



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

EC Design-Examination Certificate For Medical Devices

MDD 93/42/EEC Directive of Medical Devices Annex II, Section 4

With the expire of the certificate M.2017.106.7656 the validity of the certificate
M.2017.106.7656-1 will also end.

Company Name : SGA Mühendislik Danışmanlık Eğitim İç ve Dış Tic. A.Ş.

Company Address : Oğuzlar Mah. 1388 Sokak No:31 Balgat ANKARA / TURKEY

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

Product : Vacuum Assisted Closure Sets
- Sterile and non - sterile vacuum assisted closure sets including silver,
vacuum assisted AMD closure sets, collection sets, accessories and
foam including silver - Class III

GMDN : 47404, 47407, 47409

Certificate Number : M.2017.106.7656-1

Report Number : MD.3348.TR-044-1

Initial Assessment Date : 29.05.2014

Registration Date : 24.01.2017

Revision Date /No : -

Expiry Date : 03.06.2017


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

The EC desing examination certificate refers to the above mentioned product. It certifies that the desing documentation of the product complies with Annex II, article 4 of the directive. 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.

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