



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



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 <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

Product Description

Product code	BPIB00003
Product description	Individually Wrapped Strelie A Urine Collection Cup

Product Characteristics

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

Size

Sample volume	100 ml
Max. volume	100 ml
Diameter	45 mm
Diameter of opening	54 mm
Height of product	68 mm
Length excluding cap	65.5 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

Minimum Order QTY.	400
Pcs. / Inner Box	400
Pcs. / Box	400

Depth of Case	360 mm
Width of Case	645 mm
Height of Case	745 mm

Weight of Case	6 kg
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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.

