ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class I Devices in sterile condition, with measuring function or reusable surgical instruments)

No. G11 011099 0506 Rev. 01

Manufacturer: **ulrich GmbH & Co. KG**
Buchbrunnenweg 12
89081 Ulm
GERMANY

SRN Manufacturer: DE-MF-000006411

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result. As applicable the involvement of the notified body is limited to the aspects relating to:
- establishing, securing and maintaining sterile conditions,
- conformity of the devices with the metrological requirements,
- reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G11 011099 0506 Rev. 01

Report No.: 713213328

Preceding Certificate No.: G11 011099 0506 Rev. 00

Valid from: 2022-03-04
Valid until: 2026-04-06

Digitally signed by Dubalari Pavel
Date: 2022.11.01 10:11:35 EET
Reason: MoldSign Signature
Location: Moldova

Date of Initial Issuance: 2021-04-07

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2022-03-04

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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Product Service

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Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class I Devices in sterile condition, with measuring function or reusable surgical instruments)

No. G11 011099 0506 Rev. 01

Classification:	I
Device Group:	L091001 - INSTRUMENTS FOR INSERTION AND EXTRACTION OF MATERIALS FOR OSTEOSYNTHESIS, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
The validity of this certificate depends on conditions and/or is limited to the following:	./.

Revision History:

Rev.	Dated	Report
00	2021-04-07	713172227

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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

Christoph Dicks
Head of Certification/Notified Body

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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

TÜV SÜD Product Service

Certificate

No. Q5 011099 0059 Rev. 01

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

Certification Mark:

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). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 011099 0059 Rev. 01

Report No.: 713212284

Valid from: 2022-04-01
Valid until: 2025-03-31

Date, 2022-03-31

Christoph Dicks
Head of Certification/Notified Body

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

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

TÜV SÜD Product Service

Certificate

No. Q5 011099 0059 Rev. 01

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

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®

pezo™

PEEK 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)
- Radiolucent PEEK Optima® LT1 material
- 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
- Large selection of shapes and sizes
- Sterile packaging – 9½ years shelf life

Components

Implants	Length x width	Height	Angle	Product number
pezo-P	24x10 mm	7 to 13 mm	5°	CS 3301-07 to -13
pezo-P	29x10 mm	7 to 13 mm	5°	CS 3302-07 to -13
pezo-P	29x10 mm	8 to 13 mm	12°	CS 3303-08 to -13
pezo-T	29x11 mm	7 to 13 mm	5°	CS 3315-07 to -13
pezo-T	29x14 mm	7 to 13 mm	5°	CS 3316-07 to -13
pezo-T	34x16 mm	7 to 13 mm	5°	CS 3317-07 to -13
pezo-A	28x22 mm	8 to 14 mm	8°	CS 3331-08 to -14
pezo-A	31x25 mm	8 to 16 mm	0°	CS 3332-08 to -16
pezo-A	31x25 mm	8 to 16 mm	8°	CS 3333-08 to -16
pezo-A	31x25 mm	8 to 16 mm	12°	CS 3334-08 to -16
pezo-A	34x28 mm	8 to 16 mm	0°	CS 3335-08 to -16
pezo-A	34x28 mm	8 to 16 mm	8°	CS 3336-08 to -16
pezo-A	34x28 mm	10 to 16 mm	12°	CS 3337-10 to -16

Optional

Implants	Length x width	Height	Angle	Product number
pezo-P	24x10 mm	14 mm	5°	CS 3301-14
pezo-P	29x10 mm	14 mm	5°	CS 3302-14
pezo-P	29x10 mm	14 mm	12°	CS 3303-14
pezo-T	29x11 mm	14 mm	5°	CS 3315-14
pezo-T	29x14 mm	14 mm	5°	CS 3316-14
pezo-T	34x16 mm	14 mm	5°	CS 3317-14
pezo-A	28x22 mm	16 mm	8°	CS 3331-16
pezo-A	31x25 mm	18 mm	0°	CS 3332-18
pezo-A	31x25 mm	18 mm	8°	CS 3333-18
pezo-A	31x25 mm	18 mm	12°	CS 3334-18
pezo-A	34x28 mm	18 mm	0°	CS 3335-18
pezo-A	34x28 mm	18 mm	8°	CS 3336-18
pezo-A	34x28 mm	18 mm	12°	CS 3337-18

patented
or/and
pat. pend.

Over a Century of Innovation

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