



America

CERTIFICATE

No. QS6 065560 0003 Rev. 01

Certificate Holder: **Bien-Air Dental SA**
Länggasse 60
2504 Biel/Bienne
SWITZERLAND

Certification Mark:



Scope of Certificate: **Design, Manufacture, Distribution and Servicing of:**

- Air and Electrical Motors
- Straight and Contra-angle Handpieces
- Turbines
- Air and Electric Hoses and Couplings
- Electronic Consoles and Controllers

for Dental Applications and Oral and Maxillofacial Surgery

Standard(s): **ISO 13485:2016**

Regulatory Authority(ies): **Australia TGA, Brazil ANVISA, Health Canada, USA FDA, MHLW / PMDA. See attached for listing of specific regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website www.tuvsud.com/ps-cert
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: **F003950**

Effective Date: **2022-11-30**

Expiry Date: **2025-11-29**

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Date of Issue: 2022-12-07

(Renee Walker)
Manager, US Certification Body,
Medical and Health Services

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Regulatory Requirements: Audit/Certification Criteria

Australia

Therapeutic Goods (Medical Devices) Regulations 2002
 - Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

Brazil

- RDC ANVISA n. 16/2013
 - RDC ANVISA n. 23/2012
 - RDC ANVISA n. 67/2009

Canada

- Medical Device Regulations – Part 1- SOR 98/282

Japan

- MHLW Ministerial Ordinance 169, Article 4 to Article 68
 - PMD Act

United States

- 21 CFR Part 803
 - 21 CFR Part 806
 - 21 CFR Part 807 – Subparts A to D
 - 21 CFR Part 820

Facility(ies):

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

Bien-Air Dental SA
 Rue de l'Ouest 2b, 2340 Le Noirmont, SWITZERLAND

Bien-Air Portugal, UNIPessoal LDA
 Rua Ponte da Pedra n° 240, Centro Empresarial aaa, Edifício D4, 4470-108 Maia, PORTUGAL

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Facility Scopes:

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Länggasse 60, 2504 Biel/Bienne, SWITZERLAND

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Bien-Air Dental SA

Rue de l'Ouest 2b, 2340 Le Noirmont, SWITZERLAND

Manufacture, Distribution and Servicing of:

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 - Turbines
 - Air and Electric Hoses and Couplings
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REPs Facility ID: F003952

Bien-Air Portugal, UNIPessoal LDA

Rua Ponte da Pedra n° 240, Centro Empresarial aaa, Edifício D4, 4470-108 Maia, PORTUGAL

Manufacture and Distribution of:

- Air and Electrical Motors
- for Dental Applications and Oral and Maxillofacial Surgery
REPs Facility ID: F003951

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(Renee Walker)
Manager, US Certification Body,
Medical and Health Services