



**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.

**Adress:** Dağyaka Mahallesi 2038. Cadde Selpa Sanayi Sitesi No:4 Blok: 20/2, 06980  
Kahramankazan/Ankara/TURKEY

**Products:** Medical pathology kits and chemicals and 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.**

**DESIGN, PRODUCTION AND SALES OF MEDICAL DISINFECTANTS AND CHEMICALS AND  
AUXILIARY MATERIALS, PLASTIC AND METAL MEDICAL PRODUCTS, IVD MEDICAL  
DEVICES, SALES OF MEDICAL PATHOLOGY KITS**

**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 riskmanagement to medical devices

• **DIN EN ISO 13485**

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

Ankara, 29.03.2017

Medikal Oluşum San. ve Tic. Ltd. Şti.

Berna Başhan / General Manager

**MOS-LAB**  
**MEDİKAL OLUŞUM SANAYİ VE TİC. LTD. ŞTİ.**  
Dağyaka Mah. 2038. Cad. No:4/20/2 Kahramankazan/ANKARA  
Tel: (+90) 312 395 23 96 - Fax: (+90) 312 395 23 87  
Kahramankazan V.D.B. 13.012.2329 Ticaret Sicil No. 166286  
Mersis No: 0619 0322 9399 0010

**Medikal Oluşum San. ve Tic. Ltd. Şti.**

• Dağyaka Mahallesi 2038. Cadde Selpa Sanayi Sitesi  
No:4 Blok: 20/2, 06980 Kahramankazan/Ankara/TURKEY

• Phone:+90 312 395 23 96• Fax:+90 312 395 23 87

• [info@moslab.com](mailto:info@moslab.com) • [www.moslab.com](http://www.moslab.com)

ISO  
9001  
QUALITY  
MANAGEMENT

ISO  
13485  
MEDICAL DEVICES  
QUALITY MANAGEMENT

ISO  
22716  
GMP

ISO  
23907  
SHARPS INJURY  
PROTECTION