



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

## Production Quality Assurance for Medical Devices Directive 93/42/EEC Annex V

Company Name : Akmeda Medikal Danışmanlık Gayrimenkul Turizm San. ve Tic. Ltd. Şti.

Company Address : Ostim Osb Mah. 1212. Cadde No:2 Yenimahalle ANKARA / TURKEY

Related Directives and Annex : MDD 93/42/EEC Medical Devices Directive - Annex V

Product : Sterile Disposable Surgical Drapes and Drape sets - Class Is  
Sterile Disposable Surgical Gowns - Class Is

GMDN : 47783, 35778

Certificate Number : M.2018.106.9500

Report Number : MD.3576.IB

Initial Assessment Date : 20.03.2018

Registration Date : 04.04.2018

Revision Date /No : -

Expiry Date : 03.04.2023

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

UDEM hereby declares that the requirements of Annex V, 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 V, section 4 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 Inc. Co. 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.udem.com.tr](http://www.udem.com.tr).

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