



MEDİKAL OLUŞUM SAN. VE TİC. LTD. ŞTİ.

### EC DECLARATION OF CONFORMITY

According Directive 98/79/EC on 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

Product Code	Product Description
BPOZ00002	Innoculation Loop - Yellow 1 µL
BPOZ00001	Innoculation Loop - Blue 10 µL
BPIB00003	Urine Container 100 mL - individually packed, sterile
BPSP00008	Urine Container 200 mL
BPSP00010	Urine Container 200 mL - individually packed, sterile
BPIB00001	24 Hour Urine Container 3000 mL - white, normal capped
BPGK00001	Faeces Container 25-30 mL with spoon
BPGK00004	Sample Container 30mL
BPTA00004	Sharps Container 1 Lt
BPTA00007	Sharps Container 3 Lt
BPTA00008	Sharps Container 5 Lt
BPSP00001	Specimen Container 10 mL
BPSP00002	Specimen Container 25-30 mL
BPSP00004	Specimen Container 100 mL
BPSP00005	Urine Container 250 mL
BPSP00005-S	Urine Container 250mL, sterile, individually packaged
BPSP00011	Specimen Container 3000 mL
BPSP00013	Specimen Container 5000 mL
BPPP00001	Pasteur Pipette 3mL

**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

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Berna Başhan

General Manager

**MOS-LAB**  
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