



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





# 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

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

# 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**

<b>Date of initial registration</b>	<b>04 April 2020</b>
<b>Date of this Certificate</b>	<b>04 April 2020</b>
<b>Surveillance audit on or before</b>	<b>03 April 2021</b>
<b>Recertification Due / Certificate expiry</b>	<b>03 April 2023</b>

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

**Director**

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SMS/F109A/17/REV02

For precise and updated information concerning the present certificate mail to [info@staunchlyservices.com](mailto:info@staunchlyservices.com)

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



## Product Description

Product code	BPSP00006
Product description	Sampling containers 500 mL

## Product Characteristics

Graduation	Yes
Type of cap	Screw cap
Design	Container with enclosed lid
Application	Collection and storage of samples
Example of use	Collection container for samples
Suitable for	-

## Size

Sample volume	500 ml
Max. volume	500 ml
Diameter	94 mm
Diameter of opening	100 mm
Height of product	97 mm
Length excluding cap	95 mm

## Material & colours

Product material	Polypropylene (PP)
Colour of product	Transparent
Cap material	Polypropylene (PP)
Colour of cap	Red (Optional)

## Purity & certification

Product in accordance with MDD or IVDD	IVD
CE certified	CE
Lot or serial number	batched

## Packaging

Pcs. / inner box	200
Pcs. / box	200
Depth of case	650 mm
Width of case	390 mm
Height of case	520 mm
Case volume	0,13 cbm
Weight of case	9 kg

## Disclaimer :

User must ensure suitability of the product(s) in their application prior to use. Products conform solely to the information contained in this and other related Medikal Oluşum San. ve Tic. Ltd. Şti. Publications. The information contained in this publication is based on our research and development work and is to the best of our knowledge true and accurate Medikal Oluşum San. ve Tic. Ltd. Şti. reserves the right to make changes to specifications and information related to the products at any time. Products are not intended for human or animal diagnostic or therapeutic use but for laboratory, research or further manufacturing use only, unless otherwise specified. Statements contained herein should not be considered as a warranty of any kind, expressed or implied, and no liability is accepted for infringement of any patents.