

EC Certificate
Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60148508 0001

Report No.: 12031343 009

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

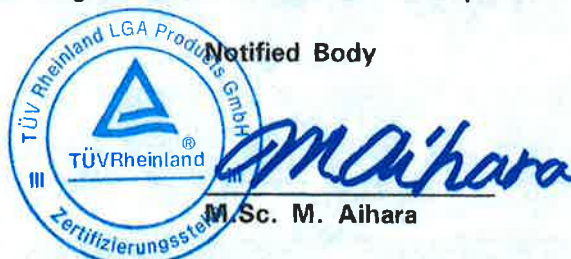
Products: Instruments and Equipment in Dental and Surgical Fields
(see attachments for products included)
Replaces Approval, Registration No.: HD 60144337 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2020-10-03

Date: 2020-10-03



TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: HD 60148508 0001
Report No.: 12031343 009

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

Products included:

- 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

Date: 2020-10-03



Notified Body

M. Aihara
M.Sc. M. Aihara

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 2/3, Rev. 0

**Attachment to
Certificate**

Registration No.: HD 60148508 0001
Report No.: 12031343 009

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

Products included:

- 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 handpiece tip
- Dental ultrasonic surgical system
- Total Surgical System
- Sterile Products:
 - Sterile Drills
 - Sterile Burs
 - Sterile Blades
 - Sterile Rasps
 - Sterile Files
- Dental suction system, non-surgical



Notified Body

Date: 2020-10-03

M.Sc. M. Aihara

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 3/3, Rev. 0

**Attachment to
Certificate**

Registration No.: HD 60148508 0001
Report No.: 12031343 009

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

Products included:

- 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

Site included:

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



Notified Body

Date: 2020-10-03


M.Sc. M. Aihara

認

証

嘱託人株式会社ナカニシ宮崎友美子の提出した別添証書の謄本は、その原本と対照し、原本と符合することを認めた。

よって、これを認証する。

令和3年 2 月 26 日、本公証人役場において
東京都台東区東上野1丁目7番2号

東京法務局所属

公証人

Notary

畑野隆二

HATANO Ryuji

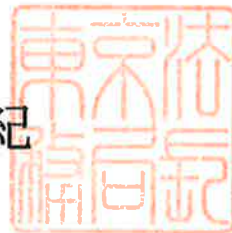
証 明

上記署名は、東京法務局所属公証人の署名に相違ないものであり、かつ、その押印は、真実のものであることを証明する。

令和3年 2 月 26 日

東京法務局長

山西宏紀



APOSTILLE

(Convention de La Haye du 5 octobre 1961)

1. Country: JAPAN
This public document
2. has been signed by HATANO Ryuji
3. acting in the capacity of Notary of the Tokyo Legal Affairs Bureau
4. bears the seal/stamp of HATANO Ryuji ,Notary
Certified
5. at Tokyo
6. FEB. 26. 2021
7. by the Ministry of Foreign Affairs
8. 21- No 012132
9. Seal/stamp:
10. Signature



Tanaka Toshie

TANAKA Toshie

For the Minister for Foreign Affairs

Registered No. 59 of 2021

NOTARIAL CERTIFICATE

This is to certify that the attached copy of the documents
produced before me by MIYAZAKI Yumiko , NAKANISHI
INC. exactly corresponds with the seen original.

畑野隆一



Notary, HATANO Ryuji

Ueno Notary's Office of Tokyo Legal Affairs

Bureau , 1-7-2 Higashiueno , Taito-ku ,

Tokyo, Japan