

**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:  
Total Surgical System

Product Name: Surgic Pro2  
Model: See No.000444-12-21-01 000 Attachment 1  
Order Code: See No.000444-12-21-01 000 Attachment 1  
Classification: Class IIa (Rule9)  
Notified Body: TÜV Rheinland LGA Products GmbH  
Tillystrasse 2, 90431 Nürnberg, Germany  
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 60148508 0001  
This Declaration of Conformity is valid until 2024-05-26.

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

Tochigi, Japan: 2021-05-21  
Date

  
Masaaki Kikuchi,  
Management Representative

Model: Surgic Pro2 NON-OPT 3.5m

Description: Surgic Pro2 NON-OPT 3.5m

Order Code: Y1004197

No.	Component name	Component model	Order code
1	Control Unit	NE335	—
2	MOTOR&CODE 3.5M	SG80M(3.5M)	Y1004213
3	Foot Control Wireless	FC-81	Z1401001
4	AC Power Cord	AC Power Cord	—
Combination Products			
No.	Product name	Model	Order code
1	Surgical Irrigation Tube	Surgical Irrigation Tube (1pc.)	ZA02630020
Manufacturer: PROMEPLA S.A.M., MDD Class: IIa, Rule: 2, CE0459			

Option

Description: Link Module

Order Code: Z1402001

No.	Component name	Component model	Order code
1	Link Module	LMP2	Z1402001

Description: Link Stand2

Order Code: Z1452001

No.	Component name	Component model	Order code
1	Link Stand2	LS-2	Z1452001