



EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

No. G10 065560 0004 Rev. 02

Manufacturer:

Bien-Air Dental SA

Länggasse 60
2504 Biel/Bienne
SWITZERLAND

SRN Manufacturer - CH-MF-000014661

Authorized Representative:

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

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s). The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.

The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.

The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples. 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:G10 065560 0004 Rev. 02](http://www.tuvsud.com/ps-cert?q=cert:G10_065560_0004_Rev.02)

Report No.: 713329222

Preceding Certificate No.: G10 065560 0004 Rev. 01

Valid from: 2024-03-07

Valid until: 2026-01-31

Date of Initial Issuance: 2021-02-01

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2024-03-07



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No. G10 065560 0004 Rev. 02

Classification: Class IIa
Device Group: Z121101 - INSTRUMENTS FOR DENTAL TREATMENT UNITS
Intended Purpose: -

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

Revision History:

Rev.	Dated	Report	Description
00	2021-02-01	713183920	-
01	2021-12-15	713217540/713208020	-
02	2024-03-07	713329222	Amended: Editorial change of authorized representative