# 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** **Initial Certification Date: 18.04.2024**
**Belge Numarası: 2024/MDQMS/000553** **İlk Belgelendirme Tarihi: 18.04.2024**

**Certification Period: 3 Years** **Certificate Validity Date: 17.04.2025**
**Belgelendirme Periyodu: 3 Yıl** **Belge Geçerlilik Tarihi: 17.04.2025**

ACCREDITED
Management Systems
Certification Body
MSCB-135

*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

**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

MOS LAB
MEDİKAL OLUŞUM SANAYİ VE TİC. LTD. ŞTİ.
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Mersis No: 0613 0322 3290 0010

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

**DAĞYAKA MAH. 2038 CAD. NO:4/20/2**
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*Has been assessed and found to comply with the requirements of:*
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## 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**
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**Certification Period: 3 Years**
**Belgelendirme Periyodu: 3 Yıl**

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

INTERNATIONAL ACCREDITATION FORUM IAF

IAS ACCREDITED Management Systems Certification Body MSCB-135

IQR ULUSLARARASI BELGELENDİRME HİZMETLERİ LTD.ŞTİ.

*IQR Sertifikasyon Onayı*

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