



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

## 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: 18.04.2023  
Belge Geçerlilik Tarihi: 18.04.2023



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



# Sertifika

## Certificate

Goldcert, assessed that the following organisation has established and maintained a proper management system according to relevant standard

### MEDİKAL OLUŞUM SANAYİ VE TİCARET LİMİTED ŞİRKETİ

Carried out at following site/s

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

for their

### ISO 9001:2015 QUALITY MANAGEMENT SYSTEM

With a scope of

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

Certificate No : GC-19-2372  
Initial Registration Date : 09/08/2019  
Certification Date : 20/06/2022 Rev:1  
Valid Until : 08/08/2025



TÜRKAK BDS NO  
YS-7CB3-3DFD

Kalite Yönetim Sistemi  
TS EN ISO/IEC 17021-1  
AB-0099-YS

General Manager

*Erdur Aydin*



This certificate is valid until the Goldcert certification requirements are complied. Certificate validity checking could be done by reading the square code on the certificate by mobile devices or by using "TÜRKAK BDS Number" from the <https://tbas.turkak.org.tr> document verification system

SERTİFİKA BELGELENDİRME DENETİM MUAYENE ve EĞİTİM HİZMETLERİ LTD. ŞTİ.  
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