

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

Registration No.: HD 60099567 0001

Report No.: 12022681 002

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 60093350 0001

Expiry Date: 2019-05-06

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: 2015-11-24

Date: 2015-11-24



Notified Body


Dipl.-Ing. O. Masur

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 60099567 0001
Report No.: 12022681 002

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: 2015-11-24



Notified Body



Dipl.-Ing. O. Masur

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: HD 60099567 0001
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Manufacturer: Nakanishi Inc.
700 Shimohinata, Kanuma,
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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

Date: 2015-11-24



Notified Body



Dipl.-Ing. O. Masur