

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II (category II)
(Devices in Class IIa, IIb or III)

No. G1 14 07 21108 023

Manufacturer: DENTSPLY DeTrey GmbH
De-Trey-Strasse 1
78467 Konstanz
GERMANY

Facility(ies): DENTSPLY DeTrey GmbH
De-Trey-Strasse 1, 78467 Konstanz, GERMANY

Product Category(ies):
Products of class IIa:
Dental Restorative Materials
(Conditioners, Adhesives, Filling Materials, Finishers & Polishers), Cements, Periodontal Dressing and Endodontic Filling Materials
Products of class III:
Sealants

The Certification Body of TUV SUD 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.: 713044962

Valid from: 2019-12-01
Valid until: 2023-11-30



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Hans-Heiner Junker

Date, 2019-12-01

TUV SUD Product Service GmbH is Notified Body with identification no. 0123