS, PLASTIC AND METAL MEDICAL  
PRODUCTS, IVD MEDICAL DEVICES, SALES OF MEDICAL PATHOLOGY KITS**

**TIBBİ DEZENFEKTANLARIN VE KİMYASALLARININ VE YARDIMCI MALZEMELERİNİN,  
PLASTİK VE METAL MEDİKAL ÜRÜNLERİN, IVD MEDİKAL CİHAZLARIN TASARIMI,  
ÜRETİMİ VE SATIŞI, TIBBİ PATOLOJİ KİTLERİN SATIŞI**

**Certificate Number: 2021/MDQMS/10172  
Belge Numarası: 2021/MDQMS/10172**

**Initial Certification Date: 19.04.2021  
İlk Belgelendirme Tarihi: 19.04.2021**

**Certification Period: 3 Years  
Belgelendirme Periyodu: 3 Yıl**

**Certificate Validity Date: 18.04.2024  
Belge Geçerlilik Tarihi: 18.04.2024**



IQR Sertifikasyon Onayı



**IQR ULUSLARARASI BELGELENDİRME HİZMETLERİ LTD.ŞTİ.**

Beşevler Mah. Kocayunus Sk. No:3 Arslan Han Plaza K:2 Nilüfer / BURSA

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**Medikal Oluşum San. ve Tic. Ltd. Şti.**

## EC DECLARATION OF CONFORMITY

**According Directive 98/79/EC on in vitro diagnostic medical devices, Annex III**

**Manufacturer:** Medikal Oluşum San. ve Tic. Ltd. Şti.

**Adress:** Dağyaka Mahallesi 2038. Cadde Selpa Sanayi Sitesi No:4 Blok: 20/2, 06980  
Kahramankazan/Ankara/TURKEY

**Products:** Medical pathology kits and chemicals and auxiliary materials, plastic and metal  
medical products

**Classification:** Other device (all devices except Annex II and self-testing devices)

**We herewith declare that the above mentioned product meets the provisions of the council  
directive 98/79/EC for medical devices. All supporting documentation is retained under the  
premises of the manufacturer.**

**DESIGN, PRODUCTION AND SALES OF MEDICAL DISINFECTANTS AND CHEMICALS AND  
AUXILIARY MATERIALS, PLASTIC AND METAL MEDICAL PRODUCTS, IVD MEDICAL  
DEVICES, SALES OF MEDICAL PATHOLOGY KITS**

**Medikal Oluşum San. ve Tic. Ltd. Şti. considers following laws, rules and standards:**

• **Directive 98/79/EC**

In-vitro-Diagnostica

• **EN ISO 14971**

Medical devices – Application of riskmanagement to medical devices

• **DIN EN ISO 13485**

Qualitysystems – Medical devices – Particular requirements for the application of EN ISO 9001

Ankara, 29.03.2017

Medikal Oluşum San. ve Tic. Ltd. Şti.

Berna Başhan / General Manager

**MOS-LAB**  
**MEDİKAL OLUŞUM SANAYİ VE TİC. LTD. ŞTİ.**  
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Kahramankazan V.D.6.13.012/2329 Ticaret Sicil No. 166286  
Mersis No: 0619 0322 9399 0010

**Medikal Oluşum San. ve Tic. Ltd. Şti.**

• Dağyaka Mahallesi 2038. Cadde Selpa Sanayi Sitesi  
No:4 Blok: 20/2, 06980 Kahramankazan/Ankara/TURKEY

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ISO  
9001  
QUALITY  
MANAGEMENT

ISO  
13485  
MEDICAL DEVICES  
QUALITY MANAGEMENT

ISO  
22716  
GMP

ISO  
23907  
SHARPS INJURY  
PROTECTION