

Certificate

The Certification Body of TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

SiCAT GmbH & Co. KG Brunnenallee 6 53177 Bonn Deutschland

has established and applies a quality management system for medical devices for the following scope:

see attachment

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:

2018-07-27

Certificate Registration No.:

SX 60131090 0001

An audit was performed. Report No.: 21231126 010

This Certificate is valid until:

2021-06-22

Certification Body



Date 2018-07-27

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety



Doc. 1/2, Rev. 0

TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg

Attachment to Certificate

Registration No.:

SX 60131090 0001

Report No.:

21231126 010

Organization:

SiCAT GmbH & Co. KG

Brunnenallee 6 53177 Bonn Deutschland

Scope:

Design and Development, Manufacturing and Distribution of

Software for Dental Diagnosis and Dental Implant and

Treatment Planning;

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

Manufacturing and Distribution of Diagnostic Devices

for Dental Applications.

Certification Body



Date: 2018-07-27





Doc. 2/2, Rev. 0

TÜV Rheinland LGA Products GmbH Tillystraße 2, 90431 Nürnberg

Attachment to Certificate

Registration No.: Report No.:

SX 60131090 0001 21231126 010

Organization:

SiCAT GmbH & Co. KG

Brunnenallee 6 53177 Bonn Deutschland

Scope:

Sites included:

SiCAT GmbH & Co. KG

Schwertberger Straße 14-16

53177 Bonn, Germany

Activities: Design and Development, Manufacturing and Distribution of Software for Dental Diagnosis and Dental

Implant and Treatment Planning;

Design and Development, Manufacturing and Distribution of Oral Appliances and Surgical Guides for Dental Applications; Manufacturing and Distribution of Diagnostic Devices for

Dental Applications.

SiCAT GmbH & Co. KG

Am Fronhof 10

53177 Bonn, Germany

Activities: Distribution of Software for Dental Diagnosis

and Dental Implant and Treatment Planning;

Distribution of Oral Appliances and Surgical Guides for Dental Applications, as well as Diagnostic Devices for

Dental Applications. Certification Body



Date: 2018-07-27

