MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

America

CERTIFICATE

No. QS6 097302 0009 Rev. 00

Certificate Holder: **DENTSPLY Implants N.V.**
Research Campus 10
3500 Hasselt
BELGIUM

Certification Mark:

Scope of Certificate: **Design, Development, Manufacture and Distribution of Surgical Guides, Surgical Instruments, Medical Image Processing, Simulation and Design Software and Suprastructures for the area of Dentistry**

Standard(s): **ISO 13485:2016**

Regulatory Authority(ies): **Australia TGA, 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: **76-414-2159**

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Expiry Date: **2022-03-11**

Date of Issue: 2019-03-29

(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**

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

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

Facility(ies):

DENTSPLY Implants N.V.
Research Campus 10, 3500 Hasselt, BELGIUM

DENTSPLY Implants N.V.
Kolonel Begaultlaan 1b, 3012 Leuven, BELGIUM

DENTSPLY Ukraine LLC
Novovokzalna str 2, 03038 Kyiv, UKRAINE

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Facility Scopes:

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Research Campus 10, 3500 Hasselt, BELGIUM

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DUNS No: 76-414-2159

DENTSPLY Implants N.V.
Kolonel Begaultlaan 1b, 3012 Leuven, BELGIUM

Design, Development, Manufacture and Distribution of Medical Image Processing, Simulation and Design Software for the area of Dentistry
DUNS No: 37-051-0580

DENTSPLY Ukraine LLC
Novovokzalna str 2, 03038 Kyiv, UKRAINE

Design, Development and Manufacture of Medical Image Processing, Simulation and Design Software and Manufacture of Surgical Guides for the area of Dentistry
DUNS No: 36-545-6838

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