



EU Quality Management System Certificate

Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter I

Certificate No. G15 065560 0006 Rev. 00

Manufacturer:

Bien-Air Dental SA

Länggasse 60
 2504 Biel/Bienne
 SWITZERLAND

SRN Manufacturer - CH-MF-000014661

**Authorized
 Representative:**

Bien-Air Europe Sarl
 19-21 rue du 8 mai 1945, 94110 Arcueil, FRANCE

The quality management system has been evaluated in accordance with Regulation (EU) 2017/745, Annex IX Chapter I with a positive result.

Details on devices covered by the quality management system are described on the following page(s). The report referenced below summarises the results of the assessment and includes reference to relevant CS, harmonised standards and test reports.

The certified quality management system is subject to periodical surveillance.

If class I devices in sterile conditions, with measuring function, or reusable surgical instruments are covered by this certificate, the audit was limited to the respective aspects relating to

- establishing, securing, and maintaining sterile conditions,
- conformity of the devices with the metrological requirements,
- reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

If class IIa or class IIb devices are covered by this certificate, the quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis. The periodical surveillance includes further assessment of the technical documentation on the basis of representative samples.

If class III or class IIb implantable devices are covered by this certificate, an EU Technical Documentation Assessment Certificate in accordance with Annex IX Chapter II is required before placing them on the market.

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:G15 065560 0006 Rev. 00

Report No.: 713370584

Preceding Certificate No.: G10 065560 0004 Rev. 02

Valid from: 2026-02-01

Valid until: 2031-01-31

Issue date: 2025-10-31

Christoph Dicks
 Head of Certification/Notified
 Body



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
BS-MDR-099



Product Service

EU Quality Management System Certificate

Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter I

Certificate No. G15 065560 0006 Rev. 00

Classification: Class IIa

Device Group: MDA 0311 - Active non-implantable dental devices

**The validity of this certificate
depends on conditions and/or
is limited to the following:**
- none -

Revision History:

Rev.	Dated	Report	Description
00	2026-02-01	713370584	Renewal of certificate