



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 09 31247 073

Manufacturer:

Sirona Dental Systems GmbH

Fabrikstr. 31
64625 Bensheim
GERMANY

Facility(ies):

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



Product Category(ies):

**Imaging Systems for Diagnosis,
Dental Equipment for Therapy and Diagnosis:
Dental Treatment Centers including the following
components:**

- Water and Air Spray Instruments
 - High Frequency Surgery
 - Scaler
 - UV Light for Hardening of Synthetic Fillings
- Electrical and Air Driven Dental Instruments:**
- Handpieces and Angle Pieces,
 - Turbines,
 - Electrical and Air Driven Motors
- Sterilizers and Desinfection Devices**
- Dental Laser Devices with Sterile Single Use
Products**
- Dental 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.

Report No.:

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Valid from:

2015-10-27

Valid until:

2020-10-26

Hans-Heiner Junker

Date, 2015-09-16



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

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