



# C E R T I F I C A T E

## Full Quality Assurance System Medical Devices Directive 93/42/EEC Annex II

Company Name : Privredno Društvo Za Proizvodnju, Trgovinu I Usluge Galenika  
Pharmacia D.O.O. Beograd

Company Address : Dr. Drage Ljocic br.3 - 11000 Belgrad SERBIA

Outsource Processes : Sterilization

Production Site : Srpskih vladara BB - 12300 Petrovac na Mlavi Belgrad SERBIA

Sterilization Adress : Vinca Institute of Nuclear Sciences PO Box 522 11001  
Belgrad SERBIA

Related Directives and Annex : MDD 93/42/EEC Medical Devices Directive - Annex II  
(Excluding Section 4)

Product : Class I – Sterile Products  
- Sterile First Bandages  
- Steril Gauzes  
- Sterile First Aid Sets  
- Steril Compres  
- Sterile First Ait Cabinets

Certificate Number : M.2015.106.4667

Report Number : UD.2873.SIB

Initial Assessment Date : 21.11.2014

Registration Date : 12.06.2015

Reissue Date/No : -

Expiry Date : 11.06.2020

UDEM International Certification  
Auditing Training Centre Industry  
and Trade Co. Ltd.

UDEM hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance audits, defined by Annex II, section 5 of the forementioned directive. According to Annex II, section 4 an EC design- examination certificate is required for placing the Class III devices on the market. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Co. Ltd. to whom it must be returned upon request. The above named company and UDEM must keep a copy of this certificate for 5 years from the registration of the certificate. Usage of the CE mark is under the responsibility of the manufacturer with the completion of EC Declaration of Conformity. The above mentioned company must notify all changes related with the approved product to UDEM. If UDEM will not renew the expiry date of this certificate in question, the mentioned company should stop placing the product on the market. The currency of the certificate can be checked through [www.udemltd.com.tr](http://www.udemltd.com.tr).

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Address: Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya – Ankara – TURKEY

Phone: +90 312 443 03 77 Fax: +90 312 441 87 72

E-mail: [info@udemltd.com.tr](mailto:info@udemltd.com.tr) [www.udemltd.com.tr](http://www.udemltd.com.tr)