



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

Supplied to: Profi Pentru Sanatate,

Address: Bulevardul Eroilor, nr. 126, Voluntari, Ilfov

Phone: +4(0)770 362 613

Email: achizitii@profipentrusanatate.ro

Web: www.profipentrusanatate.ro

Product: MOSLAB Sharps Container 0.5 L, MOSLAB Sharps Container 1 L, MOSLAB Sharps Container 1.3 L, MOSLAB Sharps Container 3 L, MOSLAB Sharps Container 5 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.

General Manager
Berna BAŞHAN

