



# EC CERTIFICATE

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

Company Name : SC Alison Hayes (Romania) S R L

Company Address : Urziceni,Soseaua Bucuresti-Buzau Km. 55,2,Jud. Ialomita, Romania

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

Product : Sterile Surgical Gowns (Standard and Reinforced) - Class Is

GMDN : 32293

Certificate Number : M.2021.106.14599

Report Number : MD.4173.IB

Initial Assessment Date : 22.01.2021

Registration Date : 20.05.2021

Revision Date /No : -

Expiry Date : 27.05.2024

  
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 aforementioned directive. UDEM's responsibility for class I devices covered by the EC certificate is limited to manufacturing issues related to safeguarding and maintaining sterile conditions, if the device is sterile; and manufacturing issues related to product's conformity with metrological requirements, if it has measurement function. 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 validity of the certificate can be checked through [www.udem.com.tr](http://www.udem.com.tr).

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