

Certificate



Certificate No.: MD 3020000 3222791-100

Manufacturer: SiCAT GmbH & Co. KG
Brunnenallee 6
53177 Bonn
Germany

D-U-N-S No.: 33-370-7003

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 (as applicable)

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 Software for Dental Diagnosis and Dental Implant and Treatment Planning, 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.: 21231126 010

Issue Date: 2018-07-09

Effective Date: 2018-07-09

Expiry Date: 2021-07-08



A blue ink signature of X. Ren, consisting of a large, stylized 'X' followed by a flourish.

Certification officer: X. Ren
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on www.certipedia.com, via the QR code or calling 1-888-743-4652.

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Manufacturer: SiCAT GmbH & Co. KG
Brunnenallee 6
53177 Bonn
Germany

Scope: The scope of Certification also includes the following additional sites:

SiCAT GmbH & Co. KG
Schwertberger Str. 14-16
53177 Bonn

Germany D-U-N-S No.: 33-370-7003

Scope: Design and Development, Manufacturing and Distribution of Software for Dental Diagnosis, Dental Implant and Treatment Planning, Oral Appliances, Surgical Guides for Dental Applications
Manufacturing and Distribution of Diagnostic Devices for Dental Applications.

SiCAT GmbH & Co. KG
Am Fronhof 10
53177 Bonn

Germany D-U-N-S No.: 33-370-7003

Scope: Distribution of Software for Dental Diagnosis, Dental Implant and Treatment Planning, Oral Appliances, Surgical Guides for Dental Applications, Diagnostic Devices for Dental Applications

Project No.: 21231126 010

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