



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://bds.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

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

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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



MOSLAB® SHARPS CONTAINERS

Technical Data Sheet 3L Sharps Container



Technical Data Sheet 3L Sharps Container

for the containment of sharps waste with a usable capacity of
2.55 L

Sharps Container 3 L

Product Ref. BPTA00007



GENERAL CHARACTERISTICS

MATERIAL

Container Base	Polypropylene
Container Top	Polypropylene

COLOUR

Body of the Container	Yellow
Top of the Container	Red and Yellow
<i>Colourants don't contain heavy metals</i>	<i>Product is latex free</i>

STERILITY

Non-sterile

CE MARKING

CE Marking not required as product is not a medical device per the EU directive 93/42/EEC, June 14th 1993.
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CONFORMITY TO REGULATORY STANDARDS

<input checked="" type="checkbox"/> Certified as compliant to the International Organization for Standardization: ISO 9001 : 2008	<input checked="" type="checkbox"/> Certified as compliant to the International Organization for Standardization: ISO 13485 : 2016

CONSERVATION

Expiry Date	Not applicable. Product is not expiration dated.
Ambient Storage Conditions	Store upright

NUMBER OF UNITS PER BOX

80

MOSLAB® SHARPS CONTAINERS

Technical Data Sheet 3L Container

PRODUCT CHARACTERISTICS - SHARPS CONTAINER 3 L

Product Reference	BPTA00007
Nominal Capacity	3L
Usable Capacity	2.55L
Product Dimensions (R(Top) x R(Bottom) x H)	160mm x 139mm x 222mm
Sharps container opening diameter	50.8mm
Temporary and permanent closure	Yes
Needle removal ports	Yes
Product Weight (empty)	223g
Wall Thickness	1.35mm
Maximum fill line visible	Yes
Lot numbered for batch management	Yes
Autoclavable	At maximum 121° C for 20 minutes
Incineration	Yes, with the production of carbon dioxide and water vapour. Doesn't produce metal substances.

LABELLING PER

CONTAINER

CASE

Name of manufacturer, division and address	x	x
Country of manufacture	x	x
Product Reference	x	x
Product Description	x	x
Lot Number	x	x
British Standard Compliant		
French Standard Compliant & Autoclavable		
UN Standard Compliant	x	
Graphical Symbol: Biologically Hazard	x	
Danger Warning	x	
Primary Barcode (EAN/JAN-13)(Product Identification)	x	x
Secondary Barcode (EAN/JAN-13)(Lot no., Quantity)		x
Nominal Capacity	x	x
Usable Capacity	x	
Instructions for Use		x
Recommendations for Disposal		
Date of first use		
Date of last use		