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

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

# C E R T I F I C A T E

## No. QS6 011099 0504 Rev. 02

**Certificate Holder:** **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**

**Standard(s):** **ISO 13485:2016**

**Regulatory Authority(ies):** **Australia TGA, Brazil ANVISA, Health Canada, Japan MHLW / PMDA, USA FDA. See attached for listing of specific regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. For details and certificate validity see:
www.tuvsud.com/ps-cert?q=cert:QS6 011099 0504 Rev. 02
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

**REPs Facility ID:** **F003619**
**Report No.:** **713263824_713255269**
**Effective Date:** **2023-05-17**
**Expiry Date:** **2025-03-20**


**Date of Issue:** 2023-07-28

( Renee Walker )
Director, US Certification Body, MHS

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**Regulatory Requirements:** **Audit/Certification Criteria**

**Australia**
Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

**Brazil**
- RDC ANVISA n. 665/2022 - Good Manufacturing Practices
- RDC ANVISA n. 551/2021
- RDC ANVISA n. 67/2009 - Vigilance

**Canada**
- Medical Device Regulations – Part 1- SOR 98/282

**Japan**
- MHLW Ministerial Ordinance 169, Article 4 to Article 68
- PMD Act

**United States**
- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807 – Subparts A to D
- 21 CFR Part 820
- 21 CFR Part 821

**Facility(ies):**

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

**ulrich GmbH & Co. KG**
Buchbrunnenweg 12/14, 89081 Ulm, GERMANY

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


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