

## 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 <sup>rd</sup> Gen.	Console intended to drive a dental micromotor	Ila	9	0123
9.	1600995-001	Console Chiropro 3 <sup>rd</sup> 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 <sup>rd</sup> 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
<b>1700298-001</b>	<b>Set Chiropro L</b>	<b>1</b>	
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

<b>1700307-001</b>	<b>Set Chiropro L + CA 20:1 L</b>	<b>1</b>	
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

<b>1700347-001</b>	<b>Set Chiropro L + CA 20:1</b>	<b>1</b>	
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

<b>1700349-001</b>	<b>Set Chiropro L US</b>	<b>1</b>	
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
-------------	--------------	---	------

<b>1700387-001</b>	<b>SET Chiropro</b>	<b>1</b>	
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

<b>1700388-001</b>	<b>SET Chiropro + CA 20:1</b>	<b>1</b>	
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

<b>1700389-001</b>	<b>SET Proimplant + CA 20:1</b>	<b>1</b>	
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

<b>1700395-001</b>	<b>SET Proimplant</b>	<b>1</b>	
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

<b>1700417-001</b>	<b>SET Chiropro L M.+CA 20:1L KM</b>	<b>1</b>	
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

<b>1700450-001</b>	<b>SET Chiropro L Morita</b>	<b>1</b>	
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

<b>1700463-001</b>	<b>SET Chiropro L US Premium</b>	<b>1</b>	
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
-------------	-------------------------------	---	------

<b>1700561-001</b>	<b>SET Chiropro L Wego</b>	<b>1</b>	
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

<b>1700562-001</b>	<b>SET Chiropro L+CA 20:1 L Wego</b>	<b>1</b>	
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

<b>1700707-001</b>	<b>SET Chiropro 3rd Gen CA 20:1 L</b>	<b>1</b>	
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

<b>1700708-001</b>	<b>SET Chiropro 3rd Gen.</b>	<b>1</b>	
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

<b>1700709-001</b>	<b>SET Chiropro+ 3rd Gen CA 20:1 L</b>	<b>1</b>	
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

<b>1700710-001</b>	<b>SET Chiropro+ 3<sup>rd</sup> Gen</b>	<b>1</b>	
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

<b>1700736-001</b>	<b>SET Chiropro 3rd Gen CA 20:1 L KM</b>	<b>1</b>	
--------------------	--	----------	--

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
1501635-010	Irrigation Line KM (10/pkg)	1	0459
1502329-002	Sterile protection Chiropro	1	0546

<b>1700737-001</b>	<b>SET Chiropro 3rd Gen KM</b>	<b>1</b>	
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
1501635-010	Irrigation Line KM (10/pkg)	1	0459
1502329-002	Sterile protection Chiropro	1	0546

<b>1700738-001</b>	<b>SET Chiropro+ 3rd Gen CA 20:1 L KM</b>	<b>1</b>	
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
1501635-010	Irrigation Line KM (10/pkg)	1	0459
1502329-002	Sterile protection Chiropro	1	0546

<b>1700739-001</b>	<b>SET Chiropro+ 3rd Gen KM</b>	<b>1</b>	
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
1501635-010	Irrigation Line KM (10/pkg)	1	0459
1502329-002	Sterile protection Chiropro	1	0546

<b>1700750-001</b>	<b>SET MEG-ENGINE II</b>	<b>1</b>	
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

<b>1700751-001</b>	<b>SET Chiropro+ 3rd Gen CA 1:2.5L</b>	<b>1</b>	
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
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

<b>1700768-001</b>	<b>SET Proimplant 3rd Gen CA 20:1 L</b>	<b>1</b>	
--------------------	---	----------	--

1601101-001	Console Prolmplant 3 <sup>rd</sup> 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

<b>1700769-001</b>	<b>SET OMS</b>	<b>1</b>	
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

<b>1700772-001</b>	<b>SET Chiropro 3rd Gen CA 20:1 L KM</b>	<b>1</b>	
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

<b>1700773-001</b>	<b>SET Chiropro+ 3rd Gen CA 20:1 L KM</b>	<b>1</b>	
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

<b>1700774-001</b>	<b>SET Prolmplant 3rd Gen CA 20:1</b>	<b>1</b>	
1601101-001	Console Prolmplant 3 <sup>rd</sup> 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

<b>1700784-001</b>	<b>SET BIOPOWER</b>	<b>1</b>	
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