Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 011099 0060 Rev. 01

Manufacturer:

ulrich GmbH & Co. KG
Buchbrunnenweg 12
89081 Ulm
GERMANY

Facility(ies):

ulrich GmbH & Co. KG
Buchbrunnenweg 12, 89081 Ulm, GERMANY

ulrich GmbH & Co. KG
Mergelgrube 1, 89081 Ulm, GERMANY

Product Category(ies): **surgical instruments, implants for osteosynthesis, interbody fusion devices, vertebral body replacements, spinal plate systems, spinal rod-screw-systems, contrast media injectors, disposables for contrast media injectors, surgical tourniquets, disposables for surgical tourniquets**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713159589

Valid from: 2020-01-15
Valid until: 2024-05-26

Date, 2020-01-15

Digitally signed by Dubalari Pavel
Date: 2022.03.17 14:14:09 EET
Reason: MoldSign Signature
Location: Moldova

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 011099 0059 Rev. 00

Holder of Certificate: **ulrich GmbH & Co. KG**
Buchbrunnenweg 12
89081 Ulm
GERMANY

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate: **Design and Development, Production and Distribution of Surgical Instruments, Implants for Osteosynthesis, Interbody Fusion Devices, Vertebral Body Replacements, Spinal Plate Systems, Spinal Rod-Screw-Systems, Contrast Media Injectors, Disposables for Contrast Media Injectors, Surgical Tourniquets, Disposables for Surgical Tourniquets; Installation of Contrast Media Injectors; Servicing of Contrast Media Injectors and Surgical Tourniquets**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 713136998

Valid from: 2019-04-01
Valid until: 2022-03-31

Date, 2019-03-01

I. Preiß

Stefan Preiß

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

TÜV®

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 011099 0059 Rev. 00

Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

ulrich GmbH & Co. KG
Buchbrunnenweg 12, 89081 Ulm, GERMANY

ulrich GmbH & Co. KG
Mergelgrube 1, 89081 Ulm, GERMANY

Scopes:

ulrich GmbH & Co. KG
Buchbrunnenweg 12, 89081 Ulm, GERMANY

Design and Development, Production and Distribution of Surgical Instruments, Implants for Osteosynthesis, Interbody Fusion Devices, Vertebral Body Replacements, Spinal Plate Systems, Spinal Rod-Screw-Systems, Contrast Media Injectors, Disposables for Contrast Media Injectors, Surgical Tourniquets, Disposables for Surgical Tourniquets;
Installation of Contrast Media Injectors; Servicing of Contrast Media Injectors and Surgical Tourniquets

ulrich GmbH & Co. KG
Mergelgrube 1, 89081 Ulm, GERMANY

Production and Distribution of Surgical Instruments, Implants for Osteosynthesis, Interbody fusion Devices, Vertebral Body Replacements, Spinal Plate Systems, Spinal Rod-Screw-Systems, Contrast Media Injectors, Disposables for Contrast Media Injectors, Surgical Tourniquets, Disposables for Surgical Tourniquets

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TÜV®

tezo™

titanium cage family

Versatile
cage family

ulrich medical

System

- Implant family for lumbar to lumbosacral interbody fusion
- Three cage types for posterior and anterior approaches (PLIF, TLIF, ALIF)
- Sophisticated toothing for easy insertion and high primary stablity
- Large filling volume for bone/ bone substitute material

One functional principle
for all cage types

Available in three sizes (S, M, L) as well as
different heights and angles

Advantages

- Inserter with the same functional principle for all cages
- Rough surface structure on the inside to promote osteo-integration
- Sterile packaging – 9½ years shelf life

Components

Implants	Length x width	Height	Angle	Product number
tezo-P	24x10 mm	7 to 13 mm	5°	CS 3401-07 bis -13
tezo-P	29x10 mm	7 to 13 mm	5°	CS 3402-07 bis -13
tezo-P	29x10 mm	8 to 13 mm	12°	CS 3403-08 bis -13
tezo-T	29x11 mm	7 to 13 mm	5°	CS 3415-07 bis -13
tezo-T	29x14 mm	7 to 13 mm	5°	CS 3416-07 bis -13
tezo-T	34x16 mm	7 to 13 mm	5°	CS 3417-07 bis -13
tezo-A	28x22 mm	8 to 16 mm	8°	CS 3431-08 bis -16
tezo-A	31x25 mm	8 to 16 mm	0°	CS 3432-08 bis -16
tezo-A	31x25 mm	8 to 16 mm	8°	CS 3433-08 bis -16
tezo-A	31x25 mm	8 to 16 mm	12°	CS 3434-08 bis -16
tezo-A	34x28 mm	8 to 16 mm	0°	CS 3435-08 bis -16
tezo-A	34x28 mm	8 to 16 mm	8°	CS 3436-08 bis -16
tezo-A	34x28 mm	10 to 16 mm	12°	CS 3437-10 bis -16

Optional

Implants	Length x width	Height	Angle	Product number
tezo-P	24x10 mm	14 mm	5°	CS 3401-14
tezo-P	29x10 mm	14 mm	5°	CS 3402-14
tezo-P	29x10 mm	14 mm	12°	CS 3403-14
tezo-T	29x11 mm	14 mm	5°	CS 3415-14
tezo-T	29x14 mm	14 mm	5°	CS 3416-14
tezo-T	34x16 mm	14 mm	5°	CS 3417-14
tezo-A	28x22 mm	18 mm	8°	CS 3431-18
tezo-A	31x25 mm	18 mm	0°	CS 3432-18
tezo-A	31x25 mm	18 mm	8°	CS 3433-18
tezo-A	31x25 mm	18 mm	12°	CS 3434-18
tezo-A	34x28 mm	18 mm	0°	CS 3435-18
tezo-A	34x28 mm	18 mm	8°	CS 3436-18
tezo-A	34x28 mm	18 mm	12°	CS 3437-18

patented
or/and
pat. pend.

Over a Century of Innovation

ulrich medical

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Phone: +49 (0)731 9654-0 | Fax: +49 (0)731 9654-2705
spine@ulrichmedical.com | www.ulrichmedical.com

WS 3400-EN R3/2018-07

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Teleflex Medical
IDA Business and Technology Park
Dublin Road
Athlone
Westmeath
Ireland

Holds Certificate No: **FM 544574**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

The design and manufacture of non-active digestive tract devices; non-active gynaecological devices, non-active regional anaesthesia devices, non-active respiratory devices, non-active surgical devices, non-active urology devices and active surgical devices.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2009-03-09
Latest Revision Date: 2020-02-12

Effective Date: 2020-02-12
Expiry Date: 2023-02-11

...making excellence a habit.™

EC Certificate Full Quality Assurance System: US97/10879.01

The management system of

Teleflex Medical

2917 Weck Drive, Research Triangle Park, NC, 27709, United States

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 11 September 2018 until 14 July 2023
and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 27 May 2021
Issue 29. Certified since 26 September 2000

Certification is based on reports numbered WWMC/06866

Multiple certificates have been issued for this scope
The main certificate is numbered US97/10879.00

Authorised by

SGS United Kingdom Ltd, Notified Body 0120

202B Worle Parkway, Weston-super-Mare, BS22 6WA UK
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS CE 02 0315 M2

Teleflex Medical

Directive 93/42/EEC

on medical devices, Annex II (excluding section 4)

Issue 29

Detailed scope

Sterile Hem-o-lok Ligation Clips.
Sterile Deknatel® PTFE pledgets.
Sterile Polyester Nonabsorbable Surgical Sutures (POLYLENE/ "cottony"™ II, "silky" II POLYDEK®, TEVDEK® II, NextStitch®,Capio™, Fixt®, NiceLoop™, TEVDEK®).
Sterile DEKLENE® II, DEKLENE® MAXXTM, CAPIOTM and FIXT® polypropylene non-absorbable surgical sutures.
Sterile BONDEK® and BONDEK® Plus Polyglycolic Acid Synthetic Absorbable Surgical Sutures.
Sterile Polyglytone 6211™ Monofilament Absorbable Surgical Sutures.
Sterile MONODEK® Polydioxanone Absorbable Surgical Sutures.
Sterile Hem-o-lok Automatic Clip Appliers.
Metal Ligation System.

Sterile External stapling system (including stainless steel staples, staplers and removers), Sterile, EFx endo fascial closuresystem (abdominal access), Sterile, EFx shield fascial closure system (abdominal access), Sterile, EFx classic fascial closuresystem (abdominal access)
Sterile stainless steel surgical Sutures
Sterile FORCE FIBER® surgical sutures.
Sterile Chest drainage and autotransfusion systems,
Sterile Thoracic Catheters,
Sterile and Non-sterile Aortic Punch,
Non-sterile Self Retaining Tissue retractor/blades

Non-sterile Anaesthesia and respiratory Circuits including breathing bags and water traps, Non-sterile Heated Humidifiers, Non-sterile Non-Prefilled Humidifiers and Nebulizers, Non-sterile Small Volume Nebulizers, Sterile Prefilled Humidifiers and Nebulizers (saline or water) with adaptors, Sterile Prefilled unit dose vial /solution for nebulisation, Non-sterile Respiratory therapy Adaptors and connectors, Sterile Column and Reservoirs including adaptors, Non-sterile Nasal cannula (including gas sampling), Non-sterile Cannula and Supply Tubing, Nonsterile CPAP Cannula System, Non-sterile Manual resuscitators and PEEP valves, Non- sterile Respiratory and anaesthesia masks, Non- sterile Gas scavenging mask, Sterile Endotracheal tubes, Sterile Endobronchial tubes, Non-sterile Suction and Aspirating Tubes, Sterile Vented Thoracic Chest Seal, Sterile Operative Cholangiogram Catheters, Sterile Abdominal Access and Insufflation devices, Sterile Capillary drains, Sterile Percutaneous Surgical System (MiniLap and Grip graspers), Sterile Percutaneous Surgical System (Mini Polar electrosurgical probe and MiniGrip Bipolar Graspers),Percutaneous surgical System (Interchangeable electrosurgical tool tips) for laparoscopic surgery. Non-sterile Heat and Moisture Exchangers

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market