

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:
Dental implant system

Product Name: Surgic Pro2
Model: See No.000444-12-21 004 Attachment 1
Order Code: See No.000444-12-21 004 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: 2020-12-24
Date


Masaaki Kikuchi,
General Manager Quality Assurance Department

Model: Surgic Pro2

Description: Surgic Pro2 OPT

Order Code: Y1004195

No.	Component name	Component model	Order code
1	Control Unit	NE335	U1188001
2	MOTOR&CODE 2M	SGL80M	Y1004211
3	Foot Control Wireless	FC-81	Z1401001
4	Handpiece	X-SG20L	C1003
5	AC Power Cord	AC Power Cord	—

Description: Surgic Pro2 NON-OPT

Order Code: Y1004196

No.	Component name	Component model	Order code
1	Control Unit	NE335	U1188001
2	MOTOR&CODE 2M	SG80M	Y1004212
3	Foot Control Wireless	FC-81	Z1401001
4	Handpiece	SG20	C1010
5	AC Power Cord	AC Power Cord	—

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

Technical Document and Change History Control Form

技術文書・変更履歴管理票

Control number 管理番号	000444-12-21	Document name 文書種類名	EC DECLARATION OF CONFORMITY			
Rev. 改定	Site 箇所	Target item 対象項目	Content of change / Reason for change 変更内容 / 変更理由	Approved by 承認	Verified by 検証	Prepared by 作成
001	N/A	General Product Group Name	General Product Group Nameの誤記訂正	菊地 19-10-10	原紙 捺印済	2019/6/12
002	N/A	EC Certificate Registration No.	EC Certificate 更新のため	菊地 19-11-15	原紙 捺印済	2019/11/15
003	N/A	<ul style="list-style-type: none"> • General Product Group Name • Attachment1 	監査の指摘により、既存製品とのGMDNコードを統一するため 監査による指摘の為、光無し一式を追加	菊地 20-02-06	原紙 捺印済	2020/2/6
004	—	改版	①EC Certificate Registration No.更新 HD 60144337 0001 → HD 60148508 0001 ②EC-DOC有効期限更新 2022-05-08 → 2024-05-26 ③更新に伴う帳票改版と記載整備 ④General Product Group Name変更/ Listingとの整合を図る。 Electric drill system for dental surgery, dental implant surgery and foot- and ankle- surgery → Dental implant system	  	 	
		Attachment 1	① (100-240V) を削除 ・Surgic Pro2 OPT(100-240V) → Surgic Pro2 OPT ・Surgic Pro2 NON-OPT(100-240V) → Surgic Pro2 NON-OPT ②Optionを追記			
		技術文書・変更履歴管理票	Rev.001~003 原紙押印済: 原紙に押印が無いので斜線とする。			