



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

Products: Medical disinfectants, medical pathology kits and chemicals, 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.

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

