



America

CERTIFICATE

No. QS6 069249 0013 Rev. 01

Certificate Holder: Dentium USA
6761 Katella Avenue
Cypress CA 90630
USA

Certification Mark:



Scope of Certificate: Design, Development, Manufacturing and Distribution of Dental Implants: Fixtures and Abutments; Distribution of Dental Instruments and Supplies

Standard(s): ISO 13485:2016

Regulatory Authority(ies): Health Canada, 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 www.tuvsud.com/ps-cert
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: F001214

Effective Date: 2022-01-26

Expiry Date: 2024-08-06

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Date of Issue: 2022-01-27

(Michael Ogunleye)
Manager, US Certification Body,
Medical and Health Services



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Regulatory Requirements: Audit/Certification Criteria

Canada

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

United States

- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807 – Subparts A to D
- 21 CFR Part 820

Facility(ies):

Dentium USA
6761 Katella Avenue, Cypress CA 90630, USA

Dentium USA
6731 Katella Avenue, Cypress, CA 90639, USA

Facility Scopes:

Dentium USA

6761 Katella Avenue, Cypress CA 90630, USA

Design, Development, Manufacturing and Distribution of Dental Implants: Fixtures and Abutments; Distribution of Dental Instruments and Supplies

REPs Facility ID: F001214

Dentium USA

6731 Katella Avenue, Cypress, CA 90639, USA

Sales, Marketing and Distribution of Dental Implants: Fixtures and Abutments; Distribution of Dental Instruments and Supplies

REPs Facility ID: F001214

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(Michael Ogunleye)
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Medical and Health Services