

EC DECLARATION OF CONFORMITY

TF No. **TF n °005** / Rev.0016

Medical Device Family
TURBINES

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

A blue ink signature of Renaud Villard.

Renaud VILLARD
Regulatory Affairs Manager

Handwritten blue ink text: "Bienne 03/06/21".

Place and date of issue

Medical Device Family

TURBINES

Product list - TF no. 005

Medical devices

No. crt	Reference number	Designation	Product Description	Class	Rule*	CE
1	1600039-001	TUR BLACK PEARL ECO 3H	Turbine GMDN 40958	Ila	9	0123
2	1600040-001	TUR BLACK PEARL ECO 4H	Turbine GMDN 40958	Ila	9	0123
3	1600373-001	TUR BORALINA	Turbine GMDN 40958	Ila	9	0123
4	1600379-001	TUR PRESTIGE	Turbine GMDN 40958	Ila	9	0123
5	1600380-001	TUR PRESTIGE L	Turbine GMDN 40958	Ila	9	0123
6	1600381-001	TUR BORA	Turbine GMDN 40958	Ila	9	0123
7	1600382-001	TUR BORA L	Turbine GMDN 40958	Ila	9	0123
8	1600471-001	TU BORA L_101947	Turbine GMDN 40958	Ila	9	0123
9	1600638-001	TUR BORA L	Turbine GMDN 40958	Ila	9	0123
10	1600641-001	TUR PRESTIGE L	Turbine GMDN 40958	Ila	9	0123
11	1600731-001	TUR BORA LK BLACKLINE	Turbine GMDN 40958	Ila	9	0123
12	1600732-001	TUR BORA LK	Turbine GMDN 40958	Ila	9	0123
13	1600734-001	TUR PRESTIGE LK	Turbine GMDN 40958	Ila	9	0123
14	1600907-001	TUR TORNADO LK	Turbine GMDN 40958	Ila	9	0123
15	1600908-001	TUR TORNADO LED	Turbine GMDN 40958	Ila	9	0123
16	1600932-001	TUR TORNADO S LK	Turbine GMDN 40958	Ila	9	0123
17	1600933-001	TUR TORNADO S LED	Turbine GMDN 40958	Ila	9	0123
18	1601085-001	TUR TORNADO X LED	Turbine GMDN 40958	Ila	9	0123
19	1601086-001	TUR TORNADO X LK	Turbine GMDN 40958	Ila	9	0123
20	1601142-001	TU eLINE LK	Turbine GMDN 40958	Ila	9	0123
21	1601152-001	TU Bora 2 LED	Turbine GMDN 40958	Ila	9	0123
22	1601153-001	TU Bora 2 LK	Turbine GMDN 40958	Ila	9	0123

Accessories: *Couplings and Connectors*

No. crt	Reference number	Designation	Product Description	Class	Rule*	CE
1	1600081-001	COUPLING UNIFIX 3H	Coupling GMDN 45121	Ila	2	0123
2	1600082-001	COUPLING UNIFIX 4H	Coupling GMDN 45121	Ila	2	0123
3	1600086-001	COUPLING UNIFIX 4H L WATER ADJ	Coupling GMDN 45121	Ila	2	0123
4	1600087-001	COUPLING UNIFIX 4H US	Coupling GMDN 45121	Ila	2	0123
5	1600089-001	ADAPTER 4H-3H	Coupling GMDN 45121	Ila	2	0123
6	1600363-001	COUPLING UNIFIX 4H L	Coupling GMDN 45121	Ila	2	0123
7	1600866-001	COUPLING LK 4HL WATER ADJ	Coupling GMDN 45121	Ila	2	0123
8	1600902-001	COUPLING LK 4H L	Coupling GMDN 45121	Ila	2	0123

Accessories: *Hoses*

No. crt	Reference number	Designation	Product Description	Class	Rule*	CE
1	1600097-001	HOSE 4VLM11 GREY	Hose GMDN 40593	Ila	2	0123
2	1600102-001	HOSE 4VLM GREY	Hose GMDN 40593	Ila	2	0123

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