

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

Registration No.: HD 60118708 0001

Report No.: 12031343 001

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 60099567 0001

Expiry Date: 2022-05-08

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: 2018-02-26

Date: 2018-02-26



Notified Body

M. Aihara
M.Sc. M. Aihara

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 60118708 0001
Report No.: 12031343 001

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: 2018-02-26



Notified Body

M. Aihara
M.Sc. M. Aihara

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: HD 60118708 0001
Report No.: 12031343 001

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

Date: 2018-02-26



Notified Body

M. Aihara
M.Sc. M. Aihara

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Doc. 3/3, Rev. 0

**Attachment to
Certificate**

Registration No.: HD 60118708 0001
Report No.: 12031343 001

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

Date: 2018-02-26



Notified Body

M. Aihara
M.Sc. M. Aihara

認 証

嘱託人株式会社ナカニシ鈴木みどり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。

令和元年 6 月 7 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

津 筈 寅 雄
TORAO TSUKUMA



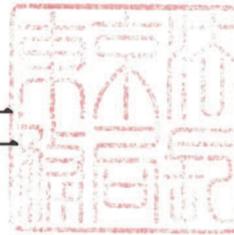
証 明

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。

令和元年 6 月 7 日

東京法務局長

岩 山 伸 二



APOSTILLE

(Convention de La Haye du 5 octobre 1961)

- 1. Country: JAPAN
This public document
- 2. has been signed by TORAO TSUKUMA
- 3. acting in the capacity of Notary of the Tokyo Legal Affairs Bureau
- 4. bears the seal/stamp of TORAO TSUKUMA, Notary

Certified

- 5. at Tokyo
- 6. JUN. 07. 2019
- 7. by the Ministry of Foreign Affairs
- 8. 19- N0051137
- 9. Seal/stamp:
- 10. Signature



T. TANAKA

Toshie TANAKA

For the Minister for Foreign Affairs

ATITIKTIES PATVIRTINIMAS
ES Direktyvos 93/42/EEB II Priedas, išskyrus 4 Straipsnį
Pilna Kokybės Užtikrinimo sistema
Medicinos prietaisai

Registracijos Nr.: HD 60118708 0001

Protokolo Nr. 12031343 001

Gamintojas: Nakanishi Inc.
700 Shimohinata, Kanuma-shi,
TOCHIGI-KEN, 322-8666
JAPONIJA

Taikymo sritis: Odontologinių ir chirurginių instrumentų bei įrenginių sritys
(dizainas, vystymas ir gamyba)

(žiūrėti pridėta produktų sąrašą)

Atitikties patvirtinimo, registracijos Nr.: HD 60099567 0001,
pakeitimas

Galiojimo laikas: 2022-05-08

Šiuo Notifikavimo įstaiga patvirtina, kad ES Direktyvos 93/42/EEB Priedo II reikalavimai, išskyrus 4 skyrių, buvo išpildyti išvardintiems produktams. Aukščiau minėtas gamintojas turi įdiegtą ir vykdomą kokybės vadybos sistemą, kuri yra periodiškai stebima, kaip nustatyta II Priedo 5 straipsnyje. Pardavimui rinkoje III klasės įrenginių apimamų šio sertifikato, yra reikalingas ES projektavimo-patikrinimo sertifikatas pagal II Priedą 4 skyrių.

Įsigaliojimo data: 2018-02-26

Notifikavimo įstaiga

Data: 2018-02-26

Dipl. Inž. M. Aihara

„TÜV Rheinland LGA Products GmbH“ – Tillystraße 2 – 90431 Niurnbergas

TÜV Rheinland LGA Products GmbH yra notifikuojanti įstaiga pagal Direktyvą 93/42/EEB
medicinos įrenginiams su identifikavimo numeriu 0197

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Niurnbergas

Priedas prie
Registracijos Nr.: HD 60118708 0001
Protokolo Nr.: 12031343 001

Gamintojas: Nakanishi Inc.
700 Shimohinata, Kanuma-shi,
TOCHIGI-KEN, 322-8666
JAPONIJA

Produktai įskaitant:

- Oriniai odontologiniai gręžimo sistemų antgaliai
- Daugkartinio naudojimo deimantiniai odontologiniai gražtai
- Odontologinių gręžimo sistemų prijungimai
- Linijinio maitinimo odontologiniai gręžimų sistemų antgaliai
- Oriniai odontologiniai skaleriai
- Orinių odontologinių skalerių antgaliukai
- Oriniai varikliai
- Nuotoliniu būdu varomi odontologiniai gręžimo sistemų varikliai
- Endodontiniai didintuvai
- Odontologiniai profilaktiniai varikliai
- Endodontinis apekso lokatorius
- Odontologiniai abrazyvios oro srovės sistemos antgaliai
- Odontologiniai abrazyvūs milteliai
- Pjaunantys galios instumentų prijungimai, darantys slankiojamąjį judesį
- Pjaunantys galios instumentų prijungimai, vibruojantys

Notifikavimo įstaiga

Data 2018-02-26

Dipl. Inž. M. Aihara

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Niurnbergas

Priedas prie
Registracijos Nr.: HD 60118708 0001
Protokolo Nr.: 12031343 001

Gamintojas: Nakanishi Inc.
700 Shimohinata, Kanuma-shi,
TOCHIGI-KEN, 322-8666
JAPONIJA

Produktai įskaitant:

- Pjaunantys galios instrumentų prijungimai, strėliniai
- Slekamojo judesio chirurginių pjūklų ašmenys, daugkartinio naudojimo
- Vibruojančių chirurginių pjūklų ašmenys, daugkartinio naudojimo
- Stėliniai chirurginiai pjovimo ašmenys, daugkartinio naudojimo
- Odontologinės implantavimo sistemos
- Chirurginiai varžtų suktuvai, daugkartinio naudojimo
- Ultragarsinių odontologinių skalerių sistemos
- Ultragarsinių odontologinių skalerių sistemų antgaliukai
- Odontologiniai ultragarsinių chirurginių sistemų antgaliukai
- Odontologinės ultragarsinės chirurginės sistemos
- Bendra chirurginė sistema
- Sterilūs produktai:
 - Sterilūs gražtai
 - Sterilūs turbininiai gražtai
 - Sterilūs ašmenys
 - Sterilūs brūžikliai
 - Sterilios adatos
- Odontologinės atsiurbimo sistemos, ne chirurginės

Notifikavimo įstaiga

Data 2018-02-26

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LGA Products GmbH
Tillystraße 2, 90431 Niurnbergas

Priedas prie
Registracijos Nr.: HD 60118708 0001
Protokolo Nr.: 12031343 001

Gamintojas: Nakanishi Inc.
700 Shimohinata, Kanuma-shi,
TOCHIGI-KEN, 322-8666
JAPONIJA

Produktai įskaitant:

- Orinės chirurginės gręžimo mašinos
- Elektrinės gręžimo sistemos odontologinei chirurgijai, odontologinei implantų chirurgijai bei kojos ir alkūnės chirurgijai
- Išorinio aušinimo tiesus antgalis kojos chirurgijai ir burnos chirurgijai

Notifikavimo įstaiga

Data 2018-02-26

Dipl. Inž. M. Aihara

EC DECLARATION OF CONFORMITY**MANUFACTURER**

NAKANISHI INC.
700 Shimohinata, Kanuma, Tochigi 322-8666, Japan

AUTHORIZED EU REPRESENTATIVE

NSK EUROPE GmbH
Elly-Beinhorn-Strasse 8, 65760 Eschborn, Germany

MEDICAL DEVICE

General Product Group Name:

Electric drill system for dental surgery, dental implant surgery and foot- and ankle- surgery

Product Name: Surgic Pro
Model: See No. 000058-12-21 005 Attachment 1
Order Code: See No. 000058-12-21 005 Attachment 1
Classification: Class IIa (Rule9)
Notified Body: TÜV Rheinland LGA Products GmbH
Tillystrasse 2, 90431 Nürnberg, Deutschland
Notified Body number: 0197

NAKANISHI INC. is exclusively responsible for the Declaration of Conformity.
The serial number applied to this product is managed by the "Shipping history data".
This Declaration of Conformity is valid for a definite number of manufactured products.

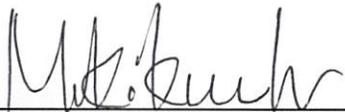
The undersigned hereby declares that the medical device, as specified above, conforms with the essential requirements listed in Annex I of EC Directive 93/42/EEC.

The Declaration of Conformity is based on the EC Directive 93/42/EEC Annex II, excluding Section 4. The Declaration of Conformity is issued under the supervision of TÜV Rheinland LGA Products GmbH, approving the conformity of Annex II Section 3 requirements, with reference to articles 1 and 3 of directive 93/42/EEC.

EC Certificate Registration No.: HD 60118708 0001
This Declaration of Conformity is valid until 2022-05-08.

And, this Declaration of Conformity includes the EC Directive 2006/42/EC.

Tochigi, Japan: 2018-03-05
Date


Masaaki Kikuchi,
General Manager Quality Assurance Department



Type: Surgic Pro

No.	Model	Order Code
1	Surgic Pro OPT(230V)	Y1001933
2	Surgic Pro NON-OPT(230V)	Y1001934
3	SGL70M	E1023001
4	SG70M	E1025001

Type: Surgic Pro +

No.	Model	Order Code
1	Surgic Pro+ OPT-D(230V)	Y1002096
2	SGL70M	E1023001
3	SG70M	E1025001



EC DECLARATION OF CONFORMITY**MANUFACTURER**

NAKANISHI INC.
700 Shimohinata, Kanuma, Tochigi 322-8666, Japan

AUTHORIZED EU REPRESENTATIVE

NSK EUROPE GmbH
Elly-Beinhorn-Strasse 8, 65760 Eschborn, Germany

MEDICAL DEVICE

General Product Group Name:
External Coolant Straight Handpiece for foot surgery and oral surgery

Product Name: Ti-Max X-SG

Model: See No. 000272-12-21 A01 Attachment 1
Order Code: See No. 000272-12-21 A01 Attachment 1
Classification: Class IIa (Rule5), Class IIa (Rule6)
Notified Body: TÜV Rheinland LGA Products GmbH
Tillystrasse 2, 90431 Nürnberg, Deutschland

Notified Body number: 0197

NAKANISHI INC. is exclusively responsible for the Declaration of Conformity.
The serial number applied to this product is managed by the "Shipping history data".
This Declaration of Conformity is valid for a definite number of manufactured products.

The undersigned hereby declares that the medical device, as specified above, conforms with the essential requirements listed in Annex I of EC Directive 93/42/EEC.

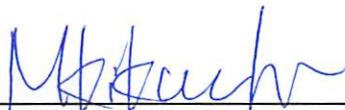
The Declaration of Conformity is based on the EC Directive 93/42/EEC Annex II, excluding Section 4. The Declaration of Conformity is issued under the supervision of TÜV Rheinland LGA Products GmbH, approving the conformity of Annex II Section 3 requirements, with reference to articles 1 and 3 of directive 93/42/EEC.

EC Certificate Registration No.: HD 60118708 0001
This Declaration of Conformity is valid until 2022-05-08.

And, this Declaration of Conformity includes the EC Directive 2006/42/EC.

Tochigi, Japan: 2018-03-08

Date


Masaaki Kikuchi,
General Manager Quality Assurance Department

FD-204-16



No.	Model	Order Code
1	X-SG65L	H1009
2	X-SG65	H1038



EC DECLARATION OF CONFORMITY

MANUFACTURER

NAKANISHI INC.
700 Shimohinata, Kanuma, Tochigi 322-8666, Japan

AUTHORIZED EU REPRESENTATIVE

NSK EUROPE GmbH
Elly-Beinhorn-Strasse 8, 65760 Eschborn, Germany

MEDICAL DEVICE

General Product Group Name:
Line-powered dental drilling system handpiece

Product Name: X-SG
Model: X-SG20L
Order Code: C1003
Classification: Class IIa (Rule5)
Notified Body: TÜV Rheinland LGA Products GmbH
Tillystrasse 2, 90431 Nürnberg, Deutschland
Notified Body number: 0197

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The serial number applied to this product is managed by the "Shipping history data".
This Declaration of Conformity is valid for a definite number of manufactured products.

The undersigned hereby declares that the medical device, as specified above, conforms with the essential requirements listed in Annex I of EC Directive 93/42/EEC.

The Declaration of Conformity is based on the EC Directive 93/42/EEC Annex II, excluding Section 4. The Declaration of Conformity is issued under the supervision of TÜV Rheinland LGA Products GmbH, approving the conformity of Annex II Section 3 requirements, with reference to articles 1 and 3 of directive 93/42/EEC.

EC Certificate Registration No.: HD 60118708 0001
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Tochigi, Japan: 2018-03-08
Date


Masaaki Kikuchi,
General Manager Quality Assurance Department

