



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 043306 0206 Rev. 03

Manufacturer:

Ivoclar Vivadent AG

Bendererstrasse 2
9494 Schaan
LIECHTENSTEIN

Product Category(ies): Dental materials: Filling materials (including sealants, liners, base materials, temporary materials), cements, adhesives, desensitizers etching materials, root canal posts, polishing instruments, resin and porcelain teeth, denture base materials, materials for inlays, onlays, crowns and bridges, precious and non-precious dental alloys, antibacterial protective varnish for dental use, dental abutments, dental curing lights, dental instruments

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.:

713152940

Valid from:

2019-12-04

Valid until:

2024-05-26

Date,

2019-12-05

Christoph Dicks
Head of Certification/Notified Body



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Facility(ies):

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Economic Processing Zone (SEPZ), 4025 Diezmo, Cabuyao City,
Laguna, PHILIPPINES

Ivoclar Vivadent AG
Bendererstrasse 2, 9494 Schaan, LIECHTENSTEIN

Ivoclar Vivadent Manufacturing Inc.
500 Memorial Drive, Somerset NJ 08873, USA

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