



CERTIFICATE

No. QS6 011099 0504 Rev. 00

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, USA FDA, MHLW / PMDA. 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. Validity of this certificate can be obtained by visiting the website <https://www.tuev-sued.de/product-testing/certificates>

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

DUNS No: **31-549-4757**

Effective Date: **2019-03-21**

Expiry Date: **2022-03-20**

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Date of Issue: 2019-04-02

(Arie Henkin)
Manager, Certification Body MHS

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Regulatory Requirements: Audit/Certification Criteria

Australia

Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1

Brazil

- RDC ANVISA n. 16/2013
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009

Canada

- Medical Device Regulations SOR/98-282, Part 1

United States

- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807
- 21 CFR Part 820
- 21 CFR Part 821

Japan

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

Facility(ies):

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

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

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Facility Scopes:

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DUNS No: 31-512-8540



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