

Certificate

Certificate No.: MD 3344595-140

Manufacturer: **SiCAT GmbH & Co. KG**
Friesdorfer Str. 131-135
53175 Bonn
Germany

REPs Facility ID: F001106

Certification criteria: ISO 13485:2016
Australia Therapeutic Goods (Medical Devices) Regulations, 2002,
Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance
Procedure
Brazil RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC
ANVISA n. 67/2009
Canada Medical Devices Regulations – Part 1 – SOR 98/282
Japan MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD
Act
United States 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 –
Subparts A to D

Scope: Design and Development, Manufacturing and Distribution of PACS
Software for Dental and ENT Applications, and of Oral Appliances
and Surgical Guides for Dental Applications.
Manufacturing and Distribution of Diagnostic Devices for Dental
Applications.

TUV Rheinland of North America, Inc., an MDSAP recognized Auditing Organization, certifies that the quality management system of the Manufacturer has been audited against and found to conform the Certification criteria for the Scope contained in this certificate. The quality management system is subject to annual surveillance audit(s).

Project No.: 3344595-140

Issue Date: 2021-06-21

Effective Date: 2021-07-03

Expiry Date: 2024-07-02



Certification officer: Dipl.-Ing. (FH) D. Wiedemuth
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on https://www.certipedia.com/quality_marks/9000008778?locale=en
or calling 1-888-743-4652.