

CERTIFICATE

No. QS6 066084 0020 Rev. 00

Regulatory Requirements: Audit/Certification Criteria

Australia

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

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):

nt-trading GmbH & Co. KG
G.-Braun-Strasse 18, 76187 Karlsruhe, GERMANY

Facility Scopes:

Design, Development, and Manufacturing of Abutments for Dental Implants and Abutment Screws and Dental Polymers and Production of Customized Dental Appliances
DUNS No: 31-280-0478



(Arie Henkin)
Manager, Certification Body MHS

TÜV SÜD
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