EC-Certificate

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

EDENTA AG
Hauptstrasse 7
9434 Au SG
Switzerland

the use of a quality assurance system in its design, development, 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 19, 2018.

The scope of validity covers the products

rotary dental instruments, parapulpal retention pins, root posts and laboratory instruments for the dental use as well as instruments for the medical podology and footcare within the Appendix to the EC Certificate

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. 41096
Approved Medical Responsible
27.10.2018

F. Müller, CEO SQS

D. Taddeo, Medical Responsible

sqs.ch

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

Swiss Made

Partner of IQNet

Appendix to the EC-Certificate

ANNEX II

Directive 93/42/EEC (without section 4)

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

Registration Number 41096

Validity from March 1, 2019 up to and including February 29, 2024

This approval includes the following Medical Device/s:

Class IIa:

Product	UMDNS-Nr.
Polishers (Rubber/Arkansas stone)	16–412
Burs dental diamond (Diamond burs)	16–670
Burs dental (Tungsten carbide- and steel burs/ Finishing instruments)	10–521
Burs MKG surgery (Instruments for surgery – burs)	11–341
Pin, dental retention (Parapulpal retention pins – dental)	16–700
Root canal pins (Root posts – dental)	16–202
Drilling instruments, root canal (root canal instruments – rotating)	16–411
Drilling instruments, orthopedics (Instruments podology/footcare)	17–761

Appendix issue date March 1, 2019