



C E R T I F I C A T E

Full Quality Assurance System Medical Devices Directive 93/42/EEC Annex II (Excluding Section 4)

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

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

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

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

Product Brand /Model /Type : AEROSPINE, BOSTONBONE MEDICAL

GMDN : 61325, 38161, 34170, 46653, 37272, 61865, 48164
Product Types are attached.

Certificate Number : M.2014.106.3179

Report Number : UD.2336.IB

Initial Assessment Date : 10.06.2014

Registration Date : 04.07.2014

Recertification Assessment Date : 08.05.2019

Reissue Date / No : 07.08.2019/01

Revision Date /No : 09.08.2019/01

Expiry Date : 27.05.2024

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

The certificate is not in force between 03.07.2019-07.08.2019.

UDEM hereby declares that the requirements of Annex II, excluding section 4 of the 93/42/EEC Directive 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 forementioned directive. According to Annex II, section 4 an EC design- examination certificate is required for placing the Class III devices on the market. 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.



Address: Mutlukent 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@udemltd.com.tr www.udem.com.tr



This document containing 3 (three) pages is the Annex of the Certificate with the revision number 01, with the number M.2014.106.3179 and with the registration date of 04.07.2014 with the revision date of 09.08.2019 issued for "Aero Medikal Sağlık Turizmi Tıbbi Ürünler ve İth. İhr. San. Tic. Ltd. Şti." by UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. that is giving service as Notified Body with the ID No: 2292 according to 93/42/EEC Medical Devices Directive

AERO SPINAL SCREW ROD SYSTEM		GMDN
Aero Spinal Stabilization polyaxial screw		61325
Aero Spinal Stabilization multifunctional screw		61325
Aero Spinal Stabilization polyaxial cannulated-cemented screw		61325
Aero Spinal Stabilization monoaxial cannulated-cemented screw		61325
Aero Spinal Stabilization monoaxial screw		61325
Aero Spinal Stabilization set screw		61325
Aero Spinal Stabilization Polyaxial spondylolisthesis screw		61325
Aero Spinal Stabilization multifunctional spondylolisthesis screw		61325
Aero Spinal Stabilization monoaxial spondylolisthesis screw		61325
Aero Spinal Stabilization Polar pedicular polyaxial screw		61325
Aero Spinal Stabilization polar pedicular multifunctional screw		61325
Aero Spinal Stabilization polar pedicular cannulated-cemented polyaxial screw		61325
Aero Spinal Stabilization polar pedicular cannulated-cemented monoaxial screw		61325
Aero Spinal Stabilization polar pedicular monoaxial screw		61325
Aero Spinal Stabilization Polar pedicular spondylolisthesis polyaxial screw		61325
Aero Spinal Stabilization polar pedicular spondylolisthesis multifunctional screw		61325
Aero Spinal Stabilization polar pedicular spondylolisthesis monoaxial screw		61325
Aero Spinal Stabilization rod		61325
Aero Spinal Stabilization transverse connector		61325
Aero Spinal Stabilization multiaxial transverse connector		61325
Aero Spinal Stabilization connector		61325
Aero Spinal Stabilization pedicular hook		61325
Aero Spinal Stabilization laminar hook		61325
Aero Spinal Stabilization sacral connector		61325
Aero Spinal Stabilization sacral-iliac screw		61325
Aero Spinal Stabilization Polyaxial hemispherical screw		61325
Aero Spinal Stabilization monoaxial hemispherical screw		61325
Aero Spinal Stabilization fixation nut		61325
Aero Spinal Stabilization Polar Connector		61325
Aero Spinal Stabilization connection holder		61325
Aero pedis pediatric polyaxial screw		61325
Aero pedis pediatric polyaxial spondylolisthesis screw		61325
Aero pediatric rod		61325
Aero pedis pediatric transverse connector		61325
Aero pedis pediatric rod connector		61325
Aero pedis pediatric connector		61325
Aero Pediatric laminar hook		61325
Aero Pediatric pedicular hook		61325
Aero Spinal Stabilization Cervical Posterior Polyaxial Screw		61325
Aero Spinal Stabilization Cervical Posterior Rod		37272
Aero Spinal Stabilization Cervical Posterior Transverse Connector		61325
AERO STERILE SPINAL CERVICAL&LOMBER PEEK CAGES		
Aero Spinal Fixation Lomber Peek Cage		38161
Aero Spinal Fixation Lomber Peek Banana Cage		38161
Aero Spinal Fixation Lomber Peek Expandable Banana Cage		38161
Aero Spinal Fixation Expandable Cervical Peek Cage		38161
Aero Spinal Fixation Cervical Polar Peek Cage With Knife		38161
Aero Spinal Fixation Cervical Peek Cage & Anatomical Structure		38161
Aero Spinal Fixation Alligator		38161
Aero Spinal Fixation Expandable Alligator Cage		38161
Aero Spinal Stabilization Stand-Alone Cage		38161
Aero Spinal Stabilization Cervical Peek Cage Screw		37272
AERO LOMBER AND CERVICAL CORPECTOMY CAGES		
Aero Spinal Fixation Lomber Corpectomy Cage		34170
Aero Spinal Fixation Cervical Corpectomy Cage		34170
AERO PLATES		
Aero Anterior Rod		61325
Aero Cervical Anterior Plate		46653
Aero Cervical Anterior Plate Screw		37272



This document containing 3 (three) pages is the Annex of the Certificate with the revision number 01, with the number M.2014.106.3179 and with the registration date of 04.07.2014 with the revision date of 09.08.2019 issued for "Aero Medikal Sağlık Turizmi Tıbbi Ürünler ve İth. İhr. San. Tic. Ltd. Şti." by UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. that is giving service as Notified Body with the ID No: 2292 according to 93/42/EEC Medical Devices Directive

AERO MOBILE DISC PROSTHESIS	
Aero Spinal Fixation Mobile Cervical Disc Prothesis	61865
Aero Spinal Fixation Sterile Mobile Cervical Disc Prothesis	48164
BOSTON BONE MEDICAL SPINAL SCREW ROD SYSTEM	
GMDN	
Boston Bone Medical Spinal Stabilization polyaxial screw	61325
Boston Bone Medical Spinal Stabilization multifunctional screw	61325
Boston Bone Medical Spinal Stabilization polyaxial cannulated-cemented screw	61325
Boston Bone Medical Spinal Stabilization monoaxial cannulated-cemented screw	61325
Boston Bone Medical Spinal Stabilization monoaxial screw	61325
Boston Bone Medical Spinal Stabilization set screw	61325
Boston Bone Medical Spinal Stabilization Polyaxial spondylolisthesis screw	61325
Boston Bone Medical Spinal Stabilization multifunctional spondylolisthesis screw	61325
Boston Bone Medical Spinal Stabilization monoaxial spondylolisthesis screw	61325
Boston Bone Medical Spinal Stabilization Polar pedicular polyaxial screw	61325
Boston Bone Medical Spinal Stabilization polar pedicular multifunctional screw	61325
Boston Bone Medical Spinal Stabilization polar pedicular cannulated-cemented polyaxial screw	61325
Boston Bone Medical Spinal Stabilization polar pedicular cannulated-cemented monoaxial screw	61325
Boston Bone Medical Spinal Stabilization polar pedicular monoaxial screw	61325
Boston Bone Medical Spinal Stabilization Polar pedicular spondylolisthesis polyaxial screw	61325
Boston Bone Medical Spinal Stabilization polar pedicular spondylolisthesis multifunctional screw	61325
Boston Bone Medical Spinal Stabilization polar pedicular spondylolisthesis monoaxial screw	61325
Boston Bone Medical Spinal Stabilization rod	61325
Boston Bone Medical Spinal Stabilization transverse connector	61325
Boston Bone Medical Spinal Stabilization multiaxial transverse connector	61325
Boston Bone Medical Spinal Stabilization connector	61325
Boston Bone Medical Spinal Stabilization pedicular hook	61325
Boston Bone Medical Spinal Stabilization laminar hook	61325
Boston Bone Medical Spinal Stabilization sacral connector	61325
Boston Bone Medical Spinal Stabilization sacral-iliac screw	61325
Boston Bone Medical Spinal Stabilization Polyaxial hemispherical screw	61325
Boston Bone Medical Spinal Stabilization monoaxial hemispherical screw	61325
Boston Bone Medical Spinal Stabilization fixation nut	61325
Boston Bone Medical Spinal Stabilization Polar Connector	61325
Boston Bone Medical Spinal Stabilization connection holder	61325
Boston Bone Medical pedis pediatric polyaxial screw	61325
Boston Bone Medical pedis pediatric polyaxial spondylolisthesis screw	61325
Boston Bone Medical pediatric rod	61325
Boston Bone Medical pedis pediatric transverse connector	61325
Boston Bone Medical pedis pediatric rod connector	61325
Boston Bone Medical pedis pediatric connector	61325
Boston Bone Medical Pediatric laminar hook	61325
Boston Bone Medical Pediatric pedicular hook	61325
Boston Bone Medical Spinal Stabilization Cervical Posterior Polyaxial Screw	61325
Boston Bone Medical Spinal Stabilization Cervical Posterior Rod	61325
Boston Bone Medical Spinal Stabilization Cervical Posterior Transverse Connector	37272
BOSTON BONE MEDICAL STERILE SPINAL CERVICAL&LUMBER PEEK CAGES	
Boston Bone Medical Spinal Fixation Lomber Peek Cage	38161
Boston Bone Medical Spinal Fixation Lomber Peek Banana Cage	38161
Boston Bone Medical Spinal Fixation Lomber Peek Expandable Banana Cage	38161
Boston Bone Medical Spinal Fixation Expandable Cervical Peek Cage	38161
Boston Bone Medical Spinal Fixation Cervical Polar Peek Cage With Knife	38161
Boston Bone Medical Spinal Fixation Cervical Peek Cage & Anatomical Structure	38161
Boston Bone Medical Spinal Fixation Alligator	38161
Boston Bone Medical Spinal Fixation Expandable Alligator Cage	38161
Boston Bone Medical Spinal Stabilization Stand-Alone Cage	38161
Boston Bone Medical Spinal Stabilization Cervical Peek Cage Screw	37272



This document containing 3 (three) pages is the Annex of the Certificate with the revision number 01, with the number M.2014.106.3179 and with the registration date of 04.07.2014 with the revision date of 09.08.2019 issued for "Aero Medikal Sağlık Turizmi Tıbbi Ürünler ve İth. İhr. San. Tic. Ltd. Şti." by UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş. that is giving service as Notified Body with the ID No: 2292 according to 93/42/EEC Medical Devices Directive

BOSTON BONE MEDICAL LUMBER AND CERVICAL CORPECTOMY CAGES	
Boston Bone Medical Spinal Fixation Lomber Corpectomy Cage	34170
Boston Bone Medical Spinal Fixation Cervical Corpectomy Cage	
BOSTON BONE MEDICAL PLATES	
Boston Bone Medical Anterior Rod	61325
Boston Bone Medical Cervical Anterior Plate	46653
Boston Bone Medical Cervical Anterior Plate Screw	37272
BOSTON BONE MEDICAL MOBILE DISC PROSTHESIS	
Boston Bone Medical Spinal Fixation Mobile Cervical Disc Prothesis	61865
Boston Bone Medical Spinal Fixation Sterile Mobile Cervical Disc Prothesis	48164





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 : 10.06.2015
Decision Date : 04.07.2015
Reissue Date : 28.06.2018/01
Expiry Date : 03.07.2022



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.udemtd.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 98 Sokak) No:10 Çankaya – Ankara - TURKEY

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

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