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	: Ortler Medikal Ürünleri Limited Şirketi
Company Address	: Mehmet Akif Ersoy Mah. 350. Sk. Profis sitesi B blok No:3 İç kapı No:15 Yenimahalle ANKARA / TURKEY
Related Directive	: 93/42/EEC Medical Devices Directive
Definition of Change	: Company adress has been changed.

Number of Related Certificate	: M.2020.106.13179
Report Number	: MD.3853
Issue Date	: 08.12.2021
Revision Date	: -
Revision Number	: 00

UDEM APPROVED 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

Technical Universal Verification

CERTIFICATE

This Certificate has been awarded to:

ORTLER MEDİKAL ÜRÜNLERİ LİMİTED ŞİRKETİ

MEHMET AKİF ERSOY MAH. 350 SK. PROFIS SİTESİ B BLOK NO: 3 İÇ KAPI NO: 15 YENİMAHALLE

ANKARA - TURKEY

In Recognition of the Organisation's Management System which complies with:

ISO 13485 : 2016

For the Scope of Activities described below:

PRODUCTION AND SALES OF SPINAL IMPLANT

Certificate No : 4191

Date of Audit : 26.08.2020

Date of Registration : 01.12.2020

Reissue Date : 16.11.2021

Expiry Date : 30.11.2022

Technical Universal Verification

This document is valid for 3 years provided that the management system is well maintained and surveillance audits are performed regularly. After performing the surveillance audits certificate will be reissued. The current status of this certificate can be viewed via www.techcert.com.tr web site. This certificate is a property of Technical Universal Verification Certification and Training Services Co., Ltd. Thus, this certificate has to be returned if required by property owner. National Accreditation Center (NAC) is an accreditation body whose headquarters is located in the United States of America, which is a member of Asia Pacific Accreditation Cooperation (APAC).

Technical Universal Verification
Belgelendirme ve Eğitim Hizmetleri Ltd. Şti.
Macun Mahallesi Batı Bulvarı ATB İş Merkezi A Blok
No: 1/3 Yenimahalle - ANKARA / TÜRKİYE
Tel.: 00 90 312 231 82 02
• web: www.techcert.com.tr
• e-mail: info@techcert.com.tr

NAC

MANAGEMENT SYSTEM
ISO/IEC 17021-1:2015
NAC-011-MS

CERTIFICATE

Full Quality Assurance System

Medical Devices Directive 93/42/EEC Annex II (Excluding Section 4)

Company Name	: Ortler Medikal Ürünleri Limited Şirketi
Company Address	: Katip Mustafa Çelebi Mah. İstiklal Cad. No:53 D:3 Beyoğlu İSTANBUL / TURKEY
Related Directives and Annex	: 93/42/EEC Medical Devices Directive - Annex II (Excluding Section 4)
Product	: 1. Non-Sterile Screw-Rod System - Class IIb - Polyaxial Screw - Monoaxial Screw - Reduction Screw - Cannulated Screw - Rod - Connector - Hook - Occipital Plate 2. Sterile PEEK Cage - Class IIb - Cervikal PEEK Cage - Cervical Bladed PEEK Cage - Cervical Expandable PEEK Cage - PLIF Cage - Expandable PLIf Cage - TLIF Cage 3. Non-Sterile Corpectomy Cage - Class IIb - Cervical Corpectomy Cage - Lumbar Corpectomy Cage 4. Non-Sterile Plate - Class IIb - Anterior Cervical Plate - Cervical Plate Screw
GMDN	: 37272, 58446, 61325, 38161 Product Types are attached.
Certificate Number	: M.2020.106.13179
Report Number	: MD.3853.IB
Initial Assessment Date	: 09.08.2019
Registration Date	: 10.01.2020
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 applied 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 II 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 validity 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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This document containing 1 (one) pages is the Annex of the Certificate with the number M.2020.106. 13179 and with the registration date of 10.01.2020 issued for "Ortler Medikal Ürünleri Limited Şirketi" 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

Product Name	GMDN
Non-Sterile Screw-Rod System	
ORTLER PEDICLE POLYAXIAL SCREW	37272
ORTLER PEDICLE POLYAXIAL MULTIFUNCTIONAL SCREW	37272
ORTLER POSTERIOR CERVICAL POLYAXIAL SCREW	37272
ORTLER PEDICLE MONOAXIAL MULTIFUNCTIONAL SCREW	37272
ORTLER PEDICLE POLYAXIAL TRACTION MULTIFUNCTIONAL SCREW	37272
ORTLER PEDICLE MONOAXIAL TRACTION MULTIFUNCTIONAL SCREW	37272
ORTLER PEDICLE POLYAXIAL CANNULATED-CEMENTED SCREW	37272
ORTLER PEDICLE POLYAXIAL MULTIFUNCTIONAL CANNULATED-CEMENTED SCREW	37272
ORTLER ROD	58446
ORTLER HIGH FLEX ROD	58446
ORTLER POSTERIOR CERVICAL ROD	58446
ORTLER SPHERICAL CONNECTOR	58446
ORTLER TRANSVERSE CONNECTOR	58446
ORTLER MULTIAXIAL TRANSVERSE CONNECTOR	58446
ORTLER LATERAL CONNECTOR	58446
ORTLER AXIAL CONNECTOR	58446
ORTER DOMINO CONNECTOR	58446
ORTLER PEDICULAR HOOK	61325
ORTLER LAMINAR HOOK	61325
OCCIPITAL PLATE	61325
STERILE PEEK CAGES	
ORTLER CERVICAL ANATOMIC CAGE	38161
ORTLER CERVICAL BLADED ANATOMIC CAGE	38161
ORTLER CERVICAL EXPANDABLE CAGE	38161
ORTLER PLIF CAGE	38161
ORTLER EXPANDBLE PLIF CAGE	38161
ORTLER TLIF CAGE	38161
NON-STERILE CORPECTOMY CAGES	
ORTLER CERVICAL CORPECTOMY CAGE	38161
ORTLER LUMBAR CORPECTOMY CAGE	38161
ORTLER LUMBAR CORPECTOMY CAGE-ANGLED	38161
NON-STERILE PLATES	
ORTLER ANTERIOR CERVICAL PLATE	61325
ORTLER CERVICAL PLATE SCREW	37272

UDEM Uluslararası Belgelendirme Denetim Eğitim Merkezi San. ve Tic. A.Ş
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UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co.