



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 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 SAN. VE TİC. LTD. ŞTİ.
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Mersis No: 0613 0322 3999 0010

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ISO
9001
QUALITY
MANAGEMENT

ISO
13485
MEDICAL DEVICES
QUALITY MANAGEMENT

ISO
22716
GMP

ISO
23907
SHARPS INJURY
PROTECTION



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



Kalite Yönetim Sistemi
TS EN ISO/IEC 17021-1

AB-0099-YS



TÜRKAK BDS NO
YS-7CB3-3DFD

General Manager

Erdin 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 <http://tbas.turkak.org.tr> document verification system

SERTİFİKA BELGELENDİRME DENETİM MUAYENE ve EĞİTİM HİZMETLERİ LTD. ŞTİ.
İkitelli OSB Giyim Sanatkarları Sanayi Sitesi 3. Ada A Blok No: 301 Başakşehir 34490 İstanbul/TÜRKİYE
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S-F.07/1



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.

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