



C E R T I F I C A T E

Full Quality Assurance System

Medical Devices Directive 93/42/EEC Annex II

This Certificate is only valid in connection with certificate;
registration no 2195-MED-1216001 issued by NB 2195.

Company Name : Aero Medikal Sağlık Turizmi Tıbbi Ürünler ve İth. İhr. San. Tic. Ltd. Şti.

Company Address : Maltepe Mah. Neyzen Tevfik Sok. No:4/5 Çankaya
ANKARA / TURKEY

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

Product : Spinal Implant Systems - Class IIb - Sterile and Non Sterile
- Screws
- Rods
- Connectors
- Cages
- Corpectomy Cage
- Disc Protheseses
- Hooks
- Cervical Plates

Product Brand /Model /Type : Aerospine

Product Types are attached.

Certificate Number : M.2014.106.3179

Report Number : UD.2336.1B

Initial Assessment Date : 10.06.2015

Registration Date : 04.07.2015

Revision Date /No : 17.08.2018/01

Expiry Date : 03.07.2021

OEM Expiry Date : 07.06.2017


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 3 of the forementioned directive. According to Annex II, section 4 an EC design-examination certificate is required for placing the Class II 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.

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