

EC DECLARATION OF CONFORMITY

TF No. 005 / Rev. 0002

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 Regulation (EU) 2017/745 which apply to them and that Annex IX (excluding chapter II) of the aforementioned Regulation has been followed for their conformity assessment. This declaration is supported by the Quality System approval to ISO 13485 issued by the below-mentioned Notified Body.

Notified Body: TÜV SÜD Product Service GmbH
Ridlerstr. 65,
D-80339 München
Germany

CE Marking

CE 0123

European Authorised Representative: Bien-Air Europe Sàrl
19-21 rue du 8 mai 1945
94110 Arcueil
France

MDR Certificate Number: G10 065560 0004

Manufacturer SRN (Single Registration Number): CH-MF-000014661

Authorised representative SRN: FR-AR-000011942



R. Villard
Regulatory Affairs Manager
Bien-Air Dental SA

Bienne, 26/07/2024

Place and date of issue

Medical Device Family

TURBINES

Product list - TF no. 005

Medical devices

Inc.	Ref. number	Designation	Basic UDI-DI	Intended purpose	Class	Rule*	CE
1	1600039-001	TU BLACK PEARL ECO 3H	++J007TUR B00014S	General dentistry	IIa	9	CE 0123
2	1600039-00IR	TU BLACK PEARL ECO 3H					
3	1600040-001	TU BLACK PEARL ECO 4H					
4	1600040-0	TU BLACK PEARL ECO 4H					
5	1600040-00IR	TU BLACK PEARL ECO 4H					
6	1600040-CHN	BLACK PEARL ECO 4V					
7	1600373-001	TU BORALINA					
8	1600373-00IR	TU BORALINA					
9	1600907-001	TU TORNADO LK					
10	1600907-0	TU TORNADO LK					
11	1600908-001	TU TORNADO LED					
12	1600908-0	TU TORNADO LED					
13	1600908-00IR	TU TORNADO LED					
14	1600932-001	TU TORNADO S LK					
15	1600932-0	TU TORNADO S LK					
16	1600933-001	TU TORNADO S LED					
17	1600933-0	TU TORNADO S LED					
18	1601152-001	TU BORA 2 LED					
19	1601152-0	TU BORA 2 LED					
20	1601153-001	TU BORA 2 LK					
21	1601153-0	TU BORA 2 LK					

*Classification rules according to the Annex VIII of the Regulation (EU) 2017/745, as amended.