EC Certificate

TÜVRheinland®

Full Quality Assurance System
MDD Annex II excl. 4

Registration No.: HD 1703016-1

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

Products: Software for dental applications and Picture Archiving and Communication Systems Software (PACS) for ENT diagnosis and treatment planning

Products included:
- SICAT FUNCTION:
  Software for dental diagnostics and therapy planning
- GALILEOS Implant:
  Software for dental implant planning
- SICAT IMPLANT:
  Software for dental diagnostics and implant planning
- SICAT ENDO:
  Software for dental diagnostics and therapy planning
- SICAT AIR:
  Software for diagnostics and therapy planning

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II section 4 is required.

Report No.: 3330951-90

Effective date: 2020-11-17

Expiry date: 2024-05-26

Issue date: 2020-11-17

TÜV Rheinland LGA Products GmbH TÜVRheinland Zertifizierungsstelle

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TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

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Manufacturer:
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Germany

Aspects of manufacture concerned with the conformity of software and hardware with measuring function for dental medicine with the metrological requirements:
- SICAT JMT+

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