



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 İht. 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 Protheses
- Hooks
- Cervical Plates

Product Brand /Model /Type

: Aerospace

Product Types are attached.

Certificate Number

: M.2014.106.3179

Report Number

: UD.2336.1B

Initial Assessment Date

: 10.06.2014

Registration Date

: 04.07.2014

Revision Date /No

: 17.08.2016/01

Expiry Date

: 03.07.2019

OEM Expiry Date

: 07.06.2017

UDBM 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 aforementioned 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 UDBM 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 UDBM. If UDBM 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 this certificate can be checked through www.udemtd.com.tr.

Address: Muflukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya - Ankara - TURKEY

Phone: +90 0312 443 03 90 Fax: +90 0312 443 03 76

E-mail: info@udemtd.com.tr www.udemtd.com.tr





CERTIFICATE

57799

This certificate was given to the below stated company by UDEM International Certification
Audit Training Cent. Ind. Co. Ltd

**Aero Medikal Sağlık Turizmi Tıbbi
Ürünler ve İth. İhr. San. Tic. Ltd. Şti.**

Mustafa Kemal Mahallesi 2131.Cadde No:25/10 Çankaya
ANKARA / TÜRKİYE

ISO 9001:2008

Scope: Manufacturing of non steril spinal system implants

EA Code: 23

Audit Date : 10.06.2014
Decision Date : 04.07.2014
Reissue Date : 28.06.2017/01
Expiry Date : 03.07.2020



UDEM International Certification
Audit Training Cent. Ind. Co. Ltd.



Hereby, UDEM International Certification Audit Training Cent. Ind. Co. Ltd, certifies that the above stated company have the appropriate management system according to the requirements of the above standard. This certificate is valid for 3 years since the decision date as long as the system is effectively maintained and surveillance audits are carried out. The validity of the certificate can be checked through www.udemltd.com.tr, www.jas-anz.org/register. The certificate is the property of UDEM International Certification Audit Training Cent. Ind. Co. Ltd and shall be returned if requested.

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

Tel: +90 312 443 03 90 (pbx) Fax: +90 312 443 03 76

E-mail: info@udemltd.com.tr Web: www.udemltd.com.tr



CERTIFICATE

85167

This certificate was given to the below stated company by UDEM International Certification Audit Training Cent. Ind. Co. Ltd. Reference standards are
TS EN ISO 13485:2003 and EN 13485:2012

**Aero Medikal Sağlık Turizmi Tıbbi
Ürünler ve İth. İhr. San. Tic. Ltd. Şti.**

Mustafa Kemal Mahallesi 2131.Cadde No:25/10 Çankaya
ANKARA / TURKEY

ISO 13485:2003

Scope: Manufacturing of non steril spinal system implants

Audit Date : 10.06.2014
Decision Date : 04.07.2014
Reissue Date : 28.06.2017/01
Expiry Date : 03.07.2020



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