



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

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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.



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LIST OF PRODUCTS	GMDN
Non-Sterile Spinal Screw Rod System	
MSFX -MIKRON SPINAL STABILISATION POLYAXIAL SCREW	37272
MSFX -MIKRON SPINAL STABILISATION MULTIFUNCTIONAL SCREW	37272
MSFX -MIKRON SPINAL STABILISATION POLYAXIAL CANNULATED-CEMENTED SCREW	37272
MSFX -MIKRON SPINAL STABILISATION MONOAXIAL CANNULATED-CEMENTED SCREW	37272
MSFX -MIKRON SPINAL STABILISATION MONOAXIAL SCREW	37272
MSFX -MIKRON SPINAL STABILIZATION POLYAXIAL SPONDYLOLISTHESIS SCREW	37272
MSFX -MIKRON SPINAL STABILIZATION MULTIFUNCTIONAL SPONDYLOLISTHESIS SCREW	37272
MSFX -MIKRON SPINAL STABILIZATION MONOAXIAL SPONDYLOLISTHESIS SCREW	37272
MSFX -MIKRON SPINAL STABILIZATION POLAR PEDICULAR POLYAXIAL SCREW	37272
MSFX -MIKRON SPINAL STABILIZATION POLAR PEDICULAR MULTIFUNCTIONAL SCREW	37272
MSFX -MIKRON SPINAL STABILIZATION POLAR CANNULATED-CEMENTED MULTIFUNCTIONAL SCREW	37272
MSFX -MIKRON SPINAL STABILIZATION POLAR PEDICULAR CANNULATED-CEMENTED MONOAXIAL SCREW	37272
MSFX -MIKRON SPINAL STABILIZATION POLAR PEDICULAR MONOAXIAL SCREW	37272
MSFX -MIKRON SPINAL STABILIZATION POLAR PEDICULAR SPONDYLOLISTHESIS POLYAXIAL SCREW	37272
MSFX -MIKRON SPINAL STABILIZATION POLAR PEDICULAR SPONDYLOLISTHESIS MULTIFUNCTIONAL SCREW	37272
MSFX -MIKRON SPINAL STABILIZATION POLAR PEDICULAR SPONDYLOLISTHESIS MONOAXIAL SCREW	37272
MSFX -MIKRON SPINAL STABILIZATION ROD	58446
MSFX -MIKRON SPINAL STABILIZATION ANTERIOR ROD	58446
MSFX -MIKRON SPINAL STABILIZATION TRANSVERSE CONNECTOR	58446
MSFX -MIKRON SPINAL STABILIZATION TRANSVERSE CERVICAL CONNECTOR ROD	58446
MSFX -MIKRON SPINAL STABILIZATION TRANSVERSE CONNECTOR HOOK	48011
MSFX -MIKRON SPINAL STABILIZATION MULTIAXIAL TRANSVERSE CONNECTOR	58446
MSFX -MIKRON SPINAL STABILIZATION LATERAL CONNECTOR	58446
MSFX -MIKRON SPINAL STABILIZATION EXTENSION CONNECTOR FOR 1 ROD	58446
MSFX -MIKRON SPINAL STABILIZATION EXTENSION CONNECTOR FOR 2 ROD	58446
MSFX -MIKRON SPINAL STABILIZATION MULTIAXIAL CONNECTOR	58446
MSFX -MIKRON SPINAL STABILIZATION PEDICULAR HOOK SMALL	61325
MSFX -MIKRON SPINAL STABILIZATION PEDICULAR HOOK OFFSET	61325
MSFX -MIKRON SPINAL STABILIZATION LAMINAR HOOK	61325
MSFX -MIKRON SPINAL STABILIZATION LAMINAR HOOK LEFT ANGLED	61325
MSFX -MIKRON SPINAL STABILIZATION LAMINAR HOOK RIGHT ANGLED	61325
MSFX -MIKRON SPINAL STABILIZATION LAMINAR HOOK OFFSET LEFT/RIGHT	61325
MSFX -MIKRON SPINAL STABILIZATION 3 TYPE HOOK LEFT	61325
MSFX -MIKRON SPINAL STABILIZATION 3 TYPE HOOK RIGHT	61325
MSFX -MIKRON SPINAL STABILIZATION INTERSPINOUS U DEVICE	37272
MSFX -MIKRON SPINAL STABILIZATION CERVICAL POSTERIOR POLYAXIAL SCREW	37272
MSFX -MIKRON SPINAL STABILIZATION CERVICAL ROD	58446
THORACOLUMBAR POSTERIOR POLYAXIAL SCREW TITANIUM SELF TAPPING	37272
THORACOLUMBAR POSTERIOR LINK CONNECTOR TITANIUM DOMINOTO FOR 1 ROD	58446
THORACOLUMBAR POSTERIOR LINK CONNECTOR TITANIUM DOMINOTO FOR 2 ROD	58446
THORACOLUMBAR POSTERIOR LINK CONNECTOR TITANIUM AXIAL	58446
THORACOLUMBAR POSTERIOR LINK CONNECTOR TITANIUM AXIAL 2	58446
MSFX -MIKRON SPINAL STABILIZATION POLYAXIAL HEMISPHERICAL SCREW	37272
MSFX -MODULER RIGID PLATE SMALL	46647
MSFX -MODULER RIGID PLATE LARGE	46647
MSFX -MODULER RIGID PLATE SACRUM	46647
MSFX -MODULAR DOUBLE SIDED DYNAMIC PLATE SMALL	46647
MSFX -MODULAR DOUBLE SIDED DYNAMIC PLATE LARGE	46647
MSFX -MODULAR SEMI RIGID PLATE SMALL	46647
MSFX -MODULAR SEMI RIGID PLATE LARGE	46647
MSFX -MIKRON SPINAL STABILIZATION SPHERICAL CONNECTOR	61325
MSFX -MIKRON SPINAL STABILIZATION SPHERICAL CROSS CONNECTOR	61325
POLYAXIAL CONNECTOR CLAMP	58446
MIDDLE CONNECTOR CLAMP	58446
CONNECTOR CLAMP	58446
MSFX -MIKRON SPINAL STABILIZATION PEDIS PEDIATRIC POLYAXIAL SCREW + Setscrew	37272
MSFX -MIKRON SPINAL STABILIZATION PEDIS PEDIATRIC POLYAXIAL SPONDYLOLISTHESIS SCREW + Setscrew	37272
MSFX -MIKRON SPINAL STABILIZATION PEDIATRIC ROD	58446
MSFX -MIKRON SPINAL STABILIZATION PEDIS PEDIATRIC ROD CONNECTOR	58446
MSFX -MIKRON SPINAL STABILIZATION PEDIS PEDIATRIC LAMINAR CONNECTOR	48011
MSFX -MIKRON SPINAL STABILIZATION PEDIS PEDIATRIC PEDICUL HOOK	48011
MSFX -MODULAR DYNAMIC PLATE SMALL	58446
MSFX -MODULAR DYNAMIC PLATE LARGE	58446
MSFX -MODULAR DYNAMIC PLATE SMALL	58446
MSFX -MIKRON SPINAL STABILIZATION PEDIS PEDIATRIC POLYAXIAL SPONDYLOLISTHESIS SCREW + Setscrew	37272
MSFX -MIKRON SPINAL STABILIZATION PEDIS PEDIATRIC TRANSVERSE CONNECTOR	58446
MSFX -MIKRON SPINAL STABILIZATION PEDIS PEDIATRIC ROD CONNECTOR	58446
MSFX -MIKRON SPINAL STABILIZATION PEDIS PEDIATRIC LATERAL CONNECTOR	58446
MSFX -MIKRON SPINAL STABILIZATION PEDIS PEDIATRIC AXIAL CONNECTOR	58446
MSFX -MIKRON SPINAL STABILIZATION MONOAXIAL HOOK TRANSVERSE CONNECTOR	58446
MSFX -MIKRON SPINAL STABILIZATION HIGH FLEX LUMBAR EXPANDABLE PEEK CAGE	38161
MSFX -MIKRON SPINAL STABILIZATION ANTERIOR TITANIUM PLATE CORPUS RIGHT	46647
MSFX -MIKRON SPINAL STABILIZATION ANTERIOR TITANIUM PLATE CORPUS LEFT	46647
MSFX -MIKRON SPINAL STABILIZATION ANTERIOR TRANSVERSE CONNECTOR	58446
MSFX -SPHERICAL TRANSVERSE CONNECTOR SCREW TO SCREW	37272
MSFX -MIKRON SPINAL STABILIZATION SPHERICAL CONNECTOR PEDIATRIC SCREW TO SCREW	37272
MSFX -MIKRON SPINAL STABILIZATION TRANSVERSE LINK AXIAL	58446
MSFX -MIKRON SPINAL STABILIZATION PEDIS TRANSVERSE LINK PEDIATRIC	58446
MSFX -MIKRON SPINAL STABILIZATION SACRAL CONNECTOR	58446
MSFX -MIKRON SPINAL STABILIZATION SACRAL MULTIAXIAL CONNECTOR	58446



This document containing 3 (three) pages is the Annex of the Certificate with the number M.2017.106.8497 and with the registration date of 07.06.2017 and with the re-issue date 15.04.2020 issued for "Mikron Makina Sanayi ve Ticaret 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.

MSFX-MIKRON SPINAL STABILIZATION SACRAL-LIAC SCREW	37272
MSFX-MIKRON SPINAL STABILIZATION ANTERIOR AGRAP PLATE	61325
MSFX-MIKRON SPINAL STABILIZATION ANTERIOR TRANSVERSE CONNECTOR	58446
Sterile Cervical & Lumbar Peek Cages	
MSFX-MIKRON SPINAL LUMBAR FUSION PEEK CAGE	38161
MSFX-MIKRON SPINAL LUMBAR FUSION PEEK CAGE ANGLED	38161
MSFX-MIKRON SPINAL STABILIZATION MINIMAL INVASIVE TLIF CAGE	38161
MSFX-MIKRON SPINAL STABILIZATION HIGH FLEX LUMBAR EXPANDABLE PEEK CAGE	38161
MSFX-MIKRON SPINAL STABILIZATION HIGH FLEX EXPANDABLE CERVICAL PEEK CAGE	38161
MSFX-MIKRON SPINAL STABILIZATION TLIF CAGE	38161
MSFX-MIKRON SPINAL FIXATION BANANA CAGE	38161
MSFX-MIKRON SPINAL STABILIZATION TLIF CAGE ANGLED	38161
MSFX-MIKRON SPINAL FIXATION BANANA CAGE ANGLED	38161
MSFX-MIKRON SPINAL STABILIZATION HIGH FLEX EXPANDABLE TLIF PEEK CAGE	38161
MSFX-MIKRON SPINAL STABILIZATION CERVICAL BLADED PEEK CAGE & ANATOMICAL SURFACE	38161
MSFX-MIKRON SPINAL STABILIZATION CERVICAL PEEK CAGE & ANATOMICAL SURFACE	38161
Non-Sterile Corpectomy Cages	
MSFX-MIKRON SPINAL STABILIZATION LUMBAR CORPECTOMY CAGE	38161
MSFX-MIKRON SPINAL STABILIZATION LUMBAR CORPECTOMY CAGE ANGLED	38161
MSFX-MIKRON SPINAL STABILIZATION CERVICAL CORPECTOMY TITANIUM CAGE	38161
MSFX-MIKRON SPINAL STABILIZATION CERVICAL CORPECTOMY TITANIUM CAGE ANGLED	38161
MSFX-MIKRON SPINAL STABILIZATION CORPECTOMY CAGE SCREW	38161
Sterile Cervical Mobile Disc Prosthesis	
MOBILE CERVICAL DISC PROSTHESIS	43084
Non-Sterile Plates	
MSFX-MIKRON SPINAL STABILIZATION CERVICAL ANTERIOR PLATE	61325
MSFX-MIKRON SPINAL STABILIZATION CERVICAL ANTERIOR PLATE SCREW	37272
MSFX-MIKRON SPINAL STABILIZATION CERVICAL ANTERIOR PLATE SCREW- REVISION	37272
Non-Sterile Bone Plates & Bone Screw	
CLAVICLE DISTAL LOCKING PLATE	46647
CLAVICLE SHAFT LOCKING PLATE	46647
CLAVICLE HOOK LOCKING PLATE	46647
HUMERUS PROXIMAL LOCKING PLATE	46647
HUMERUS DISTAL MEDIAL LOCKING PLATE	46647
HUMERUS DISTAL LATERAL LOCKING PLATE	46647
HUMERUS DISTAL POSTEROLATERAL LOCKING PLATE	46647
ULNA PROXIMAL LOCKING PLATE	46647
SMALL BROAD LOCKING PLATE	46647
SMALL NARROW LOCKING PLATE	46647
RADIUS PROXIMAL LOCKING PLATE	46647
RADIUS DISTAL VOLLARE LOCKING PLATE	46647
RADIUS DISTAL DORSAL LOCKING PLATE	46647
PELVIS RECONSTRUCTION STRAIGHT LOCKING PLATE	46647
PELVIS RECONSTRUCTION CURVED LOCKING PLATE	46647
TIBIA DISTAL MEDIAL LOCKING PLATE	46647
TIBIA DISTAL ANTEROLATERAL LOCKING PLATE	46647
FIBULA DISTAL LOCKING PLATE	46647
SMALL METAPHYSEAL LOCKING PLATE	46647
SEMITUBULAR LOCKING PLATE	46647
KALKANEUS LOCKING PLATE	46647
ULNA DISTAL LOCKING PLATE	46647
RECONSTRUCTION SHAFT LOCKING PLATE	46647
ULNA PROXIMAL HOOK LOCKING PLATE	46647
SMALL(MINI) FOOT LOCKING PLATE	46647
SMALL (MINI) FOOT STRAIGHT LOCKING PLATE	46647
SMALL HAND LOCKING PLATE	46647
SMALL HAND STRAIGHT LOCKING PLATE	46647
LARGE NARROW LOCKING PLATE	46647
LARGE BROAD LOCKING PLATE	46647
FEMUR PROXIMAL LOCKING PLATE	46647
FEMUR PROXIMAL NECK LOCKING PLATE	46647
FEMUR PROXIMAL TROCHANTER LOCKING PLATE	46647
FEMUR DISTAL LOCKING PLATE	46647
TIBIA PROXIMAL LATERAL LOCKING PLATE	46647
TIBIA PROXIMAL MEDIAL T LOCKING PLATE	46647
TIBIA PROXIMAL MEDIAL L LOCKING PLATE	46647
TIBIA DISTAL LATERAL LOCKING PLATE	46647
LARGE METAPHYSEAL LOCKING NARROW PLATE	46647
LOCKING SELF TAPPING CORTICAL SCREW	37272
LOCKING SELF DRILLING SCREW	37272
LOCKING SELF TAPPING CANCELLOUS SCREW	37272
HEXAGONAL UNLOCKED SELF TAPPING CORTICAL SCREW	37272
HEXAGONAL UNLOCKED SELF TAPPING CANCELLOUS SCREW	37272
CANNULATED FULL GROVED SCREW	37272
CANNULATED CANCELLOUS SCREW	37272
ANKLE SCREW	37272
HEXAGONAL LOCKING SELF DRILLING CANNULATED SCREW	37272
LOCKING SELF TAPPING CORTICAL SCREW	37272
UNLOCKED SELF TAPPING CORTICAL SCREW	37272
TROCAR KIRSHNER WIRE	35685
WASHER SMALL	56632
WASHER MEDIUM	56632





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WASHER LARGE	56642
WASHER EKSTRA EKSTRA LARGE	56642
WASHER EKSTRA LARGE	56642
INTRAMEDULAR NAIL INTERNAL FIXATION INTRAMEDULAR NAIL ELASTIC NAIL RADIUS/ULNA/FEMUR/TIBIA/HUMERUS NOT CANNULATED TEN ELASTIC NAIL SCREW	37272
TEN ELASTIC NAIL AND CAP SMALL	37272
TEN ELASTIC NAIL AND CAP ORTA	37272
TEN ELASTIC NAIL AND CAP LARGE	37272
INTRAMEDULAR NAIL INTERNAL FIXATION INTRAMEDULAR NAIL LOCKING REAMED NAIL TIBIA CANNULATED ANATOMIC NONCOATED TITANIUM	32854
INTRAMEDULAR NAIL INTERNAL FIXATION INTRAMEDULAR NAIL LOCKING REAMED NAIL HUMERUS CANNULATED PROXIMAL NAIL LOCKED TITANIUM	32854
INTRAMEDULAR NAIL INTERNAL FIXATION INTRAMEDULAR NAIL LOCKING REAMED NAIL FEMORAL CANNULATED ANATOMIC NONCOATED FIXED COMBINE CURVED TITANIUM	32854
INTRAMEDULAR NAIL INTERNAL FIXATION INTRAMEDULAR NAIL LOCKING REAMED NAIL FEMORAL CANNULATED LONG PROXIMAL TITANIUM	32854
INTRAMEDULAR NAIL INTERNAL FIXATION INTRAMEDULAR NAIL LOCKING REAMED NAIL HUMERUS CANNULATED PROXIMAL NAIL LOCKED TITANIUM	32854
INTRAMEDULAR NAIL INTERNAL FIXATION INTRAMEDULAR NAIL LOCKING REAMED NAIL FEMORAL CANNULATED LONG PROXIMAL TITANIUM	32854
NAIL LOCKING SCREW PROXIMAL-DISTAL-SHAFT	37272
END CAP EXTRA SMALL	37272
END CAP SMALL	37272
END CAP ORTA	37272
END CAP LARGE	37272
END CAP EXTRA LARGE	37272
END CAP EXTRA LARGE	37272
INTRAMEDULAR NAIL INTERNAL FIXATION INTRAMEDULAR NAIL LOCKING REAMED NAIL FEMORAL CANNULATED ANATOMIC NONCOATED FIXED CURVED TITANIUM	32854
INTRAMEDULAR NAIL INTERNAL FIXATION INTRAMEDULAR NAIL LOCKING REAMED NAIL HUMERUS CANNULATED PROXIMAL NAIL UNLOCKED TITANIUM	32854
INTRAMEDULAR NAIL INTERNAL FIXATION INTRAMEDULAR NAIL LOCKING REAMED NAIL FEMORAL CANNULATED ANATOMIC UNCOATED FIXED CURVED TITANIUM	32854