



America

CERTIFICATE

No. QS6 011099 0504 Rev. 03

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_03

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: F003619
Report No.: 713337003
Effective Date: 2025-03-21
Expiry Date: 2028-03-20

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Date of Issue: 2025-02-17

(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 No. 169 (2004), as amended by MHLW Ministerial Ordinance No.60 (2021)
 - Japan PMD Act (as applicable)

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 14, 89081 Ulm, GERMANY

ulrich GmbH & Co. KG

Mergelgrube 1, 89081 Ulm, GERMANY

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