



America

CERTIFICATE

No. QS6 001668 0001 Rev. 00

Certificate Holder: MCI – Medical Concept Innovation, Inc.
4592 Hiatus Road
Sunrise FL 33351
USA

Certification Mark:



Scope of Certificate: Design and Development, Manufacture and Distribution of Non-Sterile Orthopedic Implants (Plates, Meshes and Screws) and their associated Surgical Instruments (e.g. Pliers, Screwdriver, Tips, Caddies) for use in Cranial MaxilloFacial Fixation Surgery

Standard(s): ISO 13485:2016

Regulatory Authority(ies): Brazil ANVISA, 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. 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: 08-081-5653

Effective Date: 2019-04-26

Expiry Date: 2022-04-25

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Date of Issue: 2019-05-07

(Arie Henkin)
Manager, Certification Body MHS

TÜV SÜD America Inc. • 10 Centennial Drive Ste 207 • Peabody, MA 01960 USA • www.tuvsud.com

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Regulatory Requirements: Audit/Certification Criteria

Brazil

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

United States

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

Facility(ies):

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