

Certificate

Quality Management System
EN ISO 13485:2016
EN ISO 13485:2016/AC:2018
EN ISO 13485:2016/A11:2021

Registration No.: SX 1703016-1
Certificate Holder: SiCAT GmbH & Co. KG
Friesdorfer Str. 131-135
53175 Bonn
Germany

Scope: - Design and Development, Manufacturing and Distribution of
PACS Software for Dental and ENT Diagnosis, Implant and
Treatment Planning.

- Design and Development, Manufacturing and Distribution of
Oral Appliances and Surgical Guides for Dental Applications.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 1183493-100
Effective date: 2025-09-19
Expiry date: 2027-06-22
Issue date: 2025-09-19
Replaces certificate SX 1703016-1 issued 2024-05-28.

This certificate can be validated on <https://www.certipedia.com>

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