

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 Distribution
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: 2020-04-27
Certificate Registration No.: SX 60148531 0001
An audit was performed. Report No.: 12031343 011
This Certificate is valid until: 2023-04-26

Certification Body



Date 2020-04-14




Masahiro Asami

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

Doc. 1/10, Rev. 0

**Attachment to
Certificate**

Registration No.: SX 60148531 0001
Report No.: 12031343 011

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 Distribution 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: 2020-04-14


Masahiro Asami

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 2/10, Rev. 0

**Attachment to
Certificate**

Registration No.: SX 60148531 0001
Report No.: 12031343 011

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

Scope:

Scope (HQ):
Design, Development, Manufacture and Distribution 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: 2020-04-14


Masahiro Asami

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 3/10, Rev. 0

**Attachment to
Certificate**

Registration No.: SX 60148531 0001
Report No.: 12031343 011

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

Scope:

Scope (HQ):
Design, Development, Manufacture and Distribution 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
- Dental rotary cutting instruments (for laboratory use)
Distribution of
- Sterilizers (for Japan)

Certification Body



Date: 2020-04-14



Masahiro Asami

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 4/10, Rev. 0

**Attachment to
Certificate**

Registration No.: SX 60148531 0001
Report No.: 12031343 011

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: 2020-04-14



Masahiro Asami

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 5/10, Rev. 0

**Attachment to
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Registration No.: SX 60148531 0001
Report No.: 12031343 011

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
- Dental rotary cutting instruments (for laboratory use)
- Sterilizers (for Japan)

Certification Body



Date: 2020-04-14



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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 6/10, Rev. 0

**Attachment to
Certificate**

Registration No.: SX 60148531 0001
Report No.: 12031343 011

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

Distribution 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

Certification Body



Date: 2020-04-14


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LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 7/10, Rev. 0

**Attachment to
Certificate**

Registration No.: SX 60148531 0001
Report No.: 12031343 011

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

Scope:

(continued)

Distribution and Marketing of

- 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: 2020-04-14


Masahiro Asami

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 8/10, Rev. 0

**Attachment to
Certificate**

Registration No.: SX 60148531 0001
Report No.: 12031343 011

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

Scope:

(continued)
Distribution and Marketing 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
- Dental rotary cutting instruments (for laboratory use)
- Sterilizers (for Japan)

Certification Body



Date: 2020-04-14


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LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 9/10, Rev. 0

**Attachment to
Certificate**

Registration No.: SX 60148531 0001
Report No.: 12031343 011

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

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

Scope: Manufacturing of mechanical parts of products in
dental and surgical fields

Certification Body



Date: 2020-04-14



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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 10/10, Rev.0

**Attachment to
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Registration No.: SX 60148531 0001
Report No.: 12031343 011

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

Scope: Nakanishi Inc. Osaka Sales Office
Seiwa Umeda Bldg. 10F, 2-12-7 Sonezaki, Kita-ku, Osaka-shi,
Osaka 532-0057, Japan

Scope: Distribution of

- Dental rotary cutting instruments
- Surgical rotary cutting instruments
- Ultrasonic instruments
- Prophylaxis kits
- Apex locators
- Dental suction systems
- Sterile burs
- Dental rotary cutting instruments (for laboratory use)
- Sterilizers (for Japan)

Certification Body



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Masahiro Asami