

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.000058-12-21 006 Attachment 1

Order Code: See No.000058-12-21 006 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: 2018-06-20

Date


Masaaki Kikuchi General Manager Quality Assurance Department

Model: Surgic Pro+

Description: Surgic Pro+ OPT-D(230V)

Order Code: Y1002096

No.	Component name	Component model	Order code
1	Control Unit	NE250	—
2	Motor	SGL70M	E1023
3	Foot Control	FC-78	Z1102001
4	Handpiece	X-DSG20L	C1068
5	AC Power Cord	AC Power Cord	—

Description: Surgic Pro+ OPT-D(230V) AU

Order Code: Y1002236

No.	Component name	Component model	Order code
1	Control Unit	NE250	—
2	Motor	SGL70M	E1023
3	Foot Control	FC-78	Z1102001
4	Handpiece	X-DSG20L	C1068
5	AC Power Cord	AC Power Cord	—

Description: Surgic Pro+ OPT-D(230V)

Order Code: Y1003743

No.	Component name	Component model	Order code
1	Control Unit	NE250	—
2	Motor	SGL70M	E1023
3	Foot Control	FC-78	Z1102001
4	Handpiece	X-DSG20L	C1068
5	AC Power Cord	AC Power Cord	—

Description: Surgic Pro+ OPT-D(230V)

Order Code: Y1003585

No.	Component name	Component model	Order code
1	Control Unit	NE250	—
2	Motor	SGL70M	E1023
3	Foot Control	FC-78	Z1102001
4	Handpiece	X-DSG20L	C1068
5	AC Power Cord	AC Power Cord	—

Description: Surgic Pro+ OPT 230V

Order Code: Y1001932

No.	Component name	Component model	Order code
1	Control Unit	NE250	—
2	Motor	SGL70M	E1023
3	Foot Control	FC-78	Z1102001
4	Handpiece	X-SG20L	C1003
5	AC Power Cord	AC Power Cord	—

Description: Surgic Pro+ OPT 230V AU

Order Code: Y1001935

No.	Component name	Component model	Order code
1	Control Unit	NE250	—
2	Motor	SGL70M	E1023
3	Foot Control	FC-78	Z1102001
4	Handpiece	X-SG20L	C1003
5	AC Power Cord	AC Power Cord	—

Model: Surgic Pro

Description: Surgic Pro OPT 230V

Order Code: Y1001933

No.	Component name	Component model	Order code
1	Control Unit	NE294	—
2	Motor	SGL70M	E1023
3	Foot Control	FC-78	Z1102001
4	Handpiece	X-SG20L	C1003
5	AC Power Cord	AC Power Cord	—

Description: Surgic Pro OPT 230V AU

Order Code: Y1001936

No.	Component name	Component model	Order code
1	Control Unit	NE294	—
2	Motor	SGL70M	E1023
3	Foot Control	FC-78	Z1102001
4	Handpiece	X-SG20L	C1003
5	AC Power Cord	AC Power Cord	—

Description: Surgic Pro OPT 230V AU

Order Code: Y1002808

No.	Component name	Component model	Order code
1	Control Unit	NE294	—
2	Motor	SGL70M	—
3	Foot Control	FC-78	Z1102001
4	Handpiece	X-SG20L	—
5	AC Power Cord	AC Power Cord	—

Description: Surgic Pro OPT 230V

Order Code: Y1003461

No.	Component name	Component model	Order code
1	Control Unit	NE294	—
2	Motor	SGL70M	E1023
3	Foot Control	FC-78	Z1102001
4	Handpiece	X-SG20L	C1003
5	AC Power Cord	AC Power Cord	—

Description: Surgic Pro OPT(230V)

Order Code: Y1003586

No.	Component name	Component model	Order code
1	Control Unit	NE294	—
2	Motor	SGL70M	E1023
3	Foot Control	FC-78	Z1102001
4	Handpiece	X-SG20L	C1003
5	AC Power Cord	AC Power Cord	—

Description: Surgic Pro NON-OPT 230V

Order Code: Y1001934

No.	Component name	Component model	Order code
1	Control Unit	NE294	—
2	Motor	SG70M	E1025
3	Foot Control	FC-78	Z1102001
4	Handpiece	SG20	C1010
5	AC Power Cord	AC Power Cord	—

Model: Surgic Pro**Description: Surgic Pro NON-OPT 230V AU**

Order Code: Y1001937

No.	Component name	Component model	Order code
1	Control Unit	NE294	—
2	Motor	SG70M	E1025
3	Foot Control	FC-78	Z1102001
4	Handpiece	SG20	C1010
5	AC Power Cord	AC Power Cord	—

Description: Surgic Pro NON-OPT 3.5m (230V)

Order Code: Y1002731

No.	Component name	Component model	Order code
1	Control Unit	NE294	—
2	Motor	SG70M	—
3	Foot Control	FC-78	—
4	AC Power Cord	AC Power Cord	—

Description: Surgic Pro NON-OPT 230V

Order Code: Y1003462

No.	Component name	Component model	Order code
1	Control Unit	NE294	—
2	Motor	SG70M	E1025
3	Foot Control	FC-78	Z1102001
4	Handpiece	SG20	C1010
5	AC Power Cord	AC Power Cord	—

Description: Surgic Pro NON-OPT(230V)

Order Code: Y1003587

No.	Component name	Component model	Order code
1	Control Unit	NE294	—
2	Motor	SG70M	E1025
3	Foot Control	FC-78	Z1102001
4	Handpiece	SG20	C1010
5	AC Power Cord	AC Power Cord	—

Description: Surgic Pro NON-OPT 3.5m(230V)

Order Code: Y1003588

No.	Component name	Component model	Order code
1	Control Unit	NE294	—
2	Motor	SG70M	—
3	Foot Control	FC-78	—
4	AC Power Cord	AC Power Cord	—