



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
QUALITY
MANAGEMENT

ISO
13485
MEDICAL DEVICES
QUALITY MANAGEMENT

ISO
22716
GMP

ISO
23907
SHARPS INJURY
PROTECTION