Technical Data Sheet 1L Sharps Container

MOS LAB

Technical Data Sheet 1L Sharps Container

for the containment of sharps waste with a usable capacity of 0.85L

Sharps Container 1 L

Product Ref. BPTA00015



GENERAL CHARACTERISTICS

MATERIAL

Container Base	Polypropylene
Container Top	Polypropylene

COLOUR

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

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.

CONFORMITY TO REGULATORY STANDARDS

$\overline{\mathbf{A}}$	Certified as compliant to the International Organization for Standardization: ISO 9001 : 2008	\square	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

150

Technical Data Sheet 1L Container

PRODUCT CHARACTERISTICS - SHARPS CONTAINER 1L

Product Reference	BPTA00015
Nominal Capacity	1L
Usable Capacity	0.85L
Product Dimensions (R(Top) x R(Bottom) x H)	103mm x 83mm x 177mm
Sharps container opening diameter	41mm
Temporary and permanent closure	Yes
Needle removal ports	Yes
Product Weight (empty)	93g
Wall Thickness	1.32mm
Maximum fill line visible	Yes
Lot numbered for batch management	Yes
Autoclavable	At maxiumum 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, divison and address	Х	×
Country of manufacture	Х	Х
Product Reference	X	×
Product Description	Х	×
Lot Number	Х	Х
British Standard Compliant		
French Standard Compliant & Autoclavable		
UN Standard Compliant	Х	
Graphical Symbol: Biologically Hazard	Х	
Danger Warning	Х	
Primary Barcode (EAN/JAN-13) (Product Identification)	х	Х
Secondary Barcode (EAN/JAN-13) (Lot no., Quantity)		х
Nominal Capacity	Х	×
Usable Capacity	Х	
Instructions for Use		Х
Recommendations for Disposal		
Date of first use		
Date of last use		

Technical Data Sheet 2L Sharps Container

MOS LAB

Technical Data Sheet 2L Sharps Container

for the containment of sharps waste with a usable capacity of 1.7 I

Sharps Container 2 L

Product Ref. BPTA00021



GENERAL CHARACTERISTICS

MATERIAL

Container Base	Polypropylene
Container Top	Polypropylene

COLOUR

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

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.

CONFORMITY TO REGULATORY STANDARDS

\square	Certified as compliant to the International Organization for Standardization: ISO 9001 : 2008	Ø	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

Technical Data Sheet 2L Container

PRODUCT CHARACTERISTICS - SHARPS CONTAINER 2 L

Product Reference	BPTA00021
Nominal Capacity	2L
Usable Capacity	1.7L
Product Dimensions (R(Top) x R(Bottom) x H)	160mm x 134mm x 184mm
Sharps container opening diameter	50.8mm
Temporary and permanent closure	Yes
Needle removal ports	Yes
Product Weight (empty)	199g
Wall Thickness	1.75mm
Maximum fill line visible	Yes
Lot numbered for batch management	Yes
Autoclavable	At maxiumum 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, divison and address	X	Х
Country of manufacture	Х	Х
Product Reference	X	Х
Product Description	Х	Х
Lot Number	×	Х
British Standard Compliant		
French Standard Compliant & Autoclavable		
UN Standard Compliant	×	
Graphical Symbol: Biologically Hazard	×	
Danger Warning	×	
Primary Barcode (EAN/JAN-13) (Product Identification)	×	Х
Secondary Barcode (EAN/JAN-13) (Lot no., Quantity)		х
Nominal Capacity	Х	X
Usable Capacity	Х	
Instructions for Use		Х
Recommendations for Disposal		
Date of first use		
Date of last use		



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 Gertificate

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 Initial Registration Date Certification Date

: 09/08/2019

Valid Until

: 20/06/2022 Rev:1

: GC-19-2372

: 08/08/2025





General Manager

Erder Lyder



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://ibds.turkdk.org.tr document verification system

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 y

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

Director



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