

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.

Suite 48, 88-90 Hatton Garden, London, EC1N 8PN.

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

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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

Product: Embedding cassettes with lid

Product Code	Product Name
BPKK00015	Embedding cassettes with lid

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-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 SANAYİ VE TİC. LTD. ŞTİ.
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Tel: (+90) 312 395 23 96 - Fax: (+90) 312 395 23 87
Kahramankazan/Ankara T.C. Ticaret Sicil No. 166286
Mersis No: 0613032232900010

Medikal Oluşum San. ve Tic. Ltd. Şti. •
Dağyaka Mahallesi 2038. Cadde Selpa Sanayi Sitesi
No:4 Blok: 20/2, 06980 Kahramankazan/Ankara/TURKEY
• Phone: +90 312 395 23 96 • Fax: +90 312 395 23 87 •
info@moslab.com • www.moslab.com

Certified manufacturer
according to ISO 9001
and ISO 13485

ISO 13485 **ISO 9001**

MEDICAL DEVICES
QUALITY
MANAGEMENT

QUALITY
MANAGEMENT

EMBEDDING CASSETTES - “with lid”

Have same technical specifications as cassettes without lid. The efficient flow through slots maximize fluid exchange and ensure proper drainage. Lids can be opened and closed as often as necessary and always relock securely without any risk of specimen loss. Large labelling areas are located on both sides of the cassettes.



Catalogue Number	Colour	Dimensions (without lid)	Dimensions (lid closed)
BPKK00015	White (Optional)	40x28x6 mm	40x28x7 mm

Purity & certification

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

Packaging

Minimum order qty.	1000
Pcs. / box	1000
Pcs. / pallet	72000
Depth of case	380 mm
Width of case	400 mm
Height of case	150 mm
Case volume	0.02 cbm
Weight of case	3,5 kg



Disclaimer:

Use must ensure suitability of the product(s) in the 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 here in should not be considered as a warranty of any kind, expressed or implied, and no liability is accepted for infringement of any patents.

Medikal Oluşum Sanayi ve Tic. Ltd. Şti.
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