



**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





**Medikal Oluşum San. ve Tic. Ltd. Şti.**

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**Manufacturer:** Medikal Oluşum San. ve Tic. Ltd. Şti.

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**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**  
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**Medikal Oluşum San. ve Tic. Ltd. Şti.**

• Dağyaka Mahallesi 2038. Cadde Selpa Sanayi Sitesi  
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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.  
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S-F.07/1



# CERTIFICATE of Registration



*This is to Certify that the  
Medical Devices – Quality Management System  
of*

## **MEDİKAL OLUŞUM SANAYİ VE TİCARET LİMİTED ŞİRKETİ**

**DAĞYAKA MAH. 2038 CAD. NO:4/20/2  
KAHRAMANKAZAN / ANKARA / TÜRKİYE**

**has been independently assessed and is compliant  
with the requirements of**

**ISO 13485:2016**

**This Certificate is applicable to the following product or service ranges:**

**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 No :: TR51766H**

**Date of initial registration 04 April 2020**

**Date of this Certificate 04 April 2020**

**Surveillance audit on or before 03 April 2021**

**Recertification Due / Certificate expiry 03 April 2023**

This Certificate is property of Staunchly Management & System Services Ltd. and remains valid  
subject to satisfactory surveillance audits.

**Director**



**STAUNCHLY MANAGEMENT & SYSTEM SERVICES LTD.**

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**Phone : +44 345 680 0199**

**Email : info@staunchlyservices.com Web : www.staunchlyservices.com**

**SMS/F109A/17/REV02**

**For precise and updated information concerning the present certificate mail to info@staunchlyservices.com**

**This Certificate is the property of Staunchly Management & System Services Private Limited and shall be returned immediately when demanded**