

# Certificate

## Quality Management System EN ISO 13485:2016 + AC:2018 + A11:2021 ISO 13485:2016

Registration No.: SX 2002410-1  
Certificate Holder: Nakanishi Inc.  
700 Shimohinata,  
Kanuma, Tochigi  
322-8666 Japan  
Scope: Design and Development, Manufacture, Distribution and  
Service 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.: 150319730-301  
Effective date: 2026-04-27  
Expiry date: 2029-04-26  
Issue date: 2026-04-16  
Replaces certificate SX 2002410-1 issued 2025-04-28

This certificate can be validated on <https://www.certipedia.com>



Michiaki Aihara  
TÜV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany

© TÜV, TÜEV and TUV are registered trademarks. Utilisation and application requires prior approval.

# Certificate

## Quality Management System EN ISO 13485:2016 + AC:2018 + A11:2021 ISO 13485:2016

Registration No.: SX 2002410-1  
Certificate Holder: Nakanishi Inc.  
700 Shimohinata,  
Kanuma, Tochigi  
322-8666 Japan

The scope of certification also covers the following sites:

No.	Facility	Scope
/01	c/o Nakanishi Inc. 700 Shimohinata, Kanuma, Tochigi 322-8666 Japan	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 Endodontic apex locator 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 Sterile Products: - Sterile Drills - Sterile Burs - Sterile Blades - Sterile Rasps - Sterile Files Dental suction system, non-surgical Pneumatic Surgical Drilling Machine

This certificate can be validated on <https://www.certipedia.com>

# Certificate

## Quality Management System EN ISO 13485:2016 + AC:2018 + A11:2021 ISO 13485:2016

Registration No.: SX 2002410-1  
Certificate Holder: Nakanishi Inc.  
700 Shimohinata,  
Kanuma, Tochigi  
322-8666 Japan

The scope of certification also covers the following sites:

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)

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  
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

This certificate can be validated on <https://www.certipedia.com>

# Certificate

## Quality Management System EN ISO 13485:2016 + AC:2018 + A11:2021 ISO 13485:2016

Registration No.: SX 2002410-1  
Certificate Holder: Nakanishi Inc.  
700 Shimohinata,  
Kanuma, Tochigi  
322-8666 Japan

The scope of certification also covers the following sites:

/03 c/o Nakanishi Inc.  
Tokyo Sales Office  
TIXTOWER UENO 9F  
4-8-1 Higashi-ueno,  
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  
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  
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)

This certificate can be validated on <https://www.certipedia.com>