



Product Service

# EC - CERTIFICATE

## Production Quality Assurance System

(Annex V of the Directive 93/42/EEC on Medical Devices)

No. G2S 09 08 71502 003

**Manufacturer:** Galenika a.d.  
Batajnicky drum b.b.  
11080 Belgrade  
SERBIA

**EC-Representative:** Emergo Europe  
Molenstraat 15  
2513 BH The Hague  
THE NETHERLANDS

**Product Category(ies):** Adhesive strips, sterile packaging

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture according to Annex V, section 3 of the Directive 93/42/EEC on Medical Devices. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective product / product categories and conforms to the provisions of this Directive. It is subject to periodical surveillance. See also notes overleaf.

**Report No.:** 71351656

**Valid until:** 2014-08-26

**Date,** 2009-08-27

Hans-Heiner Junker



TÜV SÜD Product Service GmbH is Notified Body according to Council Directive 93/42/EEC concerning medical devices with identification no. 0123.

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**Facility(ies):**

Galenika a.d. Fabrika parafarmaceutika  
Batajnicketi drum b.b., 11080 Belgrade, SERBIA