



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

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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.

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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