



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08



Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 029125 0023 Rev. 00

Manufacturer:

Coltène/Whaledent AG

Feldwiesenstrasse 20
9450 Altstätten
SWITZERLAND

Facility(ies):

Coltène/Whaledent AG
Feldwiesenstrasse 20, 9450 Altstätten, SWITZERLAND

**Product Category(ies): Materials for Restorative Dentistry
Burs / Polishers used in Dentistry**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.:

713149029

Valid from:

2019-06-01

Valid until:

2024-05-31

Date,

2019-05-27

Stefan Preiß
Head of Certification/Notified Body

ZERTIFIKAT ♦ CERTIFICATE ♦ 認證書 ♦ CERTIFICADO ♦ CERTIFICAT