

**EC Certificate**  
**Directive 93/42/EEC Annex II, excluding Section 4**  
**Full Quality Assurance System**  
**Medical Devices**

**Registration No.:** HD 60148508 0001

**Report No.:** 12031343 009

**Manufacturer:** Nakanishi Inc.  
700 Shimohinata, Kanuma,  
Tochigi,  
322-8666 Japan

**Products:** Instruments and Equipment in Dental and Surgical Fields  
(see attachments for products included)  
Replaces Approval, Registration No.: HD 60144337 0001

**Expiry Date:** 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

**Effective Date:** 2020-10-03

**Date:** 2020-10-03



**Notified Body**

*M. Aihara*  
**M.Sc. M. Aihara**

**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**  
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.



**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

**Attachment to  
Certificate**

**Registration No.:** HD 60148508 0001  
**Report No.:** 12031343 009

**Manufacturer:** Nakanishi Inc.  
700 Shimohinata, Kanuma,  
Tochigi,  
322-8666 Japan

**Products included:**

- Pneumatic dental drilling system handpiece
- Diamond dental bur, reusable
- Dental drilling system attachment
- Line-powered dental drilling system handpiece
- Pneumatic dental scaling system handpiece
- Pneumatic dental scaling system handpiece tip
- Air Motor
- Remotely-driven dental drilling system motor
- Endodontic enlarger
- Dental-professional prophylaxis motor
- Endodontic apex locator
- Dental abrasive air jet system handpiece
- Dental abrasive powder
- Sawing power tool attachment, reciprocating
- Sawing power tool attachment, oscillating



**Notified Body**

**Date:** 2020-10-03

*M. Aihara*  
**M.Sc. M. Aihara**

**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

Doc. 2/3, Rev. 0

**Attachment to  
Certificate**

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**Report No.:** 12031343 009

**Manufacturer:** Nakanishi Inc.  
700 Shimohinata, Kanuma,  
Tochigi,  
322-8666 Japan

**Products included:**

- Sawing power tool attachment, sagittal
- Reciprocating surgical saw blade, reusable
- Oscillating surgical saw blade, reusable
- Sagittal surgical saw blade, reusable
- Dental implant system
- Surgical screwdriver, reusable
- Ultrasonic dental scaling system
- Ultrasonic dental scaling system handpiece tip
- Dental ultrasonic surgical system handpiece tip
- Dental ultrasonic surgical system
- Total Surgical System
- Sterile Products:
  - Sterile Drills
  - Sterile Burs
  - Sterile Blades
  - Sterile Rasps
  - Sterile Files
- Dental suction system, non-surgical



**Notified Body**

**Date:** 2020-10-03

*M. Aihara*  
**M.Sc. M. Aihara**



**TÜV Rheinland**  
**LGA Products GmbH**  
**Tillystraße 2, 90431 Nürnberg**

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**Attachment to  
Certificate**

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**Report No.:** 12031343 009

**Manufacturer:** Nakanishi Inc.  
700 Shimohinata, Kanuma,  
Tochigi,  
322-8666 Japan

**Products included:**

- Pneumatic Surgical Drilling Machine
- Electric drill system for dental surgery, dental implant surgery and foot- and ankle- surgery
- External Coolant Straight Handpiece for foot surgery and oral surgery

**Site included:**

A1 Factory  
990 Fukahodo, Kanuma, Tochigi, 322-0302, Japan



**Notified Body**

**Date:** 2020-10-03

  
**M.Sc. M. Aihara**