



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 082649 0002 Rev. 00

Manufacturer:

DENTSPLY Implants Manufacturing GmbH

Rodenbacher Chaussee 4
63457 Hanau
GERMANY

Facility(ies):

DENTSPLY Implants Manufacturing GmbH
Rodenbacher Chaussee 4, 63457 Hanau, GERMANY

DENTSPLY IH AB
Aminogatan 1, PO Box 14, 43121 Mölndal, SWEDEN

DENTSPLY IH Inc.
590 Lincoln Street, Waltham MA 02451, USA

Sirona Dental Systems GmbH
Fabrikstr. 31, 64625 Bensheim, GERMANY

Product Category(ies):

**Dental Implants
Abutments and Prosthetic Devices
Instruments for Surgery and Prosthetics
Fixation Devices for Bone Substitute
Materials**

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.

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Stefan Preiß