



Product Service

EC-CERTIFICATE

Full Quality Assurance System

(Annex II, section 3 of the Directive 93/42/EEC on Medical Devices)

No. G1 09 08 71502 001

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):

- Teeth, Dental Prosthetic
- Cement, Dental, Zinc Phosphate
- Dental Amalgam, Powder
- Mercury, Dental
- Casting Alloys, Dental, Precious
- Capsules, Dental Amalgam
- Cement, Dental, Resin, Composite
- Composite Restorative Materials, Dental
- Dental Etching Liquids, Gel
- Cement, Dental, Glass Ionomer
- Cement, Dental, Zinc Oxyde Eugenol
- Composite Restorative Materials, Dental, Other (Light-curing composite pit and fissure sealant)
- Cavity Liners
- Dental material, denture base, polymer based
- Dental solution, cleansing
- Dental solution, mouthwash

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective products / product categories according to Annex II section 3 of the Directive 93/42/EEC on Medical Devices. This quality assurance system conforms to the provisions of this Directive and is subject to periodical surveillance. For marketing of class III products an additional Annex II.4 certificate is mandatory. See also notes overleaf.

Report No.: 71351656
Valid until: 2014-08-26

Hans-Heiner Junker

Date, 2009-08-27



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 dentala
Milorada Gavrilovica 10, 11080 Belgrade, SERBIA