



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: Sharps Container

Product Code	Product Name
BPTA0001	Sharps Container 0,2 L
BPTA0002	Sharps Container 0,5 L
BPTA0003	Sharps Container 0,7 L
BPTA0004	Sharps Container 1 L
BPTA0005	Sharps Container 1,3 L
BPTA0006	Sharps Container 2 L

Product Code	Product Name
BPTA0007	Sharps Container 3 L
BPTA0008	Sharps Container 5 L
BPTA0009	Sharps Container 7,5 L
BPTA0010	Sharps Container 10 L
BPTA0011	Sharps Container 25-30 L
BPTA0012	Sharps Container 32 L

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 risk management to medical devices

- **DIN EN ISO 13485**

Qualitysystems – Medical devices – Particular requirements for the application of EN ISO 9001

Date of issue: 10.01.2021

Expiration date: The EC Declaration of Conformity must be kept at least ten years after the last date of manufacture of the product, unless the directive expressly indicates another term.

Berna Başhan

General Manager

