

EC DECLARATION OF CONFORMITY

TF No. **002** / Rev. 0016

Medical Device Family
CHIROPRO

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
19-21 rue du 8 mai 1945
94110 Arcueil
France



Renaud VILLARD
Regulatory Affairs Manager

Bienne 03/06/21

Place and date of issue

Medical Device Family **CHIROPRO**

Product list - TF no. 002

Medical devices

No. crt	Reference number	Designation	Product Description	Class	Rule*	CE
1.	1600613-001	Console Chiropro L	Console intended to drive a dental micromotor	Ila	9	0123
2.	1600679-001	Console Chiropro L US	Console intended to drive a dental micromotor	Ila	9	0123
3.	1600724-001	Console Chiropro	Console intended to drive a dental micromotor	Ila	9	0123
4.	1600730-001	Console ProImplant	Console intended to drive a dental micromotor	Ila	9	0123
5.	1600776-001	Console Chiropro L Morita	Console intended to drive a dental micromotor	Ila	9	0123
6.	1600855-001	Console Chiropro L Premium	Console intended to drive a dental micromotor	Ila	9	0123
7.	1600960-001	Console Chiropro L Wego	Console intended to drive a dental micromotor	Ila	9	0123
8.	1600994-001	Console Chiropro PLUS 3 rd Gen.	Console intended to drive a dental micromotor	Ila	9	0123
9.	1600995-001	Console Chiropro 3 rd Gen.	Console intended to drive a dental micromotor	Ila	9	0123
10.	1601100-001	Console MEG-ENGINE II	Console intended to drive a dental micromotor	Ila	9	0123
11.	1601101-001	Console ProImplant 3 rd Gen.	Console intended to drive a dental micromotor	Ila	9	0123
12.	1601102-001	Console OMS	Console intended to drive a dental micromotor	Ila	9	0123
13.	1601147-001	Console Biopower	Console intended to drive a dental micromotor	Ila	9	0123

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

Declaration (systems and procedure packs)

CHIROPRO systems

The assembler of the procedure packs listed below,

Bien-Air Dental SA

Länggasse 60

CH-2504 Biel/Bienne

Switzerland,

declares under its sole responsibility that, in accordance with Article 12 of European Medical Device Directive 93/42/EEC, as amended:

- the mutual compatibility of the medical devices included below referenced sets have been verified
- The attached sets have been verified in line with MDD 93/42/EEC essential requirements
- The packaging of above referenced kits was validated and instructions on how to use it have been validated

In addition, all manufacturing operations are subject to appropriate methods of internal control and inspection.

Ref. number	Designation	Qty	CE Mark
1700298-001	Set Chiropro L	1	
1600613-001	Console Chiropro L	1	0123
1600755-001	MOT MX-i LED	1	0123
1600631-001	FOOTCTRL	1	0123
1500984-010	Irrigation Line (10/pkg)	1	0459
1600606-001	Cable MX LED	1	0123

1700307-001	Set Chiropro L + CA 20:1 L	1	
1600613-001	Console Chiropro L	1	0123
1600755-001	MOT MX-i LED	1	0123
1600631-001	FOOTCTRL	1	0123
1600692-001	CA 20:1 L Micro-series	1	0123
1500984-010	Irrigation Line (10/pkg)	1	0459
1600606-001	Cable MX LED	1	0123

1700347-001	Set Chiropro L + CA 20:1	1	
1600613-001	Console Chiropro L	1	0123
1600755-001	Mot MX-i LED	1	0123
1600631-001	FOOTCTRL	1	0123
1600632-001	CA 20:1	1	0123
1500984-010	Irrigation Line (10/pkg)	1	0459
1600606-001	Cable MX LED	1	0123

1700349-001	Set Chiropro L US	1	
1600679-001	Console Chiropro L	1	0123
1600755-001	MOT MX-i LED	1	0123
1600631-001	FOOTCTRL	1	0123
1500984-010	Irrigation Line (10/pkg)	1	0459

1600606-001	Cable MX LED	1	0123
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1700387-001	SET Chiropro	1	
1600724-001	Console Chiropro	1	0123
1600825-001	MOT MX-i	1	0123
1600606-001	Cable MX LED	1	0123
1600631-001	FOOTCTRL	1	0123
1500984-010	Irrigation Line (10/pkg)	1	0459

1700388-001	SET Chiropro + CA 20:1	1	
1600724-001	Console Chiropro	1	0123
1600825-001	MOT MX-i	1	0123
1600606-001	Cable MX LED	1	0123
1600631-001	FOOTCTRL	1	0123
1600632-001	CA 20:1	1	0123
1500984-010	Irrigation Line (10/pkg)	1	0459

1700389-001	SET ProImplant + CA 20:1	1	
1600730-001	Console Proimplant	1	0123
1600825-001	MOT MX-i	1	0123
1600606-001	Cable MX LED	1	0123
1600631-001	FOOTCTRL	1	0123
1600632-001	CA 20:1	1	0123
1500984-010	Irrigation Line (10/pkg)	1	0546

1700395-001	SET ProImplant	1	
1600730-001	Console Proimplant	1	0123
1600825-001	MOT MX-i	1	0123
1600606-001	Cable MX LED	1	0123
1600631-001	FOOTCTRL	1	0123
1500984-010	Irrigation Line (10/pkg)	1	0546

1700417-001	SET Chiropro L M.+CA 20:1L KM	1	
1600776-001	Console Chiropro L		0123
1600755-001	MOT MX-i LED	1	0123
1600606-001	Cable MX LED	1	0123
1600631-001	FOOTCTRL	1	0123
1600786-001	CA 20:1 L KM Micro-Series	1	0123
1500984-010	Irrigation Line (10/pkg)	1	0459

1700450-001	SET Chiropro L Morita	1	
1600776-001	Console chiropro L_102647	1	0123
1600755-001	MOT MX-i LED	1	0123
1600606-001	Cable MX LED	1	0123
1600631-001	FOOTCTRL	1	0123
1500984-010	Irrigation Line (10/pkg)	1	0546

1700463-001	SET Chiropro L US Premium	1	
1600855-001	Console Chiropro Premium_100018	1	0123
1600755-001	MOT MX-i LED	1	0123
1600881-001	Cable MX-LED 3m	1	0123
1600631-001	FOOTCTRL	1	0123

1501738-010	Irrigation Line 3.5m (10/pkg)	1	0459
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1700561-001	SET Chiropro L Wego	1	
1600960-001	Console Chiropro L_103270	1	0123
1600755-001	MOT MX-i LED	1	0123
1600606-001	Cable MX LED	1	0123
1600631-001	FOOTCTRL	1	0123
1500984-010	Irrigation Line (10/pkg)	1	0546

1700562-001	SET Chiropro L+CA 20:1 L Wego	1	
1600960-001	Console Chiropro L_103270	1	0123
1600755-001	Mot MX-i LED	1	0123
1600606-001	Cable MX LED	1	0123
1600631-001	FOOTCTRL	1	0123
1600692-001	CA 20:1 L Micro-Series	1	0123
1500984-010	Irrigation Line (10/pkg)	1	0546

1700707-001	SET Chiropro 3rd Gen CA 20:1 L	1	
1600995-001	Console CHIROPRO 3rd Gen.	1	0123
1601008-001	MX-i LED 3rd Gen.	1	0123
1601009-001	Cable MX-i LED 3rd Gen.	1	0123
1600631-001	FOOTCTRL	1	0123
1600692-001	CA 20:1 L Micro-Series	1	0123
1500984-005	Irrigation Line (5/pkg)	1	0459
1502329-002	Sterile protection Chiropro	1	0546

1700708-001	SET Chiropro 3rd Gen.	1	
1600995-001	Console CHIROPRO 3rd Gen.	1	0123
1601008-001	MX-i LED 3rd Gen.	1	0123
1601009-001	Cable MX-i LED 3rd Gen.	1	0123
1600631-001	FOOTCTRL	1	0123
1500984-005	Irrigation Line (5/pkg)	1	0459
1502329-002	Sterile protection Chiropro	1	0546

1700709-001	SET Chiropro+ 3rd Gen CA 20:1 L	1	
1600994-001	Console CHIROPRO PLUS 3rd Gen.	1	0123
1600755-001	MOT MX-i LED	1	0123
1601069-001	Cable MX-i LED	1	0123
1600631-001	FOOTCTRL	1	0123
1600692-001	CA 20:1 L Micro-Series	1	0123
1500984-005	Irrigation Line (5/pkg)	1	0459
1502329-002	Sterile protection Chiropro	1	0546

1700710-001	SET Chiropro+ 3rd Gen	1	
1600994-001	Console CHIROPRO PLUS 3rd Gen	1	0123
1600755-001	MOT MX-i LED	1	0123
1601069-001	Cable MX-i LED	1	0123
1600631-001	FOOT CTRL	1	0123
1500984-005	Irrigation Line (5/pkg)	1	0459
1502329-002	Sterile protection Chiropro	1	0546

1700736-001	SET Chiropro 3rd Gen CA 20:1 L KM	1	
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1600995-001	Console CHIROPPO 3rd Gen.	1	0123
1601008-001	MX-i LED 3rd Gen.	1	0123
1601009-001	Cable MX-i LED 3rd Gen.	1	0123
1600631-001	FOOTCTRL	1	0123
1600786-001	CA 20:1 L KM Micro-Series	1	0123
1501635-010	Irrigation Line KM (10/pkg)	1	0459
1502329-002	Sterile protection Chiropro	1	0546

1700737-001	SET Chiropro 3rd Gen KM	1	
1600995-001	Console CHIROPPO 3rd Gen.	1	0123
1601008-001	MX-i LED 3rd Gen.	1	0123
1601009-001	Cable MX-i LED 3rd Gen.	1	0123
1600631-001	FOOTCTRL	1	0123
1501635-010	Irrigation Line KM (10/pkg)	1	0459
1502329-002	Sterile protection Chiropro	1	0546

1700738-001	SET Chiropro+ 3rd Gen CA 20:1 L KM	1	
1600994-001	Console CHIROPPO PLUS 3rd Gen.	1	0123
1600755-001	MOT MX-i LED	1	0123
1601069-001	Cable MX-i LED	1	0123
1600631-001	FOOTCTRL	1	0123
1600786-001	CA 20:1 L KM Micro-Series	1	0123
1501635-010	Irrigation Line KM (10/pkg)	1	0459
1502329-002	Sterile protection Chiropro	1	0546

1700739-001	SET Chiropro+ 3rd Gen KM	1	
1600994-001	Console CHIROPPO PLUS 3rd Gen.	1	0123
1600755-001	MOT MX-i LED	1	0123
1601069-001	Cable MX-i LED	1	0123
1600631-001	FOOTCTRL	1	0123
1501635-010	Irrigation Line KM (10/pkg)	1	0459
1502329-002	Sterile protection Chiropro	1	0546

1700750-001	SET MEG-ENGINE II	1	
1601100-001	Console MEG-ENGINE II	1	0123
1601008-001	MX-i LED 3rd Gen.	1	0123
1601009-001	Cable MX-i LED 3rd Gen.	1	0123
1600631-001	FOOTCTRL	1	0123
1600692-001	CA 20:1 L Micro-Series	1	0123
1500984-005	Irrigation Line (5/pkg)	1	0459
1502329-002	Sterile protection Chiropro	1	0546

1700751-001	SET Chiropro+ 3rd Gen CA 1:2.5L	1	
1600994-001	Console CHIROPPO PLUS 3rd Gen.	1	0123
1600755-001	MOT MX-i LED	1	0123
1601069-001	Cable MX-i LED	1	0123
1600631-001	FOOTCTRL	1	0123
1601055-001	CA 1:2.5 L MS	1	0123
1500984-005	Irrigation Line (5/pkg)	1	0459
1502329-002	Sterile protection Chiropro	1	0546

1700768-001	SET ProImplant 3rd Gen CA 20:1 L	1	
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1601101-001	Console ProImplant 3 rd Gen.	1	0123
1600598-001	CA 20:1 L	1	0123
1601008-001	MX-i LED 3rd Gen	1	0123
1601009-001	Cable MX-i LED 3rd Gen.	1	0123
1600631-001	FOOTCTRL	1	0123
1500984-005	Irrigation Line (5/pkg)	1	0459
1502329-002	Sterile protection Chiropro	1	0546

1700769-001	SET OMS	1	
1601102-001	Console OMS	1	0123
1600755-001	MOT MX-i LED	1	0123
1601069-001	Cable MX-i LED	1	0123
1600631-001	FOOTCTRL	1	0123
1500984-005	Irrigation Line (5/pkg)	1	0459
1502329-002	Sterile protection Chiropro	1	0546

1700772-001	SET Chiropro 3rd Gen CA 20:1 L KM	1	
1600995-001	Console CHIROPRO 3rd Gen.	1	0123
1601008-001	MX-i LED 3rd Gen.	1	0123
1601009-001	Cable MX-i LED 3rd Gen.	1	0123
1600631-001	FOOTCTRL	1	0123
1600786-001	CA 20:1 L KM Micro-Series	1	0123
1500984-010	Irrigation Line (10/pkg)	1	0459
1502329-002	Sterile protection Chiropro	1	0546

1700773-001	SET Chiropro+ 3rd Gen CA 20:1 L KM	1	
1600994-001	Console CHIROPRO PLUS 3rd Gen.	1	0123
1600755-001	MOT MX-i LED	1	0123
1601069-001	Cable MX-i LED	1	0123
1600631-001	FOOTCTRL	1	0123
1600786-001	CA 20:1 L KM Micro-Series	1	0123
1500984-010	Irrigation Line (10/pkg)	1	0459
1502329-002	Sterile protection Chiropro	1	0546

1700774-001	SET ProImplant 3rd Gen CA 20:1	1	
1601101-001	Console ProImplant 3 rd Gen.	1	0123
1600632-001	CA 20:1	1	0123
1601008-001	MX-i LED 3rd Gen	1	0123
1601009-001	Cable MX-i LED 3rd Gen.	1	0123
1600631-001	FOOTCTRL	1	0123
1500984-005	Irrigation Line (5/pkg)	1	0459
1502329-002	Sterile protection Chiropro	1	0546

1700784-001	SET BIOPOWER	1	
1601147-001	CONSOLE BIOPOWER	1	0123
1601008-001	MX-i LED 3rd Gen	1	0123
1600692-001	CA 20:1 L Micro-Series	1	0123
1601009-001	Cable MX-i LED 3rd Gen.	1	0123
1600631-001	FOOTCTRL	1	0123
1500984-005	Irrigation Line (5/pkg)	1	0459
1502329-002	Sterile protection Chiropro	1	0546