



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 IIc)

No. G1 16 04 19859 020

**Manufacturer:** NTI - Kahla GmbH  
Rotary Dental Instruments  
Im Carisch 3  
07758 Kahla  
GERMANY



**Facility(ies):** NTI - Kahla GmbH Rotary Dental Instruments  
Im Carisch 3, 07758 Kahla, GERMANY

**Product Category(ies):** Rotary dental and podiatric instruments,  
Parapulpal and Pulpal Restoration Pins  
for Dental Field  
(see description of products in the attachment)

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.:** 713096055

**Valid from:** 2018-06-30

**Valid until:** 2019-11-11

**Date:** 2018-06-30

  
Stefan Preuß



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

Page 1 of 2



Attachment for Certificate no. G1 16 04 19859 020  
dated 2016-05-30

Products:

- Diamond Burs
- Polishers (Silicone Rubber Polishers / Arkansas Abrasives)
- Steel Burs
- Tungsten Carbide Burs
- Instruments for Surgery (Burs / Cutters)
- Parapulpal Retention Pins (in vivo)
- Root Post Restoration Systems (in vivo)
- Finishing Instruments
- Endodontic Instruments / Root Canal Instruments (rotating)
- Podiatric Instruments

Munich, CRT-2, 2016-05-30

Stefan Preis





Management Service

# CERTIFICATE

The Certification Body  
of TÜV SÜD Management Service GmbH

certifies that



**NTI-Kahla GmbH**  
**Rotary Dental Instruments**  
Im Camisch 3  
07768 Kahla  
Germany

has established and applies  
a Quality Management System for

Development, production and distribution of  
rotary dental and podiatric instruments,  
parapulpal and pulpal restoration pins for the dental field,  
instruments for use in dental laboratories.

An audit was performed, Report No. 70033912.

Proof has been furnished that the requirements  
according to

**ISO 9001:2015**

are fulfilled.

The certificate is valid from 2018-07-18 until 2020-09-30.

Certificate Registration No.: 12 100 17727 TMS.

Product Compliance Management  
Munich, 2018-07-24



ZERTIFIKAT ◆ CERTIFICATE ◆ 認 證 書 ◆ CERTIFICADO ◆ CERTIFICAT