



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 result of the audit documented in the report dated September 9, 2014.

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 of the Directive 93/42/EEC.

Swiss Association for Quality and Management Systems SQS
Bernstrasse 103, CH-3052 Zollikofen
Issue date: January 1, 2015

This SQS Certificate is valid up to and including September 11, 2017
Registration number 41096
Approved Medical Responsible:
January 25, 2017


R. Gläuser, CEO SQS


K. Schulze, Medical Responsible



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Notified Body 1250



Swiss Made

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 January 1, 2015 up to and including September 11, 2017

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 instrument orthopedics (Instruments podology/footcare)	17-761

Appendix issue date: January 25, 2017



Trusted Cert



Notified Body 1250



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