

Certificate

Quality Management System

EN ISO 13485:2016

EN ISO 13485:2016/AC:2018

EN ISO 13485:2016/A11:2021

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.: 150300785-301

Effective date: 2025-04-28

Expiry date: 2026-04-26

Issue date: 2025-04-28

Replaces certificate SX 2002410-1 issued 2023-04-24



Nasu Yang

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

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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

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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

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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

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Kanuma, Tochigi,
322-8666 Japan

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

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