

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 ultrasonic surgical system handpiece tip

Product Name: See No. 000267-12-21-10 004 Attachment 1
Model: See No. 000267-12-21-10 004 Attachment 1
Order Code: See No. 000267-12-21-10 004 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 lot number applied to this product is managed by the "Product Procedure Sheet".
This Declaration of Conformity is valid for a definite number of manufactured products.

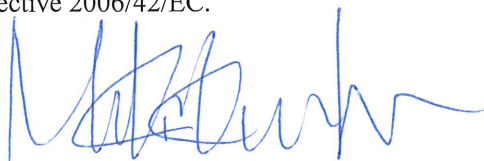
The undersigned hereby declares that the medical device, as specified above, conforms with the essential requirements listed in Annex I of EC Directive 93/42/EEC.

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: 2020-11-26
Date


Masaaki Kikuchi,
General Manager Quality Assurance Department

No.	Product name	Model	Order Code	No.	Product name	Model	Order Code
1	H-SG1	H-SG1	Z305151	41	G1-S	G1-S	Z305113
2	H-SG8	H-SG8	Z305155	42	P20-S	P20-S	Z305114
3	SG58	SG58	Z305141	43	P25R-S	P25R-S	Z305115
4	SCL1	SCL1	Z305170	44	P25L-S	P25L-S	Z305116
5	SCL1D	SCL1D	Z305171	45	E30RD-S	E30RD-S	Z305118
6	SCL2D	SCL2D	Z305182	46	E30LD-S	E30LD-S	Z305119
7	SCL3	SCL3	Z305172	47	E31D-S	E31D-S	Z305120
8	SCL3D	SCL3D	Z305173	48	E32D-S	E32D-S	Z305121
9	SCL4D	SCL4D	Z305184	49	V10-S	V10-S	Z305117
10	SCL5	SCL5	Z305174	50	Basic H-S Kit	Basic H-S Kit	Y1002775
11	SCL5D	SCL5D	Z305175	51	Bone Cut Kit	Bone Cut Kit	Y900688
12	socket lift kit for regular size implant	socket lift kit for regular size implant	Y1002841	52	Sinus Lift Kit	Sinus Lift Kit	Y900689
				53	Endo-S Kit	Endo-S Kit	Y900691
13	socket lift kit for wide size implant	socket lift kit for wide size implant	Y1002842	54	Implant Preparation Kit	Implant Preparation Kit	Y900774
14	SG1	SG1	Z305101	55	H-SG8R	H-SG8R	Z305156
15	SG1A	SG1A	Z305138	56	H-SG8L	H-SG8L	Z305157
16	SG2R	SG2R	Z305102	57	V-P10	V-P10	Y900184
17	SG2L	SG2L	Z305103	58	V-P11R	V-P11R	Y1002165
18	SG3	SG3	Z305104	59	V-P11L	V-P11L	Y1002166
19	SG4	SG4	Z305105	60	V-P12	V-P12	Y1002167
20	SG5	SG5	Z305106	61	Basic-S Kit	Basic-S Kit	Y900687
21	SG6D	SG6D	Z305107	62	SG68	SG68	Z305143
22	SG7D	SG7D	Z305108				
23	SG8	SG8	Z305109				
24	SG8A	SG8A	Z305139				
25	SG9	SG9	Z305110				
26	SG10	SG10	Z305111				
27	SG11	SG11	Z305112				
28	SG14R	SG14R	Z305122				
29	SG14L	SG14L	Z305123				
30	SG15A	SG15A	Z305124				
31	SG15B	SG15B	Z305125				
32	SG15C	SG15C	Z305126				
33	SG15D	SG15D	Z305127				
34	SG16A	SG16A	Z305128				
35	SG16B	SG16B	Z305129				
36	SG17	SG17	Z305132				
37	SG18R	SG18R	Z305133				
38	SG18L	SG18L	Z305134				
39	SG19	SG19	Z305135				
40	SG30	SG30	Z305137				