



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 : Mikron Makina Sanayi ve Ticaret Ltd. Şti.

Company Address : İvedik OSB Mah. Ağaç İşleri Sanayi Sitesi 1372. Sk. No:31 Yenimahalle
ANKARA / TURKEY

Manufacturing Site : Dağyaka Mah. Dağyaka Cad. No:38 Kahramankazan
(Branch Office) ANKARA / TURKEY

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

Product : Non-Sterile Spinal Screw Rod System - Class IIb
Sterile Cervical & Lomber Peek Cages - Class IIb
Non-Sterile Corpectomy Cages - Class IIb
Sterile Cervical Mobile Disc Prosthesis - Class IIb
Non-Sterile Plates - Class IIb
Non-Sterile Bone Plates & Bone Screw - Class IIb

GMDN : 37272, 43084, 38161, 34170, 46647, 56642, 35685, 58446, 48011,
61325, 32854

Product Types are attached.

Certificate Number : M.2017.106.8497

Report Number : MD.3468.YB

Initial Assessment Date : 22.05.2017

Registration Date : 07.06.2017

Recertification Assessment Date : 20.12.2019

Reissue Date / No : 15.04.2020/01

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 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