

DECLARATION OF CONFORMITY**MANUFACTURER**

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

AUTHORIZED EU REPRESENTATIVE

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

MEDICAL DEVICE

Ultrasonic Surgical Systems

Model No: See Attachment 1
Product Name: See Attachment 1

Classification : Class II a (Rule 9)

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 in the EC Directive 93/42/EEC Annex II and supported by the TÜV Rheinland LGA Products GmbH, Tillystrasse 2, 90431 Nürnberg (0197) Annex II certificate, with reference to articles 1 and 3 of directive 93/42/EEC.

Certificate Registration No: HD 60039342 0001

And, this declaration of conformity includes the EC Directive 2006/42/EC.

Tochigi, Japan: Oct 3, 2013



Kensuke Nakanishi, Quality Assurance Dept. Manager

Product Name: VarioSurg 3**Components:**

No.	Name	Model
1	Control unit for 230V	NE288
2	Handpiece	VS3-LED-HPSC
3	Foot Control	FC-78
4	AC Power Cord for 230V	—
5	Tip	
	Bone Surgery / Sinus Lift	① SG1
		② SG2R
		③ SG2L
		④ SG8
		⑤ SG14R
		⑥ SG14L
		⑦ SG19
		⑧ SG6D
		⑨ SG7D
		⑩ SG1A
		⑪ SG8A
		⑫ SG30
		⑬ SG58
		⑭ H-SG1
		⑮ H-SG8
	Scraper	① SG3
		② SG4
		③ SG5
	Sinus Membrane Tool	① SG9
		② SG10
		③ SG11
	Implant Preparation	① SG15A
		② SG15B
		③ SG16A
		④ SG16B
		⑤ SG15C
		⑥ SG15D

No.	Name	Model		
5	Tip	Socket Lift	①	SCL1
			②	SCL1D
			③	SCL11D
			④	SCL2D
			⑤	SCL12D
			⑥	SCL3
			⑦	SCL3D
			⑧	SCL13D
			⑨	SCL4D
			⑩	SCL14D
			⑪	SCL5
			⑫	SCL5D
			⑬	SCL15D
		Retrograde Endo	①	E30RD-S
			②	E30LD-S
			③	E31D-S
			④	E32D-S
		Extraction	①	SG17
			②	SG18R
			③	SG18L
		Scaling	①	G1-S
		Perio (Root Planing / Maintenance)	①	P20-S
			②	P25R-S
			③	P25L-S
			④	V10-S
			⑤	V-P10
			⑥	V-P12
			⑦	V-P11R
			⑧	V-P11L
			⑨	V-P26R
			⑩	V-P26L

No.	Name	Model	
6	Tip Wrench	①	CR-30
		②	CR-40 (VS Tip Wrench)
		③	E Tip Replacement Wrench
7	Irrigation Tube	—	
8	SG Link Cable	LC-1	

Accessories:

No.	Name	Model
9	Tube Holder	—
10	Irrigation Pole	—
11	Tip Holder	—
12	Sterilization Cassette	VA-SG-CASE
13	Handpiece Stand	—
14	SG Link Stand	—
15	Carrying Case	Carrying Case

Set:

	Set Name	Model
1	VarioSurg 3 Complete Sets	VarioSurg 3 (230V)
2	VarioSurg 3 Complete Sets without Foot Control	VarioSurg 3 (230V) Non FT