

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

Straight and Geared Angle Handpieces

Model name : See Attachment AT-DC-1-022

Model number : See Attachment AT-DC-1-022

Classification : Class IIa (Rule 5)

The serial number applied to this product is managed by the "Shipping history data".

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 60022568 0001

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

Tochigi, Japan: Sep 8, 2010



Yoshihiro Kanno, Quality Assurance Dept. Manager

管理番号	DC-C-1-02
発行部署	技術管理部

EC適合宣言書チェックリスト (ZLGガイドライン3.9 A4準拠)

製品カテゴリー名称			Straight and Geared Angle Handpieces		承認	作成
No.	宣言書内容	チェック	備考			
1	製造業者又は権限代理人の名称及び住所	ok				
2	適合宣言後のEC指令及びそれらの附属書	ok				
3	製造業者は適合宣言に排他的責任を負うという陳述	ok				
4	宣言の対象：製品データ(製品名、型式又はモデルNo.)	ok				
5	例えば、製品番号、ロット、バッチ又はシリアルNo.を参照する適合宣言	ok				
6	追加情報(例えば、適用規格、規格文書)	ok				
7	適合宣言の場所及び日付	ok				
8	法的に拘束力がある署名と認可された人の職務	ok				
9	適合評価手順に関わる公認機関の名称、住所および識別番号	ok				

※チェック欄には”OK”を記載する。

Attachment-1

Document Number: AT-DC-1-02Revision Number: 2Approval: N. ZaneffoDate: 03/09/10List of Existing 'Declaration of Conformities' (List of products labeled with the CE-Mark)

No.	Model No.: Catalogue No.*:	Product Name*:	Classification according. MDD*:	Date of Declaration of Conformity*:	Person/Depart ment in charge*:	Manufacturing Location*:	Distributor in EU*:	Responsible European Representative*:	Supplier name	Supplier activities
1	NAC-Y	Contra Angle Head	II a (Rule 5)	12/3/1998	Technical Affairs Department	Nakanishi Inc.	All EU Representative	NSK EUROPE GmbH		
2	BA 001	Contra Angle Head	II a (Rule 5)	12/3/1998						
3	NRS-Y	Reduction Contra Angle Head	II a (Rule 5)	12/3/1998						
4	BB-Y	Contra Angle Head	II a (Rule 5)	12/3/1998						
5	BA 004	Contra Angle Head	II a (Rule 5)	12/3/1998						
6	EC	1:1 Shank	II a (Rule 5)	12/3/1998						
7	BA100	1:1 Shank	II a (Rule 5)	18/8/1998						
8	TE-Y	Contra Angle Head	II a (Rule 5)	18/8/1998						
9	BA 028	Contra Angle Head	II a (Rule 5)	18/8/1998						
10	AR-YS	Prophy Head	II a (Rule 5)	18/8/1998						
11	BA 002	Prophy Head	II a (Rule 5)	18/8/1998						
12	AR-YK	Prophy Head	II a (Rule 5)	18/8/1998						
13	E10R	10:1 Speed Reduction Shank	II a (Rule 5)	12/3/1998						
14	NBBW-Y	Contra Angle Head	II a (Rule 5)	18/8/2001						
15	E64R	64:1 Speed Reduction Shank	II a (Rule 5)	12/3/1998						
16	E16R	16:1 Speed Reduction Shank	II a (Rule 5)	12/3/1998						
17	E4R	4:1 Speed Reduction Shank	II a (Rule 5)	12/3/1998						
18	FBG-E	1:4 Speed Increasing Handpiece	II a (Rule 5)	12/3/1998						
19	E256R	256:1 Speed Reduction Shank	II a (Rule 5)	12/3/1998						
20	E1024R	1024:1 Speed Reduction Shank	II a (Rule 5)	12/3/1998						

*The wording used to describe the contents of the columns can be changed according to the system and products of the company, some of the columns might not be necessary.

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21	EVA-Y	Contra Angle Head	II a (Rule 5)	18/8/2001	Technical Affairs Department	Nakanishi Inc.	All EU Representative	NSK EUROPE GmbH		
22	NM-Y	Contra Angle Head	II a (Rule 5)	18/8/2001						
23	E16RI	16:1 Speed Reduction Shank	II a (Rule 5)	12/3/1998						
24	E64RI	64:1 Speed Reduction Shank	II a (Rule 5)	12/3/1998						
25	E1024RI	1024:1 Speed Reduction Shank	II a (Rule 5)	12/3/1998						
26	E10RI	10:1 Speed Reduction Shank	II a (Rule 5)	12/3/1998						
27	E256RI	256:1 Speed Reduction Shank	II a (Rule 5)	12/3/1998						
28	IS-95	1:5 Speed Increasing Handpiece (Internal Sensor)	II a (Rule 5)	12/3/1998						
29	BA 216	1:5 Speed Increasing Handpiece (Internal Sensor)	II a (Rule 5)	12/3/1998						
30	E256R-TL	256:1 Speed Reduction Shank (with Torque Limit)	II a (Rule 5)	12/3/1998						
31	E1024R-TL	1024:1 Speed Reduction Shank (with Torque Limit)	II a (Rule 5)	12/3/1998						
32	SGM-I	Contra Angle Head	II a (Rule 5)	18/8/2001						
33	DEC342	Contra Angle Head	II a (Rule 5)	18/8/2001						
34	ES-95	1:5 Speed Increasing Handpiece	II a (Rule 5)	12/3/1998						
35	IS-85	1:5 Speed Increasing Handpiece (Internal Sensor)	II a (Rule 5)	18/8/2001						
36	DEC340	10:1 Speed Reduction Shank	II a (Rule 5)	18/8/2001						
37	ES-85	1:5 Speed Increasing Handpiece	II a (Rule 5)	18/8/2001						
38	EVA2-Y	Contra Angle Head	II a (Rule 5)	18/8/2001						
39	E32RI	32:1 Speed Reduction Shank	II a (Rule 5)	18/8/2001						
40	NAC-E	1:1 Contra Angle Handpiece (Latch Type)	II a (Rule 5)	12/3/1998						

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41	BA 101	1:1 Contra Angle Handpiece (Latch Type)	II a (Rule 5)	18/8/2001	Technical Affairs Department	Nakanishi Inc.	All EU Representative	NSK EUROPE GmbH		
42	NRS-E	10:1 Contra Angle Handpiece (Latch Type)	II a (Rule 5)	12/3/1998						
43	BB-E	1:1 Contra Angle Handpiece (Latch Type)	II a (Rule 5)	12/3/1998						
44	BA 104	1:1 Contra Angle Handpiece (Latch Type)	II a (Rule 5)	18/8/2001						
45	BA 102	1:1 Prophy Head Handpiece (Screw In Type)	II a (Rule 5)	18/8/2001						
46	BA-AR(K)	1:1 Prophy Head Handpiece (Snap On Type)	II a (Rule 5)	18/8/2001						
47	ARS-HA	Prophy Head	II a (Rule 5)	18/8/2001						
48	ARK-HA	Prophy Head	II a (Rule 5)	18/8/2001						
49	N-HA	Contra Angle Head	II a (Rule 5)	18/8/2001						
50	TE-HA	Contra Angle Head	II a (Rule 5)	18/8/2001						
51	VM-Y	Contra Angle Head	II a (Rule 5)	18/8/2001						
52	BA 009	Contra Angle Head	II a (Rule 5)	18/8/2001						
53	NPB-Y	Contra Angle Head	II a (Rule 5)	18/8/2001						
54	BA 005	Contra Angle Head	II a (Rule 5)	18/8/2001						
55	NFB-Y	Contra Angle Head	II a (Rule 5)	18/8/2001						
56	NPB-E	Type)	II a (Rule 5)	18/8/2001						
57	BA 105	Type)	II a (Rule 5)	18/8/2001						
58	NFB-E	Button Type)	II a (Rule 5)	18/8/2001						
59	SGP-I	Contra Angle Head	II a (Rule 5)	18/8/2001						
60	IS-25	1:1 Contra Angle Handpiece (Internal Spray)	II a (Rule 5)	12/3/1998						

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Revision Number: 2

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61	BA 205	1:1 Contra Angle Handpiece (Internal Spray)	II a (Rule 5)	12/3/1998	Technical Affairs Department	Nakanishi Inc.	All EU Representative	NSK EUROPE GmbH		
62	IS-15	4:1 Contra Angle Handpiece (Internal Spray)	II a (Rule 5)	12/3/1998						
63	BA 225	4:1 Contra Angle Handpiece (Internal Spray)	II a (Rule 5)	12/3/1998						
64	TEP-Y	Contra Angle Head	II a (Rule 5)	18/8/2001						
65	TEP-HA	Contra Angle Head	II a (Rule 5)	18/8/2001						
66	IS-35	Endodontic Handpiece (90° turn/Internal Spray)	II a (Rule 5)	12/3/1998						
67	IS-40	Spray)	II a (Rule 5)	12/3/1998						
68	IS-45	Spray)	II a (Rule 5)	18/8/2001						
69	IS-55L	Profin Handpiece (L=1.4mm/Internal Spray)	II a (Rule 5)	12/3/1998						
70	IS-55S	Profin Handpiece (L=0.4mm/Internal Spray)	II a (Rule 5)	12/3/1998						
71	TEQ-Y	Contra Angle Head	II a (Rule 5)	18/8/2001						
72	TEQ-HA	Contra Angle Head	II a (Rule 5)	18/8/2001						
73	IS-75	Spray)	II a (Rule 5)	12/3/1998						
74	BA 228	Spray)	II a (Rule 5)	12/3/1998						
75	IS-20	1:1 Contra Angle Handpiece (FG bur/Internal Spray)	II a (Rule 5)	12/3/1998						
76	VM-HA	Contra Angle Head	II a (Rule 5)	18/8/2001						
77	E20R	20:1 Speed Reduction Shank	II a (Rule 5)	18/8/2001						
78	IS-10	Spray)	II a (Rule 5)	18/8/2001						
79	IS-30	Endodontic Handpiece (90° turn/Internal Spray)	II a (Rule 5)	18/8/2001						
80	IS-70	Spray)	II a (Rule 5)	18/8/2001						

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81	NM-HA	Contra Angle Head	II a (Rule 5)	18/8/2001	Technical Affairs Department	Nakanishi Inc.	All EU Representative	NSK EUROPE GmbH		
82	IS-5	16:1 Contra Angle Handpiece (Internal Spray)	II a (Rule 5)	18/8/2001						
83	SGA-E	Angle Surgical Handpiece	II a (Rule 5)	12/3/1998						
84	SGAL-E	Angle Surgical Handpiece	II a (Rule 5)	18/8/2001						
85	SGS-E	Straight Surgical Handpiece	II a (Rule 5)	12/3/1998						
86	SGSL-E	Straight Surgical Handpiece	II a (Rule 5)	18/8/2001						
87	Podospray	Podiatry Handpiece	II a (Rule 5)	18/8/2001						
88	Spray Master	Podiatry Handpiece	II a (Rule 5)	18/8/2001						
89	EX-5	4:1 Straight Handpiece	II a (Rule 5)	12/3/1998						
90	EX-6	1:1 Straight Handpiece	II a (Rule 5)	12/3/1998						
91	BA 170	1:1 Straight Handpiece	II a (Rule 5)	18/8/2001						
92	IS-65	1:1 Straight Handpiece (Internal Spray)	II a (Rule 5)	12/3/1998						
93	BA 270	1:1 Straight Handpiece (Internal Spray)	II a (Rule 5)	12/3/1998						
94	Omnicut	Podiatry Handpiece	II a (Rule 5)	12/3/1998						
95	EX-6A	1:1 Straight Handpiece	II a (Rule 5)	18/8/2001						
96	SGA-E2G	1:2 Angle Surgical Handpiece	II a (Rule 5)	18/8/2001						
97	SGS-E2G	1:2 Straight Surgical Handpiece	II a (Rule 5)	18/8/2001						
98	E5L	Ti-Max E5L	II a (Rule 5)	18/8/2001						
99	E15L	Ti-Max E15L	II a (Rule 5)	18/8/2001						
100	E20L	Ti-Max E20L	II a (Rule 5)	18/8/2001						

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101	E25L	Ti-Max E25L	II a (Rule 5)	18/8/2001	Technical Affairs Department	Nakanishi Inc.	All EU Representative	NSK EUROPE GmbH		
102	E95L	Ti-Max E95L	II a (Rule 5)	18/8/2001						
103	E65L	Ti-Max E65L	II a (Rule 5)	18/8/2001						
104	E5	Ti-Max E5	II a (Rule 5)	18/8/2001						
105	E15	Ti-Max E15	II a (Rule 5)	18/8/2001						
106	E20	Ti-Max E20	II a (Rule 5)	18/8/2001						
107	E25	Ti-Max E25	II a (Rule 5)	18/8/2001						
108	E95	Ti-Max E95	II a (Rule 5)	18/8/2001						
109	E65	Ti-Max E65	II a (Rule 5)	18/8/2001						
110	Ti10L	optic)	II a (Rule 5)	14/3/2003						
111	Ti10LJ	optic)	II a (Rule 5)	14/3/2003						
112	Ti15L	optic)	II a (Rule 5)	14/3/2003						
113	Ti15LJ	optic)	II a (Rule 5)	14/3/2003						
114	Ti20L	1:1 FG Bur Contra Angle Handpiece (Internal Spray, with optic)	II a (Rule 5)	14/3/2003						
115	Ti20LJ	1:1 FG Bur Contra Angle Handpiece (Internal Spray, with optic)	II a (Rule 5)	14/3/2003						
116	Ti25L	1:1 Latch Bur Contra Angle Handpiece (Internal Spray, with optic)	II a (Rule 5)	14/3/2003						
117	Ti25LJ	1:1 Latch Bur Contra Angle Handpiece (Internal Spray, with optic)	II a (Rule 5)	14/3/2003						
118	Ti85L	1:5 Speed increased Contra Angle Handpiece (Internal Spray, with optic)	II a (Rule 5)	14/3/2003						
119	Ti85LJ	1:5 Speed increased Contra Angle Handpiece (Internal Spray, with optic)	II a (Rule 5)	14/3/2003						
120	Ti95L	1:5 Speed increased Contra Angle Handpiece (Internal Spray, with optic)	II a (Rule 5)	14/3/2003						

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121	Ti95LJ	For Profin tips Contra Angle Handpiece (Internal Spray, with optic)	II a (Rule 5)	14/3/2003	Technical Affairs Department	Nakanishi Inc.	All EU Representative	NSK EUROPE GmbH		
122	Ti65L	1:1 Straight Handpiece (Internal Spray, with optic)	II a (Rule 5)	14/3/2003						
123	Ti65LJ	1:1 Straight Handpiece (Internal Spray, with optic)	II a (Rule 5)	14/3/2003						
124	Ti55L	For Profin tips Contra Angle Handpiece (Internal Spray, with optic)	II a (Rule 5)	14/3/2003						
125	Ti55LJ	For Profin tips Contra Angle Handpiece (Internal Spray, with optic)	II a (Rule 5)	14/3/2003						
126	Ti50L	For EVA tips Contra Angle Handpiece (Internal Spray, with optic)	II a (Rule 5)	14/3/2003						
127	Ti50LJ	For EVA tips Contra Angle Handpiece (Internal Spray, with optic)	II a (Rule 5)	14/3/2003						
128	Ti35L	4:1 Endodontic Handpiece (90°turn, Hand File, Internal Spray)	II a (Rule 5)	14/3/2003						
129	Ti35LJ	4:1 Endodontic Handpiece (90°turn, Hand File, Internal Spray)	II a (Rule 5)	14/3/2003						
130	Ti45L	4:1 Endodontic Handpiece (90°turn, Hand File, Up and Down Internal Spray)	II a (Rule 5)	14/3/2003						
131	Ti45LJ	4:1 Endodontic Handpiece (90°turn, Hand File, Up and Down Internal Spray)	II a (Rule 5)	14/3/2003						
132	Ti75L	128:1 Endodontic Handpiece (360°Rotation, Ni-Ti File, Internal Spray)	II a (Rule 5)	14/3/2003						
133	Ti75LJ	128:1 Endodontic Handpiece (360°Rotation, Ni-Ti File, Internal Spray)	II a (Rule 5)	14/3/2003						
134	Ti10	16:1 Contra Angle Handpiece (Internal Spray)	II a (Rule 5)	14/3/2003						
135	Ti15	4:1 Contra Angle Handpiece (Internal Spray)	II a (Rule 5)	14/3/2003						
136	Ti20	1:1 FG Bur Contra Angle Handpiece (Internal Spray)	II a (Rule 5)	14/3/2003						
137	Ti25	1:1 Latch Bur Contra Angle Handpiece (Internal Spray)	II a (Rule 5)	14/3/2003						
138	Ti85	1:5 Speed Increased Contra Angle Handpiece (Internal Spray)	II a (Rule 5)	14/3/2003						
139	Ti95	1:5 Speed Increased Contra Angle Handpiece (Internal Spray)	II a (Rule 5)	14/3/2003						
140	Ti65	1:1 Straight Handpiece (Internal Spray)	II a (Rule 5)	14/3/2003						

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141	Ti55	For Proxim tips Contra Angle Handpiece (internal Spray)	II a (Rule 5)	14/3/2003	Technical Affairs Department	Nakanishi Inc.	All EU Representative	NSK EUROPE GmbH		
142	Ti50	For EVA tips Contra Angle Handpiece (internal Spray)	II a (Rule 5)	14/3/2003						
143	Ti35	(90°turn, Hand File, Internal Spray)	II a (Rule 5)	14/3/2003						
144	Ti45	(90°turn, Hand File, Up and Down Internal Spray)	II a (Rule 5)	14/3/2003						
145	Ti75	(360°Rotation, Ni-Ti File, Internal Spray)	II a (Rule 5)	14/3/2003						
146	NML-F16R	(360°Rotation, For ENDO-MATE TC)	II a (Rule 5)	14/3/2003						
147	NMA-F16R	(360°Rotation, with Apex Locator Probe)	II a (Rule 5)	14/3/2003						
148	TEP-F	(90°turn, Hand File, For ENDO-MATE TC)	II a (Rule 5)	14/3/2003						
149	TEQ-F	(90°turn, Engine File, For ENDO-MATE TC)	II a (Rule 5)	14/3/2003						
150	VM-F	(Up Down, Hand File, For ENDO-MATE TC)	II a (Rule 5)	14/3/2003						
151	ARS-F4R	(Screw-in type, For TASKAL Wizard)	II a (Rule 5)	14/3/2003						
152	ARK-F4R	4:1 Propphy Head (Snap-on type, For TASKAL Wizard)	II a (Rule 5)	14/3/2003						
153	NAC-F4R	(Engine Rubber Cup, For TASKAL Wizard)	II a (Rule 5)	14/3/2003						
154	TEQ-F4R	(EVA tips, Up Down, For TASKAL Wizard)	II a (Rule 5)	14/3/2003						
155	EVA-F	EVA Head (EVA tips, Up Down, For TASKAL Wizard)	II a (Rule 5)	14/3/2003						
156	PR-F	(For Disposable Propphy Head, For TASKAL Wizard)	II a (Rule 5)	14/3/2003						
157	F10R	10:1 Speed Reduction shank	II a (Rule 5)	27/4/2004						
158	F20R	20:1 Speed Reduction shank	II a (Rule 5)	27/4/2004						
159	Ti75L	1/128 Speed Reduction Contra Angle Handpiece	II a (Rule 5)	27/4/2004						
160	Ti70L	1/64 Speed Reduction Contra Angle Handpiece	II a (Rule 5)	27/4/2004						

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161	Ti57L	Prophy Angle Handpiece	II a (Rule 5)	27/4/2004	Technical Affairs Department	Nakanishi Inc.	All EU Representative	NSK EUROPE GmbH		
162	Ti70	1/64 Speed Reduction Contra Angle Handpiece	II a (Rule 5)	27/4/2004						
163	E16	1:1 Latch Bur Contra Angle Handpiece	II a (Rule 5)	27/4/2004						
164	C20	20:1 Speed Reduction Contra Angle Handpiece	II a (Rule 5)	27/4/2004						
165	E128R	128:1 Speed Reduction Shank	II a (Rule 5)	02/6/2004						
166	E20RI	20:1 Speed Reduction Shank	II a (Rule 5)	02/6/2004						
167	NFB-PTL	Contra Angle Head for Phatelus Air Motor	II a (Rule 5)	02/6/2004						
168	NPB-PTL	Contra Angle Head for Phatelus Air Motor	II a (Rule 5)	02/6/2004						
169	TE-PTL	Contra Angle Head for Phatelus Air Motor	II a (Rule 5)	02/6/2004						
170	VM-PTL	Contra Angle Head for Phatelus Air Motor	II a (Rule 5)	02/6/2004						
171	NRS-PTL	Motor	II a (Rule 5)	02/6/2004						
172	BA 409	Head	II a (Rule 5)	02/6/2004						
173	SGX-E10R	Angle Handpiece 10:1 Reduction	II a (Rule 5)	27/10/2004						
174	SGX-E20R	Angle Handpiece 20:1 Reduction	II a (Rule 5)	27/10/2004						
175	SGX-E1024R	Angle Handpiece 1024:1 Reduction	II a (Rule 5)	27/10/2004						
176	SGM-E20RI	Implant Handpiece Miniature Head 20:1 Hand	II a (Rule 5)	27/10/2004						
177	SGP-E20RI	Implant Handpiece PB 20:1 Reducer	II a (Rule 5)	27/10/2004						
178	SGM-E32RI	Implant Handpiece Miniature Head 32:1	II a (Rule 5)	27/10/2004						
179	SGP-E32RI	Implant Handpiece PB 32:1 Reducer	II a (Rule 5)	27/10/2004						
180	TEP-E10R	10:1 Endodontic Handpiece	II a (Rule 5)	27/10/2004						

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Attachment-1

Document Number: AT-DC-1-02Revision Number: 2List of Existing 'Declaration of Conformities' (List of products labeled with the CE-Mark)

No.	Model No.: Catalogue No. *:	Product Name*:	Classification according. MDD*:	Date of Declaration of Conformity*:	Person/Depart ment in charge*:	Manufacturing Location*:	Distributor in EU*:	Responsible European Representative*:	Supplier name	Supplier activities
181	Ti57	Ti-Max Ti57 PMTC Handpiece	II a (Rule 5)	27/10/2004	Technical Affairs Department	Nakanishi Inc.	All EU Representative	NSK EUROPE GmbH		
182	Ti57L	Ti-Max Ti57L PMTC Handpiece w/Light	II a (Rule 5)	27/10/2004						
183	NRS2-Y	Contra Angle Head 10:1 speed reduction	II a (Rule 5)	27/10/2004						
184	TEP-E4R	4:1 Endodontic Handpiece	II a (Rule 5)	27/10/2004						
185	NAC-E64R	64:1 Contra Angle Handpiece	II a (Rule 5)	27/10/2004						
186	FB-Y	Contra Angle Handpiece	II a (Rule 5)	27/10/2004						
187	NM-E64R	64:1 Contra Angle Handpiece Mini. Head	II a (Rule 5)	27/10/2004						
188	NMA-F4R	4:1 Contra Angle Handpiece Mini. Head	II a (Rule 5)	27/10/2004						
189	FFB-Y	Contra Angle Head	II a (Rule 5)	27/10/2004						
190	Ti95EX	Ti-Max Ti95EX 1:5 Increaser	II a (Rule 5)	27/10/2004						
191	Ti-SG20	Ti-Max Ti-SG20 Implant Handpiece 20:1	II a (Rule 5)	27/10/2004						
192	Ti-SG20L	Ti-Max Ti-SG20L Implant Handpiece 20:1 w/ Light	II a (Rule 5)	27/10/2004						
193	NCX-70	1:1 Contra Angle Handpiece	II a (Rule 5)	27/10/2004						
194	NCX-71	4:1 Contra Angle Handpiece	II a (Rule 5)	27/10/2004						
195	NCX-73	16:1 Contra Angle Handpiece	II a (Rule 5)	27/10/2004						
196	MP-F	Miniature Head for ENDO-MATE DT, TC	II a (Rule 5)	27/10/2004						
197	MP-F4R	4:1 Miniature Head f/ENDO-MATE DT,TC	II a (Rule 5)	27/10/2004						
198	MP-F10R	10:1 Miniature Head f/ENDO-MATE DT,TC	II a (Rule 5)	27/10/2004						
199	MP-F16R	16:1 Miniature Head f/ENDO-MATE DT,TC	II a (Rule 5)	27/10/2004						
200	MP-F20R	20:1 Miniature Head f/ENDO-MATE DT,TC	II a (Rule 5)	27/10/2004						

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Document Number: AT-DC-1-02

Revision Number: 2

List of Existing 'Declaration of Conformities' (List of products labeled with the CE-Mark)

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201	MP-E	1:1 Contra Angle Handpiece	II a (Rule 5)	27/10/2004	Technical Affairs Department	Nakanishi Inc.	All EU Representative	NSK EUROPE GmbH		
202	MP-E4R	4:1 Contra Angle Handpiece	II a (Rule 5)	27/10/2004						
203	MP-E10R	10:1 Contra Angle Handpiece	II a (Rule 5)	27/10/2004						
204	MP-E16R	16:1 Contra Angle Handpiece	II a (Rule 5)	27/10/2004						
205	MP-E64R	64:1 Contra Angle Handpiece	II a (Rule 5)	27/10/2004						
206	Ti12	10:1 Contra Angle Handpiece (Internal Spray)	II a (Rule 5)	27/10/2004						
207	Ti12L	optic)	II a (Rule 5)	27/10/2004						
208	NMAS-F4R	4:1 Contra Angle Handpiece	II a (Rule 5)	09/12/2004						
209	NMAS-F16R	16:1 Contra Angle Handpiece	II a (Rule 5)	09/12/2004						
210	NMAS-F20R	20:1 Contra Angle Handpiece	II a (Rule 5)	09/12/2004						
211	MPA-F4R	4:1 Contra Angle Handpiece	II a (Rule 5)	09/12/2004						
212	MPA-F16R	16:1 Contra Angle Handpiece	II a (Rule 5)	09/12/2004						
213	MPA-F20R	20:1 Contra Angle Handpiece	II a (Rule 5)	09/12/2004						
214	MPA-E16R	16:1 Contra Angle Handpiece	II a (Rule 5)	09/12/2004						
215	MPA-E64R	64:1 Contra Angle Handpiece	II a (Rule 5)	09/12/2004						
216	MPAS-F4R	4:1 Contra Angle Handpiece	II a (Rule 5)	09/12/2004						
217	MPAS-F10R	10:1 Contra Angle Handpiece	II a (Rule 5)	09/12/2004						
218	MPAS-F16R	16:1 Contra Angle Handpiece	II a (Rule 5)	09/12/2004						
219	MPAS-F20R	20:1 Contra Angle Handpiece	II a (Rule 5)	09/12/2004						
220	MPAS-E16R	16:1 Contra Angle Handpiece	II a (Rule 5)	09/12/2004						

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221	MPAS-E64R	64:1 Contra Angle Handpiece	II a (Rule 5)	09/12/2004	Technical Affairs Department	Nakanishi Inc.	All EU Representative	NSK EUROPE GmbH		
222	Ti-SG65L	Ti-Max Ti-SG65 Implant Handpiece w/ Light	II a (Rule 5)	11/08/2005						
223	FPB-Y	Contra Angle Head	II a (Rule 5)	08/12/2005						
224	NAC-W	Contra Angle Head	II a (Rule 5)	28/2/2007						
225	EC	1:1 Shank	II a (Rule 5)	28/2/2007						
226	ECM	1:1 Shank	II a (Rule 5)	28/2/2007						
227	ER4	4:1 Speed Reduction Shank	II a (Rule 5)	28/2/2007						
228	ER4M	4:1 Speed Reduction Shank	II a (Rule 5)	28/2/2007						
229	ER10	10:1 Speed Reduction Shank	II a (Rule 5)	28/2/2007						
230	ER10M	10:1 Speed Reduction Shank	II a (Rule 5)	28/2/2007						
231	ER16	16:1 Speed Reduction Shank	II a (Rule 5)	28/2/2007						
232	ER16M	16:1 Speed Reduction Shank	II a (Rule 5)	28/2/2007						
233	ER64	64:1 Speed Reduction Shank	II a (Rule 5)	28/2/2007						
234	ER64M	64:1 Speed Reduction Shank	II a (Rule 5)	28/2/2007						
235	Ti-ENDO	128:1 Angle Handpiece	II a (Rule 5)	28/2/2007						
236	EX-ENDO128	128:1 Angle Handpiece	II a (Rule 5)	28/2/2007						
237	TI-SG25L	Ti-Max Ti-SG25L Implant Handpiece w/	II a (Rule 5)	28/2/2007						
238	ER16i	16:1 Speed Reduction Shank	II a (Rule 5)	28/2/2007						
239	ER20i	20:1 Speed Reduction Shank	II a (Rule 5)	28/2/2007						
240	ER32i	32:1 Speed Reduction Shank	II a (Rule 5)	28/2/2007						

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241	ER64i	64:1 Speed Reduction Shank	II a (Rule 5)	28/2/2007	Technical Affairs Department	Nakanishi Inc.	All EU Representative	NSK EUROPE GmbH		
242	ER256i	256:1 Speed Reduction Shank	II a (Rule 5)	28/2/2007						
243	SGM-ER16i	Implant Handpiece Miniature Head 16:1	II a (Rule 5)	28/2/2007						
244	SGM-ER20i	Implant Handpiece Miniature Head 20:1	II a (Rule 5)	28/2/2007						
245	SGM-ER32i	Implant Handpiece Miniature Head 32:1	II a (Rule 5)	28/2/2007						
246	SGM-ER64i	Implant Handpiece Miniature Head 64:1	II a (Rule 5)	28/2/2007						
247	SGM-ER256i	Implant Handpiece Miniature Head 256:1	II a (Rule 5)	28/2/2007						
248	SGMS-ER20i	Implant Handpiece Miniature Head 20:1	II a (Rule 5)	28/2/2007						
249	SGQ-ER20h	Implant Handpiece Miniature Head 20:1	II a (Rule 5)	28/2/2007						
250	EX-5B	4:1 Straight Handpiece	II a (Rule 5)	28/2/2007						
251	EX-5BM	4:1 Straight Handpiece	II a (Rule 5)	28/2/2007						
252	EX-6B	1:1 Straight Handpiece	II a (Rule 5)	28/2/2007						
253	EX-6BM	1:1 Straight Handpiece	II a (Rule 5)	28/2/2007						
254	EX-6C	1:1 Straight Handpiece	II a (Rule 5)	28/2/2007						
255	EX-6CM	1:1 Straight Handpiece	II a (Rule 5)	28/2/2007						
256	EX-6D	1:1 Straight Handpiece	II a (Rule 5)	28/2/2007						
257	EX-6DM	1:1 Straight Handpiece	II a (Rule 5)	28/2/2007						
258	X95L	1:5 Speed Increased Contra Angle Handpiece (Internal Spray, with optic)	II a (Rule 5)	28/2/2007						
259	X25L	1:1 Latch Bur Contra Angle Handpiece (Internal Spray, with optic)	II a (Rule 5)	28/2/2007						
260	X15L	optic)	II a (Rule 5)	28/2/2007						

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261	X12L	10:1 Contra Angle Handpiece (Internal Spray, with optic)	II a (Rule 5)	28/2/2007	Technical Affairs Department	Nakanishi Inc.	All EU Representative	NSK EUROPE GmbH		
262	X10L	optic)	II a (Rule 5)	28/2/2007						
263	X20L	1:1 FG Bur Contra Angle Handpiece (Internal Spray, with optic)	II a (Rule 5)	28/2/2007						
264	X65L	1:1 Straight Handpiece (Internal Spray, with optic)	II a (Rule 5)	28/2/2007						
265	SGS-ES	1:1 Straight Surgical Handpiece Short type	II a (Rule 5)	28/2/2007						
266	SGS-EM	1:1 Straight Surgical Handpiece Medium type	II a (Rule 5)	28/2/2007						
267	SGS-EL	1:1 Straight Surgical Handpiece Long type	II a (Rule 5)	28/2/2007						
268	SGS-E2S	1:2 Straight Surgical Handpiece Short type	II a (Rule 5)	28/2/2007						
269	SGS-E2M	1:2 Straight Surgical Handpiece Medium type	II a (Rule 5)	28/2/2007						
270	SGS-E2L	1:2 Straight Surgical Handpiece Long type	II a (Rule 5)	28/2/2007						
271	FPB-EC	1:1 Contra Angle Handpiece (Push Type)	II a (Rule 5)	28/2/2007						
272	NAC-EC	1:1 Contra Angle Handpiece (Latch Type)	II a (Rule 5)	28/2/2007						
273	BB-EC	1:1 Contra Angle Handpiece (Latch Type)	II a (Rule 5)	28/2/2007						
274	NBBW-EC	1:1 Contra Angle Handpiece (Latch Type)	II a (Rule 5)	28/2/2007						
275	NM-EC	1:1 Contra Angle Handpiece (Latch Type)	II a (Rule 5)	28/2/2007						
276	FFB-EC	1:1 Contra Angle Handpiece (Push Type)	II a (Rule 5)	28/2/2007						
277	NRS2-EC	10:1 Contra Angle Handpiece (Push Type)	II a (Rule 5)	28/2/2007						
278	AR-EC (S)	1:1 Contra Angle Handpiece (Prophy)	II a (Rule 5)	28/2/2007						
279	AR-EC (K)	1:1 Contra Angle Handpiece (Prophy)	II a (Rule 5)	28/2/2007						
280	AR-ER4 (S)	4:1 Contra Angle Handpiece (Prophy)	II a (Rule 5)	28/2/2007						

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281	AR-ER4 (K)	4:1 Contra Angle Handpiece (Prophy)	II a (Rule 5)	28/2/2007	Technical Affairs Department	Nakanishi Inc.	All EU Representative	NSK EUROPE GmbH		
282	EVA-ER4	4:1 Contra Angle Handpiece (EVA)	II a (Rule 5)	28/2/2007						
283	MP-ER64	64:1 Contra Angle Handpiece(Push Type)	II a (Rule 5)	28/2/2007						
284	MPA-ER64	64:1 Contra Angle Handpiece(Push Type)	II a (Rule 5)	28/2/2007						
285	MPAS-ER64	64:1 Contra Angle Handpiece(Push Type)	II a (Rule 5)	28/2/2007						
286	NRS2-ER10	100:1 Contra Angle Handpiece (Push Type)	II a (Rule 5)	28/2/2007						
287	TEP-ER10	10:1 Contra Angle Handpiece (90°turn, Hand File)	II a (Rule 5)	28/2/2007						
288	NM-PTL	Contra Angle Head for Phatelus Air Motor	II a (Rule 5)	1/3/2007						
289	ARS-PTL	Contra Angle Head for Phatelus Air Motor	II a (Rule 5)	1/3/2007						
290	EVA-PTL	Contra Angle Head for Phatelus Air Motor	II a (Rule 5)	1/3/2007						
291	Ti85LA	1:5 Speed Increased Contra Angle Handpiece (Internal Spray, with optic)	II a (Rule 5)	19/3/2007						
292	SGA-ES	1:1 Straight Surgical Handpiece Short type	II a (Rule 5)	2/5/2007						
293	SGA-EM	1:1 Straight Surgical Handpiece Medium type	II a (Rule 5)	2/5/2007						
294	SGA-EL	1:1 Straight Surgical Handpiece Long type	II a (Rule 5)	2/5/2007						
295	SGA-E2S	1:2 Straight Surgical Handpiece Short type	II a (Rule 5)	2/5/2007						
296	SGA-E2M	1:2 Straight Surgical Handpiece Medium type	II a (Rule 5)	2/5/2007						
297	SGA-E2L	1:2 Straight Surgical Handpiece Long type	II a (Rule 5)	2/5/2007						
298	EVA-E	1:1 Contra Angle Handpiece (EVA)	II a (Rule 5)	21/9/2007						
299	NRS2-ECM	10:1 Contra Angle Handpiece (Push Type)	II a (Rule 5)	10/10/2007						
300	AR-ECM(S)	1:1 Contra Angle Handpiece (Prophy)	II a (Rule 5)	10/10/2007						

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301	AR-ECM(K)	1:1 Contra Angle Handpiece (Prophy)	II a (Rule 5)	10/10/2007	Technical Affairs Department	Nakanishi Inc.	All EU Representative	NSK EUROPE GmbH		
302	MP-ER64M	64:1 Contra Angle Handpiece(Push Type)	II a (Rule 5)	10/10/2007						
303	MPA-ER64M	64:1 Contra Angle Handpiece(Push Type)	II a (Rule 5)	10/10/2007						
304	MPAS-ER64M	64:1 Contra Angle Handpiece(Push Type)	II a (Rule 5)	10/10/2007						
305	NRS2-ER10M	100:1 Contra Angle Handpiece (Push Type)	II a (Rule 5)	10/10/2007						
306	TEP-ER10M	10:1 Contra Angle Handpiece (90°turn, Hand File)	II a (Rule 5)	10/10/2007						
307	EX-6L	1:1 Straight Handpiece	II a (Rule 5)	26/10/2007						
308	SGM-E10RI	Implant Handpiece Miniature Head 10:1	II a (Rule 5)	26/10/2007						
309	SGM-E16RI	Implant Handpiece Miniature Head 16:1	II a (Rule 5)	26/10/2007						
310	SGM-E64RI	Implant Handpiece Miniature Head 64:1	II a (Rule 5)	26/10/2007						
311	SGM-E256RI	Implant Handpiece Miniature Head 256:1	II a (Rule 5)	26/10/2007						
312	SGM-E1024RI	Implant Handpiece Miniature Head 1024:1	II a (Rule 5)	26/10/2007						
313	SGP-E10RI	Implant Handpiece PB 10:1 Reducer	II a (Rule 5)	26/10/2007						
314	SGP-E16RI	Implant Handpiece PB 16:1 Reducer	II a (Rule 5)	26/10/2007						
315	SGP-E64RI	Implant Handpiece PB 64:1 Reducer	II a (Rule 5)	26/10/2007						
316	SGP-E256RI	Implant Handpiece PB 256:1 Reducer	II a (Rule 5)	26/10/2007						
317	SGP-E1024RI	Implant Handpiece PB 1024:1 Reducer	II a (Rule 5)	26/10/2007						
318	X95	1:5 Speed Increased Contra Angle Handpiece (Internal Spray, non-optic)	II a (Rule 5)	13/2/2008						
319	X25	1:1 Latch Bur Contra Angle Handpiece (Internal Spray, non-optic)	II a (Rule 5)	13/2/2008						
320	X15	4:1 Contra Angle Handpiece (internal spray, non- optic)	II a (Rule 5)	13/2/2008						

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321	X12	10:1 Contra Angle Handpiece (internal spray, non-optic)	II a (Rule 5)	13/2/2008	Technical Affairs Department	Nakanishi Inc.	All EU Representative	NSK EUROPE GmbH		
322	X10	10:1 Contra Angle Handpiece (internal spray, non-optic)	II a (Rule 5)	13/2/2008						
323	X20	1:1 FG Bur Contra Angle Handpiece (Internal Spray, non-optic)	II a (Rule 5)	13/2/2008						
324	X65	1:1 Straight Handpiece (Internal Spray, non-optic)	II a (Rule 5)	13/2/2008						
325	NAC-GS	1:1 Contra Angle Handpiece (Latch Type)	II a (Rule 5)	13/5/2008						
326	GS65	1:1 Straight Handpiece	II a (Rule 5)	13/5/2008						
327	X35	10:1 Contra Angle Handpiece (non-optic)	II a (Rule 5)	30/5/2008						
328	X35L	10:1 Contra Angle Handpiece (with optic)	II a (Rule 5)	30/5/2008						
329	X70	64:1 Contra Angle Handpiece (non-optic)	II a (Rule 5)	30/5/2008						
330	X70L	64:1 Contra Angle Handpiece (with optic)	II a (Rule 5)	30/5/2008						
331	X75	128:1 Contra Angle Handpiece (non-optic)	II a (Rule 5)	30/5/2008						
332	X75L	128:1 Contra Angle Handpiece (with optic)	II a (Rule 5)	30/5/2008						
333	X50	4:1 Contra Angle Handpiece (non-optic)	II a (Rule 5)	30/5/2008						
334	X50L	4:1 Contra Angle Handpiece (with optic)	II a (Rule 5)	30/5/2008						
335	X55	4:1 Contra Angle Handpiece (non-optic)	II a (Rule 5)	30/5/2008						
336	X55L	4:1 Contra Angle Handpiece (with optic)	II a (Rule 5)	30/5/2008						
337	X57	16:1 Contra Angle Handpiece (non-optic)	II a (Rule 5)	30/5/2008						
338	X57L	16:1 Contra Angle Handpiece (with optic)	II a (Rule 5)	30/5/2008						
339	TEP-ER4M	4:1 Contra Angle Handpiece	II a (Rule 5)	2/6/2008						
340	X-SG20L	Ti-Max X-SG20L Implant Handpiece 20:1 w/ Light	II a (Rule 5)	6/2/2009						

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341	SG20	S-Max SG20 Implant Handpiece 20:1	II a (Rule 5)	6/2/2009	Technical Affairs Department	Nakanishi Inc.	All EU Representative	NSK EUROPE GmbH		
342	X-SG93	Ti-Max X-SG93 Contra Angle Handpiece 1:3	II a (Rule 5)	6/3/2009						
343	X-SG93L	Ti-Max X-SG93L Contra Angle Handpiece 1:3 w/ Light	II a (Rule 5)	6/3/2009						
344	X-SG25L	Ti-Max X-SG25L Contra Angle Handpiece 1:1 w/ Light	II a (Rule 5)	17/3/2009						
345	M15	S-Max M15	II a (Rule 5)	17/3/2009						
346	M15L	S-Max M15L	II a (Rule 5)	17/3/2009						
347	M25	S-Max M25	II a (Rule 5)	17/3/2009						
348	M25L	S-Max M25L	II a (Rule 5)	17/3/2009						
349	M95	S-Max M95	II a (Rule 5)	17/3/2009						
350	M95L	S-Max M95L	II a (Rule 5)	17/3/2009						
351	M65	S-Max M65	II a (Rule 5)	24/3/2009						
352	X-SG65L	Ti-Max X-SG65L Straight Handpiece 1:1 w/ Light	II a (Rule 5)	18/5/2009						
353	EVA-ER4M	4:1 Contra Angle Handpiece (EVA)	II a (Rule 5)	13/7/2010						
354	NBB-Y	Contra Angle Head	II a (Rule 5)	18/8/2001						
355										
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