

No. 000058-12-21 005

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

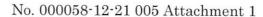
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Powerful Partners®





Type: Surgic Pro

No.	Model	Order Code
		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



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