



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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Classification: Other device (all devices except Annex II and self-testing devices)

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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

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Mersis No: 0613 0322 3999 0010

Medikal Oluşum San. ve Tic. Ltd. Şti.

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

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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
Tel: +90 212 407 01 00 Faks: +90 212 407 00 17 info@goldcert.com.tr

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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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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