

EC DECLARATION OF CONFORMITY

TF No. **006** / Rev. 0016

Medical Device Family
ELECTRIC MICROMOTORS

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

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CE Marking

CE 0123

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Bienne 03/06/21

Place and date of issue

Medical Device Family
ELECTRIC MICROMOTORS

Product list - TF no. 006

Medical devices

No. crt	Reference number	Designation	Product Description	Class	Rule*	CE
1.	1600071-001	MOT MC3 IR	Micromotor MC3 IR	Ila	9	0123
2.	1600073-001	MOT MC2 IR	Micromotor MC2 IR	Ila	9	0123
3.	1600075-001	MOT MC2 GT AV	Micromotor MC2 GT AV	Ila	9	0123
4.	1600077-001	MOT MC3 LK	Micromotor MC3 LK	Ila	9	0123
5.	1600078-001	MOT ISOLITE LK	Micromotor ISOLITE LK	Ila	9	0123
6.	1600375-001	MOT MX	Micromotor MX	Ila	9	0123
7.	1600633-001	MOT MC2 40 GT IR	Micromotor MC2 40 GT IR	Ila	9	0123
8.	1600677-001	MOT MX2	Micromotor MX2	Ila	9	0123
9.	1600680-001	MOT MC3 (LED)	Micromotor MC3 LED	Ila	9	0123
10.	1600681-001	MOT ISOLITE (LED)	Micromotor ISOLITE LED	Ila	9	0123
11.	1600711-001	MOT MX2_100781	Micromotor MX2 for 100781	Ila	9	0123
12.	1600751-001	MOT MCX LED	Micromotor MCX LED	Ila	9	0123
13.	1600755-001	MOT MX-i LED	Micromotor MX-i LED	Ila	9	0123
14.	1600780-001	MOT MCX	Micromotor MCX	Ila	9	0123
15.	1600825-001	MOT MX-i	Micromotor MX-i	Ila	9	0123
16.	1600875-001	MOT MX-i LED_102971	Micromotor MX-i LED for 102971	Ila	9	0123
17.	1600957-001	MOT MCX LED_102516	Micromotor MCX LED 102516	Ila	9	0123
18.	1600987-001	MOTOR MC3 LED_100130	Micromotor MC3 LED for 100130	Ila	9	0123
19.	1600991-001	MOT MCX LED_102062	Micromotor MCX-LED for 102062	Ila	9	0123
20.	1601008-001	MOT MX-I LED 3RD GEN	Micromotor MX-I LED 3RD GEN	Ila	9	0123
21.	1601010-001	MOT MCX LED_103343	Micromotor MCX LED for 103343	Ila	9	0123
22.	1601042-001	MOTOR MC3 IR_100130	Micromotor MC3 IR for 100130	Ila	9	0123
23.	1601046-001	MOT MX2_102345	Micromotor MX2 for 102345	Ila	9	0123
24.	1601049-001	MOT MCX LED_102345	Micromotor MCX for 102345	Ila	9	0123
25.	1601158-001	MOT MCX LED 100016	Micromotor MCX LED for 100016	Ila	9	0123

Accessories: Hoses/Couplings

No. crt	Reference number	Designation	Product Description	Class	Rule*	CE
1.	104.33.30-001	HOSE 4VLM GREY_100718	Board to micromotor connecting hose 4VLM GREY for 100718	Ila	2	0123
2.	104.38.07-001	HOSE 4VLM11 SURF6_102342	Board to micromotor connecting hose 4VLM11 SURF6 for 102342	Ila	2	0123
3.	112.43.19-001	TY T_100781 RAL 7035	Board to micromotor connecting hose TY T for 100781	Ila	2	0123
4.	112.43.20-001	HOSE ISOLITE SWIVEL_100392	Board to micromotor connecting hose ISOLITE SWIVEL for 100392	Ila	2	0123
5.	1600097-001	HOSE 4VLM11 GREY	Board to micromotor connecting hose 4VLM11 GREY	Ila	2	0123
6.	1600102-001	HOSE 4VLM GREY	Board to micromotor connecting hose 4VLM Ø10 GREY	Ila	2	0123
7.	1600120-001	HOSE ISOLITE/MC2 GREY	Board to micromotor connecting hose ISOLITE/MC2 GREY	Ila	2	0123
8.	1600132-001	HOSE ISOLITE SWIVEL GREY	Board to micromotor connecting hose ISOLITE SWIVEL GREY	Ila	2	0123
9.	1600134-001	HOSE ISOLITE WATER ADJ GREY	Board to micromotor connecting hose ISOLITE WATER ADJ GREY	Ila	2	0123
10.	1600298-001	HOSE ISOLITE/MC2 SWIVEL GREY	Board to micromotor connecting hose ISOLITE/MC2 SWIVEL GREY	Ila	2	0123
11.	1600315-001	HOSE ISOLITE/MC2 COILED BLACK	Board to micromotor connecting hose ISOLITE/MC2 COILED BLACK	Ila	2	0123
12.	1600387-001	HOSE 4VX GREY	Board to micromotor connecting hose 4VX GREY	Ila	2	0123
13.	1600397-001	HOSE 4VR400 GREY	Board to micromotor connecting hose 4VR400 GREY	Ila	2	0123
14.	1600423-001	HOSE 4VR400 SURF6_102342	Board to micromotor connecting hose 4VR400 SURF6 for 102342	Ila	2	0123
15.	1600428-001	HOSE B-4VX GREY	Board to micromotor connecting hose B-4VX GREY	Ila	2	0123
16.	1600487-050	HOSE 4VLR11_100392	Board to micromotor connecting hose 4VLR Ø11 for 100392	Ila	2	0123
17.	1600509-001	TY 4VX_102339	Board to micromotor connecting hose 4VX for 102339	Ila	2	0123

No. crt	Reference number	Designation	Product Description	Class	Rule*	CE
18.	1600516-001	HOSE MC2 GREY	Board to micromotor connecting hose MC2 GREY	Ila	2	0123
19.	1600536-001	HOSE 4VX GREY	Board to micromotor connecting hose 4VX GREY	Ila	2	0123
20.	1600537-001	HOSE B-4VX GREY	Board to micromotor connecting hose B-4VX GREY	Ila	2	0123
21.	1600606-001	CABLE MX LED	Board to micromotor connecting cable MX LED	Ila	2	0123
22.	1600660-001	4BVX_102516	Board to micromotor connecting hose 4BVX for 102516	Ila	2	0123
23.	1600661-001	TY 4VX 1.365m_102339	Board to micromotor connecting hose 4VX 1.365m for 102339	Ila	2	0123
24.	1600662-001	TY 4VR 400 1.365M_102339	Board to micromotor connecting hose 4VR 400 1.365M for 102339	Ila	2	0123
25.	1600663-001	TY MC2 E 1.365m_102339	Board to micromotor connecting hose MC2 E 1.365M for 102339	Ila	2	0123
26.	1600664-001	TY MC2 LE T 1.365m_102339	Board to micromotor connecting hose MC2 LE T 1.365M for 102339	Ila	2	0123
27.	1600683-001	HOSE 4VLM11 GREY_102578	Board to micromotor connecting hose 4VLM Ø11 2.2m GREY for_102578	Ila	2	0123
28.	1600700-001	HOSE MX2 400 GREY	Board to micromotor connecting hose MX2 400 GREY	Ila	2	0123
29.	1600753-001	COUPLING SOCKET B B-MX2	COUPLING SOCKET B B-MX2 connect to micromotors	Ila	2	0123
30.	1600756-001	HOSE MCX GREY	Board to micromotor connecting hose MCX GREY	Ila	2	0123
31.	1600762-001	HOSE B-MX2 GREY	Board to micromotor connecting hose B-MX2 GREY	Ila	2	0123
32.	1600772-001	HOSE MX2 400° GREY_100718	Board to micromotor connecting hose MX2 400° GREY	Ila	2	0123
33.	1600773-001	HOSE MX2 400°_100781	Board to micromotor connecting hose MX2 400°	Ila	2	0123
34.	1600781-001	HOSE MX2 400 GREY 2.2m	Board to micromotor connecting hose MX2 400 GREY 2.2m	Ila	2	0123
35.	1600783-001	HOSE MX2 400 SURF 6_102342	Board to micromotor connecting hose MX2 400 SURF 6 for 102342	Ila	2	0123
36.	1600809-001	HOSE MX2 400 GREY 20.2x40	Board to micromotor connecting hose MX2 400 GREY Ø20.2x40	Ila	2	0123

No. crt	Reference number	Designation	Product Description	Class	Rule*	CE
37.	1600820-001	HOSE MCX GREY_102342	Board to micromotor connecting hose MCX GREY for 102342	Ila	2	0123
38.	1600824-001	HOSE B-MCX GREY	Board to micromotor connecting hose B-MCX GREY	Ila	2	0123
39.	1600843-001	HOSE B-MX2 GREY_102516	Board to micromotor connecting hose B-MCX GREY for 102516	Ila	2	0123
40.	1600844-001	HOSE B-MCX GREY_102516	Board to micromotor connecting hose B-MCX GREY_for 102516	Ila	2	0123
41.	1600850-001	COUPLING SOCKET B B-MX2_102516	COUPLING SOCKET B B-MX2 connect to micromotors for 102516	Ila	2	0123
42.	1600881-001	CABLE MX LED 3M	Board to micromotor connecting cable MX LED 3M	Ila	2	0123
43.	1600885-001	HOSE ISOLITE/MC2 GREY_100991	Board to micromotor connecting hose ISOLITE/MC2 GREY for 100991	Ila	2	0123
44.	1600920-001	HOSE MCX GREY 2.2m	Board to micromotor connecting hose MCX GREY 2.2m	Ila	2	0123
45.	1600958-001	HOSE ISOLITE WATER ADJ GREY	Board to micromotor connecting hose ISOLITE WATER ADJ GREY	Ila	2	0123
46.	1600971-001	HOSE B-MX2 GREY 102345	Board to micromotor connecting hose B-MX2 GREY for 102345	Ila	2	0123
47.	1600974-001	COUPLING SOCKET BB-MX2_102345	COUPLING SOCKET BB-MX2 connect to micromotors for 102516	Ila	2	0123
48.	1600986-001	HOSE 4VLM Ø11 grey_100130	Board to micromotor connecting hose 4VLM Ø11 grey for 100130	Ila	2	0123
49.	1601009-001	CABLE MX-I LED 3RD GEN	Board to micromotor connecting cable MX-I LED 3RD GEN	Ila	2	0123
50.	1601069-001	CABLE MX-i LED	Board to micromotor connecting cable MX-i LED	Ila	2	0123
51.	1601081-001	HOSE MCX 400 GREY	Board to micromotor connecting hose MCX 400 GREY	Ila	2	0123
52.	1601096-001	HOSE MCX GREY 400° Ø20.2x40	Board to micromotor connecting hose MCX-400° GREY Ø20.2x40	Ila	2	0123
53.	1601097-001	HOSE MCX 400°_100781	Board to micromotor connecting hose MCX 400° for 100781	Ila	2	0123

No. crt	Reference number	Designation	Product Description	Class	Rule*	CE
54.	1601159-001	HOSE MCX 100016	Board to micromotor connecting hose MCX for 100016	Ila	2	0123
55.	1601160-001	CABLE MX-i LED 1.4m_100781	Board to micromotor connecting cable MX-i LED	Ila	2	0123
56.	1601161-001	CABLE MX-i LED 0.8m_100781	Board to micromotor connecting cable MX-i LED	Ila	2	0123

Accessories: Boards

No. crt	Reference number	Designation	Product Description	Class	Rule*	CE
1.	1500554-001	BOARD RELAY	Dual motor switch board	Ila	9	0123
2.	1501566-001	BOARD DMCX without white box	Board to control MCX micromotor	Ila	9	0123
3.	1501657-001	BOARD iCHIROPRO	Board to control MX-i micromotor	Ila	9	0123
4.	1502046-001	BOARD DMX-i	Board to control MX-i micromotor	Ila	9	0123
5.	1502116-001	PL DMX3 M_100781	Board to control MX2, MX-i and MCX micromotors for 100781	Ila	9	0123
6.	1502121-001	BOARD DMX3 M BtoW	Board to control MX2, MX-i and MCX micromotors	Ila	9	0123
7.	1502122-001	BOARD DMX3 M Bornier	Board to control MX2, MX-i and MCX micromotors	Ila	9	0123
8.	1502123-001	BOARD DMX3 M BtoB	Board to control MX2, MX-i and MCX micromotors	Ila	9	0123
9.	1502140-001	DMX3 CAN	Board to control MX2, MX-i and MCX micromotors	Ila	9	0123
10.	1502379-001	DMX3_100989	Board to control MX2, MX-i and MCX micromotors	Ila	9	0123
11.	1502456-001	DMX3 M_101726	Board to control MX2, MX-i and MCX micromotors	Ila	9	0123
12.	1502695-001	BOARD DMCX M BtoW	Board to control MCX micromotor	Ila	9	0123
13.	1502696-001	BOARD DMCX M Bornier	Board to control MCX micromotor	Ila	9	0123
14.	1502697-001	BOARD DMCX M BtoB	Board to control MCX micromotor	Ila	9	0123
15.	1600145-001	CONVERTER PL 970 MC2	Board to control MC2 / MC3 motor	Ila	9	0123
16.	1600146-001	CONVERTER PL 970 FO MC2	Board to control MC2 / MC3 motor	Ila	9	0123
17.	1600149-001	CONVERTER PLPE 970	Board to control MC2 / MC3 motor	Ila	9	0123

No. crt	Reference number	Designation	Product Description	Class	Rule*	CE
18.	1600150-001	CONVERTER PLPE 970 FO	Board to control MC2 / MC3 motor	Ila	9	0123
19.	1600151-001	CONVERTER PLPE 970 FO 170 kPA	Board to control MC2 / MC3 motor	Ila	9	0123
20.	1600666-001	BOARD DMX2 PRO	Board to control MX2 micromotor	Ila	9	0123
21.	1600666-050	BOARD DMX2 PRO	Board to control MX2 micromotor	Ila	9	0123
22.	1600696-001	BOARD DMX2 PLUS	Board to control MX2 micromotor	Ila	9	0123
23.	1600811-001	BOARD DMCX	Board to control MCX micromotor	Ila	9	0123
24.	1600903-00A	BOARD DMX3 FULL OPEN	Board to control MX2, MX-i and MCX micromotors	Ila	9	0123
25.	1600903-00B	BOARD DMX3 MCX 100 RPM	Board to control one MCX micromotor	Ila	9	0123
26.	1600903-0DI	DMX3_100989	Board to control MX2, MX-i and MCX micromotors for 100989	Ila	9	0123
27.	1600903-0GC	DMX3_102516	Board to control MX2, MX-i and MCX micromotors for 102516	Ila	9	0123
28.	1600982-001	BOARD DMX3 CAN BOX	Box containing board to control MX2, MX-i and MCX micromotors	Ila	9	0123

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