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

Digitally signed by Ceaicovschi Tudor
Date: 2022.08.10 10:45:42 EEST
Reason: MoldSign Signature
Location: Moldova

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

Bien-Air Dental SA
Länggasse 60 Case postale CH-2500 Bienne 6 Switzerland Tel +41(0)32 344 64 64 Fax +41(0)32 344 64 91 dental@bienair.com www.bienair.com

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	IIa	9	0123
2.	1600679-001	Console Chiropro L US	Console intended to drive a dental micromotor	IIa	9	0123
3.	1600724-001	Console Chiropro	Console intended to drive a dental micromotor	IIa	9	0123
4.	1600730-001	Console ProImplant	Console intended to drive a dental micromotor	IIa	9	0123
5.	1600776-001	Console Chiropro L Morita	Console intended to drive a dental micromotor	IIa	9	0123
6.	1600855-001	Console Chiropro L Premium	Console intended to drive a dental micromotor	IIa	9	0123
7.	1600960-001	Console Chiropro L Wego	Console intended to drive a dental micromotor	IIa	9	0123
8.	1600994-001	Console Chiropro PLUS 3rd Gen.	Console intended to drive a dental micromotor	IIa	9	0123
9.	1600995-001	Console Chiropro 3rd Gen.	Console intended to drive a dental micromotor	IIa	9	0123
10.	1601100-001	Console MEG-ENGINE II	Console intended to drive a dental micromotor	IIa	9	0123
11.	1601101-001	Console ProImplant 3rd Gen.	Console intended to drive a dental micromotor	IIa	9	0123
12.	1601102-001	Console OMS	Console intended to drive a dental micromotor	IIa	9	0123
13.	1601147-001	Console Biopower	Console intended to drive a dental micromotor	IIa	9	0123

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

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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

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1600606-001	Cable MX LED	1	0123

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

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1501738-010	Irrigation Line 3.5m (10/pkg)	1	0459

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 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

1700737-001	**SET Chiropro 3rd Gen 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
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 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

1700739-001	**SET Chiropro+ 3rd Gen 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
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 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

1700768-001	**SET ProImplant 3rd Gen CA 20:1 L**	**1**	

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1601101-001	Console ProImplant 3rd 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 3rd 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

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www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 065560 0002 Rev. 01

Manufacturer:

Bien-Air Dental SA
Länggasse 60
2504 Biel/Bienne
SWITZERLAND

Product Category(ies): **Air and electrical motors, straight and contra-angle handpieces, turbines, air and electrical hoses and couplings and electronic consoles for: dental applications, oral and maxillofacial surgery**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713176166

Valid from: 2020-04-29
Valid until: 2024-05-26

Date, 2020-04-29

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 065560 0004 Rev. 00

Manufacturer:

Bien-Air Dental SA
Länggasse 60
2504 Biel/Bienne
SWITZERLAND

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).
The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10 065560 0004 Rev. 00

Report No.: 713183920

Valid from: 2021-02-01
Valid until: 2026-01-31

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2021-02-01

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BS-MDR-099

Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

No. G10 065560 0004 Rev. 00

Device Group:	Z121101 - INSTRUMENTS FOR DENTAL TREATMENT UNITS
Classification:	IIa
Intended Purpose:	-
The validity of this certificate depends on conditions and/or is limited to the following:	./.

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Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 065560 0002 Rev. 01

Manufacturer:

Bien-Air Dental SA
Länggasse 60
2504 Biel/Bienne
SWITZERLAND

Product Category(ies): **Air and electrical motors, straight and contra-angle handpieces, turbines, air and electrical hoses and couplings and electronic consoles for: dental applications, oral and maxillofacial surgery**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713176166

Valid from: 2020-04-29
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Christoph Dicks
Head of Certification/Notified Body

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