



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.

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

Products: Medical disinfectants, medical pathology kits and chemicals, 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.

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

- **Directive 98/79/EC**

In-vitro-Diagnostic

- **EN ISO 14971**

Medical devices – Application of risk management to medical devices

- **DIN EN ISO 13485**

Quality systems – Medical devices – Particular requirements for the application of EN ISO9001

Date of issue: 10.01.2021

Expiration date: 10.01.2031

Berna Başhan

General Manager





CERTIFICATE

MOS LAB 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 9001:2015

*The Quality Management System is applicable to:
Kalite Yönetim Sistemi:*

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

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

**Certificate Number: QMS-001235
Belge Numarası: QMS-001235**

**Initial Certification Date: 18.04.2024
İlk Belgelendirme Tarihi: 18.04.2024**

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

**Certificate Validity Date: 17.04.2025
Belge Geçerlilik Tarihi: 17.04.2025**



IQR Sertifikasyon Onayı

IQR ULUSLARARASI BELGELENDİRME HİZMETLERİ LTD.ŞTİ.

Beşevler Mah. Kocayunus Sk. No:3 Arslan Han Plaza K:2 Nilüfer / BURSA
Tel.: +90.224.266 00 16 Faks: +90.224.249 41 13 www.iqrcert.com e-posta: info@iqrcert.com



CERTIFICATE

MOS LAB **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, MEDICAL
PATHOLOGY KITS AND CHEMICALS AND AUXILIARY MATERIALS PLASTIC
AND METAL MEDICAL PRODUCTS**

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

Certificate Number: 2024/MDQMS/000553
Belge Numarası: 2024/MDQMS/000553

Initial Certification Date: 18.04.2024
İlk Belgelendirme Tarihi: 18.04.2024

Certification Period: 3 Years
Belgelendirme Periyodu: 3 Yıl

Certificate Validity Date: 17.04.2025
Belge Geçerlilik Tarihi: 17.04.2025



IQR Sertifikasyon Onayı

IQR ULUSLARARASI BELGELENDİRME HİZMETLERİ LTD.ŞTİ.

Beşevler Mah. Kocayunus Sk. No:3 Arslan Han Plaza K:2 Nilüfer / BURSA
Tel.: +90.224.266 00 16 Faks: +90.224.249 41 13 www.iqrcert.com e-posta: info@iqrcert.com