



# Certificate

No. Q5 065560 0001 Rev. 02

**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 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:Q5 065560 0001 Rev. 02](http://www.tuvsud.com/ps-cert?q=cert:Q5_065560_0001_Rev_02)

**Report No.:** 713237352

**Valid from:** 2022-12-02

**Valid until:** 2025-12-01

**Date,** 2022-11-14

Christoph Dicks  
Head of Certification/Notified Body

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**Applied Standard(s):** EN ISO 13485:2016  
Medical devices - Quality management systems -  
Requirements for regulatory purposes  
(ISO 13485:2016)  
DIN EN ISO 13485:2016

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

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**Bien-Air Portugal, UNIPESSOAL LDA**

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

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- Air and electrical motors
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**Bien-Air Dental SA**

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

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- Air and electrical motors

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