CERTIFICATE

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 (Branch Office)	: Dağyaka Mah. Dağyaka Cad. No:38 Kahramankazan 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

APPROVED 2292

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 sertificate is limited to manufacturing issues related to safeguarding and maintaining sterile conditions, if the dev,ce 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 returnedupon 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 thecompletion of EC Declaration of Conformity. The above mentioned company must notify all changes relatedwith the approved product to UDEM. If UDEM will not renew the expiry date of this certificate in question, thementioned 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 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.

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 OFSET	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 OFSET LEFT/RIGHT	61325
MSFX -MIKRON SPINAL STABILIZATION 3 TYPE HOOK LEFT	61325
MSFX -MIKRON SPINAL STABILIZATION 3 TYPE HOOK RIGHT	61325
MSFX-MIKRON SPINAL FIKSATION INTERSPINOUS U DEVICE	37272
MSFX-MIKRON SPINAL STABILIZATION CERVICAL POSTERIOR POLIAXIAL SCREW	37272
MSFX-MIKRON SPINAL STABILIZATION CERVICAL ROD	58446
THORACOLUMBAR POSTERIOR POLIAXIAL SCREW TITANIUM SELF TAPPING	37272
THORACOLUMBAR POSTERIOR LINK CONNECTOR TITANIUM DOMINOTO FOR 1 ROD	58446
THORACOLUMBAR POSTERIOR LINK CONNECTOR TITANIUM DOMINOTOR FOR 2 ROD	58446
THORACOLUMBAR POSTERIORLINK CONNECTOR TITANIUM AXIAL	58446
THORACOLUMBAR POSTERIORLINK 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

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

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-ILIAC SCREW	37272
MSFX-MIKRON SPINAL STABILIZATION ANTERIOR AGRAF 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	56642
WASHER MEDIUM	56642

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

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 NECK/CONDILLAR LOCKING IMPLANTS ALL INSTRUMANTATION, ROUGHSHOD BLADE SCREW	37272
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 CAPI 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

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

MEDICAL DEVICES CHANGE CONFIRMATION FORM

The validity of the Change Confirmation Form expires when the validity period of related EC Certificate/s expires. The Change Confirmation Form alone has no function.

Company Name	: Mikron Makina Sanayi ve Ticaret Ltd. Şti.
Company Address	: İvedik OSB Mah. Ağaç İşleri Sanayi Sitesi 1372. Sk. No:31-29 Yenimahalle ANKARA / TURKEY
Related Directive	: 93/42/EEC Medical Devices Directive
Definition of Change	: GMDN codes has been changed to; 61325 for Nonsterile spinal screw and rod system, 60762 for Sterile cervical and lumbar peek cage, 34170 for Nonsterile corpectomy cage, 48164 for Sterile cervical mobile disc prosthesis, 61325 for Nonsterile cervical plates, Nonsterile bone screws; 56642, plates 61573, washers 61670, nail cap screws 46139, femur nails 56643, humerus nails 56644, tibia nails 56645.

Number of Related Certificate	: M.2017.106.8497
Report Number	: MD.3468
Issue Date	: 11.05.2022
Revision Date	: -
Revision Number	: 00

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

UDEM declares that the mentioned changes have been confirmed as non-significant changes according to MDR Article 120-3 and MDCG 2020-3 with this Change Confirmation Form. This form has been prepared to be shared with authorities or third parties upon request.

UDEM

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@udem.com.tr www.udem.com.tr

MEDICAL DEVICES CHANGE CONFIRMATION FORM

The validity of the Change Confirmation Form expires when the validity period of related EC Certificate/s expires. The Change Confirmation Form alone has no function.

Company Name	: Mikron Makina Sanayi ve Ticaret Ltd. Şti.
Company Address	: İvedik OSB Mah. Ağaç İşleri Sanayi Sitesi 1372. Sk. No:31 Yenimahalle ANKARA / TÜRKİYE
Manufacturing Address	: Dağyaka Mah. 623 Cad. No:17 Kahramankazan ANKARA / TÜRKİYE
Related Directive	: 93/42/EEC Medical Devices Directive
Definition of Change	: Manufacturing address has been changed.

Number of Related Certificate	: M.2017.106.8497
Report Number	: MD.3468
Issue Date	: 11.05.2022
Revision Date	: 06.06.2023
Revision Number	: 01

UDEM APPROVE 2292

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

UDEM declares that the mentioned changes have been confirmed as non-significant changes according to MDR Article 120-3 and MDCG 2020-3 with this Change Confirmation Form. This form has been prepared to be shared with authorities or third parties upon request.

UDEM

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@udem.com.tr www.udem.com.tr

MEDICAL DEVICES CHANGE CONFIRMATION FORM

The validity of the Change Confirmation Form expires when the validity period of related EC Certificate/s expires. The Change Confirmation Form alone has no function.

Company Name : Mikron Makina Sanayi ve Ticaret Ltd. Şti.

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

Manufacturing Address : Dağyaka Mah. 623 Cad. No:17 Kahramankazan ANKARA / TÜRKİYE

Related Directive : 93/42/EEC Medical Devices Directive

Definition of Change : MDI IMPLANT, ZETA IMPLANT, ORTHOWIND, QNA trademarks have been added on the certificate

Number of Related Certificate	: M.2017.106.8497
Report Number	: MD.3468
Issue Date	: 11.05.2022
Revision Date	: 16.02.2024
Revision Number	: 02

UDEM APPROVED 22 02

UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co.
Mustafa MEMİŞOĞLU
General Manager

UDEM declares that the mentioned changes have been confirmed as non-significant changes according to MDR Article 120-3 and MDCG 2020-3 with this Change Confirmation Form. This form has been prepared to be shared with authorities or third parties upon request.

UDEM

Address: Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya Ankara - TÜRKİYE
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MEDICAL DEVICES CHANGE CONFIRMATION FORM

The validity of the Change Confirmation Form expires when the validity period of related EC Certificate/s expires. The Change Confirmation Form alone has no function.

Company Name : Mikron Makina Sanayi ve Ticaret Ltd. Şti.

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

Related Directive : 93/42/EEC Medical Devices Directive

Definition of Change : GMDN Change

Product Group	GMDN
Non-Sterile Spinal Screw Rod System	Spinal screws; 46651, Connectors; 65114, Hooks; 65115, Rods; 65116, Spinal plates; 46653, U devices; 61533
Non-sterile Plates (Cervical Plates and Screws)	Cervical plates; 46653, Cervical plate screws; 46651
Non-sterile Corpectomy Cages	Corpectomy cages; 34170
Sterile Peek Cages	Peek cages; 60762
Sterile Mobile Cervical Disc Prostheses	Mobile cervical disc prosthesis; 48164
Non-sterile Bone Plates and Bone Screws	Plates; 46647, for CMF plates; 46642, Screws; 66947, CMF screws; 46638, Kirschner wire; 62729, bone washers; 61670
Non-sterile Nails and Screws	Screws; 66947, End caps; 46139, Femur nails; 33187, Flexible nails; 55851, Humerus nails; 38153, Tibia nails; 38152, Arthrodesis nails; 44854

Number of Related Certificate : M.2017.106.8497

Report Number : MD.3468

Issue Date : 11.05.2022

Revision Date : 04.02.2025

Revision Number : 03

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

UDEM declares that the mentioned changes have been confirmed as non-significant changes according to MDR Article 120-3 and MDCG 2020-3 with this Change Confirmation Form. This form has been prepared to be shared with authorities or third parties upon request.

UDEM

Address: Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya Ankara - TÜRKİYE
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15/04/2024

NOTIFIED BODY CONTRACT CONFIRMATION LETTER

CONTRACT CONFIRMATION LETTER NO: CL.CONTRACT.UDEM.0192/P1

Subject: Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

To whom it may concern,

This letteris the official document of UDEM A.Ş., a Notified Body (NB) designated in accordance with Regulation (EU) 2017/745 (MDR) and identified in NANDO with the number 2292, in accordance with the first subparagraph of Chapter 4.3 of Annex VII of the MDR and confirms that UDEM A.Ş. has received an application and has signed a written contract in accordance with the second subparagraph of Chapter 4.3 of Annex VII to the MDR with the following manufacturer:

Company Name:	MİKRON MAKİNA SAN. VE TİC. LTD. ŞTİ.
Company Address:	DAĞYAKA MAHALLESİ 623 CADDE NO:17 KAHRAMANKAZAN / ANKARA
SRN Number (if any):	TR-MF-000020641

The devices covered by the above-mentioned official application and written contract are defined in the tables below. Table 1 describes the devices for which an MDR application has been received, a written contract has been made and UDEM A.Ş. is also responsible for the appropriate surveillance of the relevant devices within the scope of the 93/42/EEC Medical Device Directive (MDD). Table 2 identifies devices for which an MDR application has been received and a written contract has been concluded, but for which UDEM A.Ş. has not yet taken appropriate surveillance responsibility for the relevant devices under the MDD.

For devices covered by certificates issued under the MDD which expire after 26 May 2021 and before 20 March 2023 without withdrawal, this letter also confirms that the manufacturer has provided evidence that the competent authority of the Member State under the MDR up to the date of expiry of the MDD certificate has granted an exception or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of the MDR or Article 97(1) of the MDR for the devices concerned until 20 March 2023.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120(3c) of MDR (as amended by (EU) 2023/607), are shown below:

UDEM ULUSLARARASI BELGELENDİRME DENETİM EĞİTİM MERKEZİ SAN. VE TİC. A.Ş.
Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Ümitköy Çankaya/Ankara
0(312) 443 03 90
mdr@udem.com.tr

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for class IIb devices other than those covered above, class IIa devices and class I devices placed on the market in a sterile condition or with a measurement function,
- 31 December 2028 for devices for which the conformity assessment procedure in accordance with Directive 93/42/EEC does not require the involvement of a notified body, for which a declaration of conformity was issued before 26 May 2021 and for which the conformity assessment procedure in accordance with the MDR requires the involvement of a notified body.

UDEM A.Ş. General Manager Name-Surname:	MUSTAFA MEMİŞOĞLU
Date:	15.04.2024
Stamp-Signature:	UDEM ULUSLARARASI BELGELENDİRME UDEM DEN. EĞT. MERK. SAN. ve TİC. A.Ş. Mutlukent Mah. 2073 Sk. No:10 Ümitköy Çankaya / ANKARA Tel: (0 312) 443 03 90 (pbx) Fax: (0.312) 443 03 DOĞANBEY Vergi Dairesi 885 044 25

Table-1 The Devices Covered in the Scope of this Letter and for which UDEM A.Ş. is Responsible for the Appropriate Surveillance of the Related Devices within the Scope of the MDD

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
SPINAL CAGES -Sterile Cervical & Lomber Peek Cages -Non-Sterile Corpectomy Cages	Class III	N/A	Certificate 1: M.2017.106.8497 Certificate 1: 2292
BONE PLATES AND SCREWS	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate 1: M.2017.106.8497 Certificate 1: 2292
SPINAL FIXATION SYSTEM -Non-Sterile Spinal Screw Rod System -Non-Sterile Plates	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate 1: M.2017.106.8497 Certificate 1: 2292
NAILS & SCREWS	Class IIb implantable non-WET device & Class IIb excluding Class IIb implantable non-WET	N/A	Certificate 1: M.2017.106.8497 Certificate 1: 2292
CERVICAL DISC PROSTHESIS -Sterile Cervical Mobile Disc Prosthesis	Class III	N/A	Certificate 1: M.2017.106.8497 Certificate 1: 2292

Tablo-2 The Devices Covered in the Scope of this Letter and for which UDEM A.Ş. is Not Responsible for the Appropriate Surveillance of the Related Devices within the Scope of the MDD

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
RE-USABLE SURGICAL INSTRUMENTS	Class I devices that qualify as re-usable surgical instruments	N/A	N/A

CONTRACT CONFIRMATION LETTER REVISION HISTORY

Date	Contract Confirmation Letter Revision Number	Revision Explanation
15/04/2024	CL.CONTRACT.UDEM.0192/P1	Preparation of contract confirmation letter

UDEM ULUSLARARASI BELGELENDİRME DENETİM EĞİTİM MERKEZİ SAN. VE TİC. A.Ş.
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