



Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00



Product Service

Certificate

No. Q5 065560 0001 Rev. 04

Holder of Certificate: **Bien-Air Dental SA**

Länggasse 60
2504 Biel/Bienne
SWITZERLAND

Certification Mark:



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

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 065560 0001 Rev. 04](http://www.tuvsud.com/ps-cert?q=cert:Q5_065560_0001_Rev_04)

Report No.: 713386367

Valid from: 2026-01-15

Valid until: 2028-12-01

Date, 2026-01-15

Christoph Dicks
Head of Certification/Notified Body



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Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

Facility(ies): **Bien-Air Dental SA**
Länggasse 60, 2504 Biel/Bienne, SWITZERLAND

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Bien-Air Portugal UNIPESOAAL LDA
Rua de José Francisco da Conceição, n°141, 4470-044 Maia,
PORTUGAL

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

Manufacture and Distribution of:

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