



Certificate

SQS herewith certifies that the company named below has a management system which meets the requirements of the standard specified below.



acurata GmbH & Co. KG
Schulstraße 25
94169 Thurmansbang
Germany

Scope of certification

Whole Company

Field of activity

Design, development, manufacturing and distribution of rotating dental instruments, rotating instruments for podiatry and rotating instruments for industry

Normative base

ISO 9001:2015

Quality Management System

Scope(s) 19

Validity 01.03.2019–28.02.2022
Issue 01.03.2019

Reg. no. 43168

X. Edlmann, President SQS

F. Müller, CEO SQS



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Swiss Association for Quality and Management Systems SQS
Bernstrasse 103, 3052 Zollikofen, Switzerland



Swiss Made





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Scope of certification

Whole Company

Field of activity

Design, development, manufacturing and distribution of rotating dental instruments, rotating instruments for podiatry and rotating instruments for industry

Normative base

EN ISO 13485:2016 Medical devices – Quality Management System

Validity 01.03.2019–28.02.2022
Issue 01.03.2019

Reg. no. 45132

X. Edelman, President SQS

F. Müller, CEO SQS



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Swiss Association for Quality and Management Systems SQS
Bernstrasse 103, 3052 Zollikofen, Switzerland



Swiss Made



SQS as a conformity assessment body identification number 1250 herewith certifies the company

acurata GmbH & Co. KG
Schulstraße 25
94169 Thurmansbang
Germany

the use of a quality assurance system in its manufacturing and distribution which fulfills the requirements set out in:

ANNEX II

Directive 93/42/EEC (without section 4)

This approval is based on the report dated October 11, 2018.

The scope of validity covers the products

Dental diamond coated instruments
Dental tungsten carbide instruments
Dental polishers and abrasives
Dental steel products
Rotating instruments for podiatry

The following CE label can be applied to these products mentioned in the Appendix of this certificate

CE 1250

A condition for the validity of this certificate is a regular examination in accordance with Annex II.5 of the Directive 93/42/EEC.

Validity 01.03.2019–29.02.2024
Issue 01.03.2019

Reg. no. 43505
Approved Medical Responsible
28.01.2019



F. Müller, CEO SQS



D. Taddeo, Medical Responsible



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Swiss Association for Quality and
Management Systems SQS
Bernstrasse 103, 3052 Zollikofen, Switzerland



ANNEX II

Directive 93/42/EEC (without section 4)

This Appendix is valid only in connection with the following certificate:

Registration Number 43505

Validity from March 01, 2019 up to and including February 29, 2024

This approval includes the following Medical Device/s:

- Burs, dental, Diamond (UMDNS 16-670)
- Burs, dental, Carbide (UMDNS 16-668)
- Burnishers (UMDNS 16-412)
- Burns, dental, Steel (UMDNS 16-669)
- Rotating instruments for podiatry

Appendix issue date: March 1, 2019



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