

EC DECLARATION OF CONFORMITY

TF n° 004 / Rev.0017

Medical Device Family
CONTRA-ANGLES & HANDPIECES

The Legal Manufacturer,

Bien-Air Dental SA

Länggasse 60
CH-2504 Bienne
Switzerland,

declares under its sole responsibility that the medical devices and their accessories listed below, meet the provisions of the European Medical Device Directive 93/42/EEC which apply to them and that Annex II (excl. section 4) of the aforementioned directive, has been followed for their conformity assessment.


Notified Body

TÜV SÜD Product Service GmbH
Ridlerstr. 65,
D-80339 München
Germany

CE Marking

CE 0123

European Authorised Representative: Bien-Air France
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94110 Arcueil
France



Renaud VILLARD
Regulatory Affairs Manager



Place and date of issue

Medical Device Family
CONTRA-ANGLES & HANDPIECES

Product list - TF no. 004

Medical devices

No. crt	Reference number	Designation	Product Description	Class	Rule*	CE
1	1600052-001	PM 1:1 EXT SPRAY	Hand Piece GMDN 38611	Ila	9	0123
2	1600200-001	CA 1:1 EXT SPRAY	Contra-Angle GMDN 38611	Ila	9	0123
4	1600289-001	PM 10:1 PROPHY	Hand Piece GMDN 38611	Ila	9	0123
5	1600290-001	CA 15:1 PROPHY	Contra-Angle GMDN 38611	Ila	9	0123
6	1600325-001	CA 1:5	Contra-Angle GMDN 38611	Ila	9	0123
7	1600383-001	PM 1:1	Hand Piece GMDN 38611	Ila	9	0123
8	1600384-001	CA 1:1 L	Contra-Angle GMDN 38611	Ila	9	0123
9	1600385-001	CA 10:1 L	Contra-Angle GMDN 38611	Ila	9	0123
10	1600386-001	CA 1:5 L	Contra-Angle GMDN 38611	Ila	9	0123
11	1600424-001	CA 1:1	Contra-Angle GMDN 38611	Ila	9	0123
12	1600425-001	CA 10:1	Contra-Angle GMDN 38611	Ila	9	0123
13	1600436-001	PM 1:2	Hand Piece GMDN 38611	Ila	9	0123
14	1600598-001	CA 20:1 L	Contra-Angle GMDN 38611	Ila	9	0123
15	1600632-001	CA 20:1	Contra-Angle GMDN 38611	Ila	9	0123
16	1600682-001	PM 1:1 - 100017	Hand Piece GMDN 38611	Ila	9	0123
17	1600690-001	CA 1:5 L MICRO-SERIES	Contra-Angle GMDN 38611	Ila	9	0123
18	1600691-001	CA 1:1 L MICRO-SERIES	Contra-Angle GMDN 38611	Ila	9	0123
19	1600692-001	CA 20:1 L MICRO-SERIES	Contra-Angle GMDN 38611	Ila	9	0123
20	1600693-001	PM 1:1 MICRO-SERIES	Hand Piece GMDN 38611	Ila	9	0123
21	1600785-001	CA 20:1 L KM	Contra-Angle GMDN 38611	Ila	9	0123
22	1600786-001	CA 20:1 L KM MICRO-SERIES	Contra-Angle GMDN 38611	Ila	9	0123
23	1600873-001	CA 20:1 L MICRO-SERIES	Contra-Angle GMDN 38611	Ila	9	0123
24	1600874-001	CA 20:1 L KM MICRO-SERIES	Contra-Angle GMDN 38611	Ila	9	0123
25	1600938-001	CA 1:1 L EVO15 MICRO-SERIES	Contra-Angle GMDN 38611	Ila	9	0123
26	1600939-001	CA 1:1 L EVO15	Contra-Angle GMDN 38611	Ila	9	0123
27	1600940-001	CA 1:5 L EVO15 MICRO-SERIES	Contra-Angle GMDN 38611	Ila	9	0123
28	1600941-001	CA 1:5 L EVO15	Contra-Angle GMDN 38611	Ila	9	0123
29	1600955-001	CA ENDO	Contra-Angle GMDN 38611	Ila	9	0123
30	1601055-001	CA 1:2.5 L MS	Contra-Angle GMDN 38611	Ila	9	0123
31	1601143-001	CA eLINE 1:1 L	Contra-Angle GMDN 38611	Ila	9	0123
32	1601138-001	CA NOVA 1:5L MS	Contra-Angle GMDN 38611	Ila	9	0123
33	1601139-001	CA NOVA 1:5L	Contra-Angle GMDN 38611	Ila	9	0123
34	1601136-001	CA NOVA 1:1L MS	Contra-Angle GMDN 38611	Ila	9	0123
35	1601137-001	CA NOVA 1:1L	Contra-Angle GMDN 38611	Ila	9	0123

* Classification rules per Annex IX of the European Directive 93/42/EEC, as amended.