

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

Date: 2020-10-03



Notified Body

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M.Sc. M. Aihara

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 2/3, Rev. 0

**Attachment to
Certificate**

Registration No.: HD 60148508 0001
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
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**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 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



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Date: 2020-10-03


M.Sc. M. Aihara