



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 15 06 81854 012

**Manufacturer:** DENTSPLY Implants  
Manufacturing GmbH

Steinzeugstraße 50  
68229 Mannheim  
GERMANY

**Product Category(ies):** Dental Implants  
Maxillo Facial Implants  
Abutments and Prosthetic Devices  
Instruments for Surgery and Prosthetics  
Bone Reconstruction Material and Fixation Devices

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.:** 713048908

**Valid from:** 2015-06-23

**Valid until:** 2018-06-30



**Date,** 2015-06-24

Hans-Heiner Junker

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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**Facility(ies):**

DENTSPLY Implants Manufacturing GmbH  
Steinzeugstraße 50, 68229 Mannheim, GERMANY

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