

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:
Ultrasonic dental scaling system

Product Name: See No. 000018-12-21-04 008 Attachment 1
Model: See No. 000018-12-21-04 008 Attachment 1
Order Code: See No. 000018-12-21-04 008 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: 2023-06-01
Date


Masaaki Kikuchi,
Management Representative

Product Name: Varios 170

Type: Varios 170

No.	Model	Order Code
1	VA170 BEL SET	Y1002781
2	VA170S8	Y1004144
3	VA170 BEL SET2	Y1004147
4	VA170S5	Y1002115
5	VA170S1	Y1001352
6	VA170S2	Y1001442

Order Code : Y1002781

Components:

No.	Name	Model	Order Code
1	Handpiece (Non-Optic)	VA2-HP	E350050
2	Hose (Non Optic)	VA170-SC	E350056
3	Control Unit (VA170)	Varios 170 H23 Built-in Module	U1006005
4	Tip		
	Varios Tip G4	G4	Z217104
	Varios Tip G6	G6	Z217106
	Varios Tip G8	G8	Z217108

Order Code : Y1004144

Components:

No.	Name	Model	Order Code
1	Handpiece (Non-Optic)	VA2-HP	E350050
2	Hose (Non Optic)	VA170-SC	E350056
3	Control Unit (VA170)	Varios 170 Built-in Module	U1006001
4	Tip		
	Varios Tip G4	G4	Z217104
	Varios Tip G16	G16	Z217120
	Varios Tip G8	G8	Z217108

Order Code : Y1004147

Components:

No.	Name	Model	Order Code
1	Handpiece (Non-Optic)	VA2-HP(Varios2)	E350050
2	Hose (Non Optic)	VA170-SC	E350056
3	Control Unit (VA170)	Varios 170 H23 Built-in Module	U1006005
4	Tip		
	Varios Tip G4	G4	Z217104
	Varios Tip G16	G16	Z217120
	Varios Tip G8	G8	Z217108

Order Code :Y1002115

Components:

No.	Name	Model	Order Code
1	Handpiece (Non-Optic)	VA2-HP(Varios2)	E350050
2	Hose (Non Optic)	VA170-SC	E350056
3	Control Unit (VA170)	Varios 170 Built-in Module	U1006001
4	Tip		
	Varios Tip G4	G4	Z217104
	Varios Tip G6	G6	Z217106
	Varios Tip G8	G8	Z217108

Order Code :Y1001352

Components:

No.	Name	Model	Order Code
1	Handpiece (Non-Optic)	VA2-HP(Varios2)	E350050
2	Hose (Non Optic)	VA170-SC	E350056
3	Control Unit (VA170)	Varios 170 Built-in Module	U1006001
4	Tip		
	Varios Tip G4	G4	Z217104
	Varios Tip G6	G6	Z217106
	Varios Tip G8	G8	Z217108

Order Code :Y1001442

Components:

No.	Name	Model	Order Code
1	Handpiece (Non-Optic)	VA2-HP(Varios2)	E350050
2	Hose (Non Optic)	VA170-SC	E350056
3	Control Unit (VA170)	Varios 170 Built-in Module	U1006001
4	Tip		
	Varios Tip G4	G4	Z217104
	Varios Tip G6	G6	Z217106
	Varios Tip G8	G8	Z217108

Product Name: Varios 170 LUX

Type: Varios 170 LUX

No.	Model	Order Code
1	VA170LUXS5	Y1002114
2	VA170LUXS1	Y1001351
3	VA170LUX BEL SET	Y1002780
4	VA170LUXS8	Y1004145
5	VA170LUX BEL SET2	Y1004146
6	VA170LUXS2	Y1001441

Order Code : Y1002114

Components:

No.	Name	Model	Order Code
1	Handpiece (Optic)	VA2-LUX-HP (Varios2 Lux)	E351050
2	Hose (Optic)	VA170LUX-SC	E351056
3	Control Unit (VA170)	Varios 170 Built-in Module	U1006001
4	Tip		
	Varios Tip G4	G4	Z217104
	Varios Tip G6	G6	Z217106
	Varios Tip G8	G8	Z217108

Order Code : Y1001351

Components:

No.	Name	Model	Order Code
1	Handpiece (Optic)	VA2-LUX-HP (Varios2 Lux)	E351050
2	Hose (Optic)	VA170LUX-SC	E351056
3	Control Unit (VA170)	Varios 170 Built-in Module	U1006001
4	Tip		
	Varios Tip G4	G4	Z217104
	Varios Tip G6	G6	Z217106
	Varios Tip G8	G8	Z217108

Order Code : Y1002780

Components:

No.	Name	Model	Order Code
1	Handpiece (Optic)	VA2-LUX-HP (Varios2 Lux)	E351050
2	Hose (Optic)	VA170LUX-SC	E351056
3	Control Unit (VA170)	Varios 170 H23 Built-in Module	U1006005
4	Tip		
	Varios Tip G4	G4	Z217104
	Varios Tip G6	G6	Z217106
	Varios Tip G8	G8	Z217108

Order Code : Y1004145

Components:

No.	Name	Model	Order Code
1	Handpiece (Optic)	VA2-LUX-HP (Varios2 Lux)	E351050
2	Hose (Optic)	VA170LUX-SC	E351056
3	Control Unit (VA170)	Varios 170 Built-in Module	U1006001
4	Tip		
	Varios Tip G4	G4	Z217104
	Varios Tip G16	G16	Z217120
	Varios Tip G8	G8	Z217106

Order Code : Y1004146

Components:

No.	Name	Model	Order Code
1	Handpiece (Optic)	VA2-LUX-HP (Varios2 Lux)	E351050
2	Hose (Optic)	VA170LUX-SC	E351056
3	Control Unit (VA170)	Varios 170 H23 Built-in Module	U1006005
4	Tip		
	Varios Tip G4	G4	Z217104
	Varios Tip G16	G16	Z217120
	Varios Tip G8	G8	Z217106

Order Code : Y1001441

Components:

No.	Name	Model	Order Code
1	Handpiece (Optic)	VA2-LUX-HP (Varios2 Lux)	E351050
2	Hose (Optic)	VA170LUX-SC	E351056
3	Control Unit (VA170)	Varios 170 Built-in Module	U1006001
4	Tip		
	Varios Tip G4	G4	Z217104
	Varios Tip G6	G6	Z217106
	Varios Tip G8	G8	Z217106

Product Name: Varios 370

Type: Varios 370

No.	Model	Order Code
1	VA370 (230V)	Y1001340
2	VA370	Y1001389

Components:

No.	Name	Model	Order Code
1	Handpiece (Non-Optic)	VA2-HP	E350050
2	Control Unit VA370 with Hose (Non	VA370	U1007002
3	Tip		
	Varios Tip G4	G4	Z217104
	Varios Tip G6	G6	Z217106
	Varios Tip G8	G8	Z217108
4	FOOT CONTROL	FC-71	Z1008002

Product Name: Varios 370 Lux

Type: Varios 370 Lux

No.	Model	Order Code
1	VA370 LUX(230V)	Y1001343
2	VA370 LUX	Y1001386

Components:

No.	Name	Model	Order Code
1	Handpiece (Optic)	VA2-LUX-HP (Varios2 Lux	E351050
2	Control Unit VA370 with Hose (Optic)	VA370 Lux	U1007001
3	Tip		
	Varios Tip G4	G4	Z217104
	Varios Tip G6	G6	Z217106
	Varios Tip G8	G8	Z217108
4	FOOT CONTROL	FC-71	Z1008002

Product Name: Varios 970

Type: Varios 970

No.	Model	Order Code
1	VA970 (230V)	Y1001175
2	VA970	Y1004160

Order Code : Y1001175

Components:

No.	Name	Model	Order Code
1	Handpiece (Non-Optic)	VA2-HP (Varios2)	E350050
2	Hose (Non Optic)	VA970-SC	E350055
3	Control Unit VA970 (230V)	NE255	U1016001
4	Tip		
	Varios Tip G4	G4	Z217104
	Varios Tip G6	G6	Z217106
	Varios Tip G8	G8	Z217108
5	FOOT CONTROL	FC-70	Z1008001
6	VA Bottle 400 SET	VA-BOTTLE-400	Z1047002

Order Code : Y1004160

Components:

No.	Name	Model	Order Code
1	Handpiece (Non-Optic)	VA2-HP (Varios2)	U1006001
2	Hose (Non Optic)	VA970-SC	E350055
3	Control Unit VA970 (230V)	NE255	U1016001
4	Tip		
	Varios Tip G4	G4	Z217104
	Varios Tip G16	G16	Z217120
	Varios Tip G8	G8	Z217108
5	FOOT CONTROL	FC-70	Z1008001
6	VA Bottle 400 SET	VA-BOTTLE-400	Z1047002

Product Name: Varios 970 Lux

Type: Varios 970 Lux

No.	Model	Order Code
1	VA970 LUX(230V)	Y1001168
2	VA970 LUX	Y1004161

Order Code : Y1001168

Components:

No.	Name	Model	Order Code
1	Handpiece (Optic)	VA2-LUX-HP (Varios2 Lux)	E351050
2	Hose (Optic)	VA970LUX-SC	E351055
3	Control Unit VA970 (230V)	NE255	U1016001
4	Tip		
	Varios Tip G4	G4	Z217104
	Varios Tip G16	G6	Z217106
	Varios Tip G8	G8	Z217108
5	FOOT CONTROL	FC-70	Z1008001
6	VA Bottle 400 SET	VA-BOTTLE-400	Z1047002

Order Code : Y1004161

Components:

No.	Name	Model	Order Code
1	Handpiece (Optic)	VA2-LUX-HP (Varios2 Lux)	U1006001
2	Hose (Optic)	VA970LUX-SC	E351055
3	Control Unit VA970 (230V)	NE255	U1016001
4	Tip		
	Varios Tip G4	G4	Z217104
	Varios Tip G16	G16	Z217120
	Varios Tip G8	G8	Z217108
5	FOOT CONTROL	FC-70	Z1008001
6	VA Bottle 400 SET	VA-BOTTLE-400	Z1047002