MOS LAB

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

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ISO 9001	ISO 13485	ISO 22716	ISO 23907
QUALITY MANAGEMENT	MEDICAL DEVICES QUALITY MANAGEMENT	GMP	SHARPS INJURY PROTECTION