

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

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

has established and applies a quality management system for medical devices
for the following scope:

**Design, Development, Manufacture, Servicing and Sales of
Instruments and Equipment in Dental and Surgical Field
(see attachments for products and additional sites included)**

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2018-12-27
Certificate Registration No.: SX 60135465 0001
An audit was performed. Report No.: 12031343 002
This Certificate is valid until: 2020-04-26



Date 2018-12-27

Certification Body




Masahiro Asami

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel.: +49 221 806-1371 Fax: +49 221 806-3935 e-mail: cert-validity@de.tuv.com <http://www.tuv.com/safety>

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60135465 0001
Report No.: 12031343 002

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

Scope: Products and Sites included:

Nakanishi Inc. Head Office Factory
700 Shimohinata Kanuma, Tochigi, 332-8666, Japan

Scope (HQ) :
Design, Development, Manufacture and Sales of
- 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
- Endodonic apex locator

Certification Body



Date: 2018-12-27


Masahiro Asami

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60135465 0001
Report No.: 12031343 002

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

Scope:

Scope (HQ):

Design, Development, Manufacture and Sales of

- Dental abrasive air jet system handpiece
- Dental abrasive powder
- Sawing power tool attachment, reciprocating
- Sawing power tool attachment, oscillating
- 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
- Dental ultrasonic surgical system handpiece tip
- Total Surgical System

Certification Body



Date: 2018-12-27



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LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60135465 0001
Report No.: 12031343 002

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

Scope: Scope (HQ) : Design, Development, Manufacture and Sales of

- Sterile Products:
 - Sterile Drills
 - Sterile Burs
 - Sterile Blades
 - Sterile Rasps
 - Sterile Files
- Dental suction system, non-surgical
- 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

Certification Body



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Registration No.: SX 60135465 0001
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Organization: Nakanishi Inc.
700 Shimohinata, Kanuma,
Tochigi, 322-8666
Japan

Scope: (continued)

Servicing of

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

Certification Body



Date: 2018-12-27


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

Scope: (continued)

Servicing of

- Sawing power tool attachment, oscillating
- Sawing power tool attachment, sagittal
- Dental implant system
- Surgical screwdriver, reusable
- Ultrasonic dental scaling system
- Dental ultrasonic surgical system
- Total Surgical System
- Dental suction system, non-surgical
- 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

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

Scope: Products and Sites included:
Nakanishi Inc. Tokyo Sales Office TIXTOWER UENO 9F,
Higashiueno 4-8-1, Taito-ku, Tokyo 110-0015, Japan

Sales and Marketing of

- 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

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Scope:

(continued)

Sales and Marketing of

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- Sawing power tool attachment, oscillating
- Sawing power tool attachment, sagittal
- Reciprocating surgical saw blade, reusable
- Oscillating surgical saw blade, reusable
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Scope:

(continued)
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