EC DECLARATION OF CONFORMITY

TF No. 004 */ Rev. 0002*

Medical Device Family

CA&HP

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 Regulation (EU) 2017/745 which apply to them and that Annex IX (excluding chapter II) of the aforementioned Regulation has been followed for their conformity assessment. This declaration is supported by the Quality System approval to ISO 13485 issued by the below-mentioned Notified Body.

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

CE Marking

CE 0123

European Authorised Representative: Bien-Air Europe Sàrl
19-21 rue du 8 mai 1945
94110 Arcueil
France

MDR Certificate Number: G10 065560 0004

Manufacturer SRN (Single Registration Number): CH-MF-000014661

Authorised representative SRN: FR-AR-000011942

R. Villard
Quality & Regulatory Affairs
Manager
Bien-Air Dental SA

Bienne
05/03/2024

Place and date of issue

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Medical Device Family

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Product list - TF no. 004

Medical devices

Inc.	Ref. number	Designation	Basic UDI-DI	Intended purpose	Class	Rule*	CE
1	1600052-001	PM 1:1 EXT SPRAY	++J007CAHP0001GQ	Device intended for use in general dentistry for restorative dentistry and prophylaxis. Device intended for use in oral surgery, maxillofacial surgery and periodontology.	IIa	9	CE 0123
2	1600052-0	PM 1:1 EXT SPRAY					
3	1601190-001	PM 1:1 TWIST DRILL		Device intended for use in oral surgery, maxillofacial surgery and periodontology.			
4	1601190-GOV	PM 1:1 TWIST DRILL					
5	1600436-001	PM 1:2	++J007CAHP0001GQ	Device intended for use in oral surgery, maxillofacial surgery and periodontology.	IIa	9	CE 0123
6	1600436-GOV	PM 1:2					
7	1601163-001	CA 1:2.5 L	++J007CAHP0001GQ	Device intended for use in oral surgery, maxillofacial surgery and periodontology	IIa	9	CE 0123
8	1601164-001	CA 1:2.5 L MS					
9	1600289-001	PM 10:1 PROPHY	++J007CAHP0001GQ	Devices intended for used in general dentistry for dental prophylaxis.	IIa	9	CE 0123
10	1600290-001	CA 15:1 PROPHY					
11	1600383-001	PM 1:1	++J007CAHP0001GQ	Devices intended for use in general dentistry for restorative dentistry.	IIa	9	CE 0123
12	1600383-0	PM 1:1					
13	1600693-001	PM 1:1 MICRO-SERIES					
14	1600693-0	PM 1:1 MICRO-SERIES					
15	1600682-001	PM 1:1 BAJ					
16	1600325-001	CA 1:5	++J007CAHP0001GQ	Devices intended for use in general dentistry for restorative dentistry.	IIa	9	CE 0123
17	1600386-001	CA 1:5 L					
18	1600386-0	CA 1:5 L					
19	1600690-001	CA 1:5 L MICRO-SERIES					
20	1600690-0	CA 1:5 L MICRO-SERIES					

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Inc.	Ref. number	Designation	Basic UDI-DI	Intended purpose	Class	Rule*	CE
21	1601138-001	CA NOVA 1:5L MS					
22	1601138-0	CA NOVA 1:5L MS					
23	1601139-001	CA NOVA 1:5L					
24	1601139-0	CA NOVA 1:5L					
25	1601254-001	CA NOVA 1:5					
26	1601144-001	CA eLINE 1:5 L					
27	1600598-001	CA 20:1 L	++J007CAHP0001GQ	Devices intended for used in implantology	IIa	9	CE 0123
28	1600632-001	CA 20:1					
29	1600692-001	CA 20:1 L MICRO-SERIES					
30	1600692-0	CA 20:1 L MICRO-SERIES					
31	1600692-GOV	CA 20:1 L MICRO-SERIES					
32	1600785-001	CA 20:1 L KM					
33	1600786-001	CA 20:1 L KM MICRO-SERIES					
34	1600873-001	CA 20:1 L MICRO-SERIES					
35	1600874-001	CA 20:1 L KM MICRO-SERIES					
36	1600384-001	CA 1:1 L	++J007CAHP0001GQ	Devices intended for use in general dentistry for restorative dentistry, dental prophylaxis, orthodontics and endodontics.	IIa	9	CE 0123
37	1600384-0	CA 1:1 L					
38	1600424-001	CA 1:1					
39	1600424-0	CA 1:1					
40	1600691-001	CA 1:1 L MICRO-SERIES					
41	1600691-0	CA 1:1 L MICRO-SERIES					
42	1601136-001	CA NOVA 1:1L MS					
43	1601136-0	CA NOVA 1:1L MS					
44	1601137-001	CA NOVA 1:1L					
45	1601137-0	CA NOVA 1:1L					
46	1601253-001	CA NOVA 1:1					
47	1601143-001	CA eLINE 1:1 L					

**Classification rules according to the Annex VIII of the Regulation (EU) 2017/745, as amended.*

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