

# Certificate

## Quality Management System EN ISO 13485:2016

Registration No.: SX 2002410-1

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

Scope: Design, Development, Manufacture and Servicing and Distribution of  
Instruments and Equipment in Dental and Surgical Field.  
(see attachments for products and additional sites included)

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.  
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

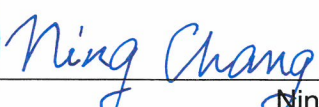
Report No.: 150234653-340

Effective date: 2022-07-01

Expiry date: 2023-04-26

Issue date: 2022-07-01



  
Ning N. C. Chang  
TÜV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany

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700 Shimohinata,  
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322-8666 Japan

The scope of certification also covers the following:

| No. | Facility   | Scope  |
|-----|--|--|
| /01 | c/o Nakanishi Inc.<br>700 Shimohinata,<br>Kanuma, Tochigi,<br>322-8666 Japan | Design, Development, Manufacture and Distribution of<br>Pneumatic dental drilling system handpiece<br>Diamond dental bur, reusable<br>Dental drilling system attachment<br>Line-powered dental drilling system handpiece<br>Pneumatic dental scaling system handpiece<br>Pneumatic dental scaling system handpiece tip<br>Air Motor<br>Remotely-driven dental drilling system motor<br>Endodontic enlarger<br>Dental-professional prophylaxis motor<br>Endodontic apex locator<br>Dental abrasive air jet system handpiece<br>Dental abrasive powder<br>Sawing power tool attachment, reciprocating<br>Sawing power tool attachment, oscillating<br>Sawing power tool attachment, sagittal<br>Reciprocating surgical saw blade, reusable<br>Oscillating surgical saw blade, reusable<br>Sagittal surgical saw blade, reusable<br>Dental implant system |

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

The scope of certification also covers the following:

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  
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)

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

The scope of certification also covers the following:

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  
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

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700 Shimohinata,  
Kanuma, Tochigi,  
322-8666 Japan

The scope of certification also covers the following:

External coolant Straight Handpiece for foot surgery and oral surgery  
Dental rotary cutting instruments (for laboratory use)  
Sterilizers (for Japan)

/02 c/o Nakanishi Inc.  
A1 Factory  
990 Fukahodo,  
Kanuma, Tochigi,  
322-0302 Japan

Manufacturing of mechanical parts of products in dental and surgical fields.

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700 Shimohinata,  
Kanuma, Tochigi,  
322-8666 Japan

The scope of certification also covers the following:

|   |   |
|---|---|
| /03 c/o Nakanishi Inc.<br>Tokyo Sales Office<br>TIXTOWER UENO 9F<br>4-8-1 Higashi-ueno,<br>Taito-ku, Tokyo,<br>110-0015 Japan | Distribution and Marketing of<br>Pneumatic dental drilling system handpiece<br>Diamond dental bur, reusable<br>Dental drilling system attachment<br>Line-powered dental drilling system handpiece<br>Pneumatic dental scaling system handpiece<br>Pneumatic dental scaling system handpiece tip<br>Air Motor<br>Remotely-driven dental drilling system motor<br>Endodontic enlarger<br>Dental-professional prophylaxis motor<br>Endodontic apex locator<br>Dental abrasive air jet system handpiece<br>Dental abrasive powder<br>Sawing power tool attachment, reciprocating<br>Sawing power tool attachment, oscillating<br>Sawing power tool attachment, sagittal<br>Reciprocating surgical saw blade, reusable<br>Oscillating surgical saw blade, reusable<br>Sagittal surgical saw blade, reusable<br>Dental implant system<br>Surgical screwdriver, reusable |
|---|---|

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**EN ISO 13485:2016**

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Dental ultrasonic surgical system  
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Total Surgical System  
Sterile Products:  
- Sterile Drills  
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- Sterile Rasps  
- Sterile Files  
Dental suction system, non-surgical  
Pneumatic Surgical Drilling Machine  
Electric drill system for dental surgery, dental implant surgery  
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External Coolant Straight Handpiece for foot surgery and oral  
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