



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 098596 0007 Rev. 04

Manufacturer:

Dent4You AG

Bahnhofstrasse 2
9435 Heerbrugg
SWITZERLAND

SRN Manufacturer - CH-MF-000028926

Authorized Representative:

Coltène/Whaledent GmbH + Co. KG
Raiffeisenstraße 30, 89129 Langenau, GERMANY

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 098596 0007 Rev. 04

Report No.: 713226886_BriCri

Preceding Certificate No.: G10 098596 0007 Rev. 03

Valid from: 2025-02-21

Valid until: 2026-09-28

Date of Initial Issuance: 2021-09-29

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2025-02-21



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Classification:	Class IIa
Device Group:	D0599 - OXYGEN PRODUCERS FOR DISINFECTION OF MEDICAL DEVICES - OTHER Z12011301 - CLEANING AND DISINFECTION EQUIPMENT Z12011305 - SMALL LOAD AUTOCLAVES WITH A CHAMBER SMALLER THAN 1 STANDARD STERILISATION UNIT
Intended Purpose:	./.
Classification:	Class IIa
Device Group:	Q010199 - CONSERVATIVE DENTISTRY AND ENDODONTICS DEVICES - OTHER
Intended Purpose:	./.
Classification:	Class IIa
Device Group:	Q010201 - DENTAL IMPRESSION MATERIALS
Intended Purpose:	./.
Classification:	Class IIa
Device Group:	Z121101 - INSTRUMENTS FOR DENTAL TREATMENT UNITS
Intended Purpose:	./.
Classification:	Class IIa
Device Group:	Q010507 - ENDODONTIC INSTRUMENTS (CANAL ENLARGERS, FILES, RASPS, ETC.), SINGLE-USE
Intended Purpose:	./.
Classification:	Class IIa
Device Group:	Q010205 - PRE-FORMED RESINS AND DENTAL CROWNS
Intended Purpose:	./.
Classification:	Class IIa
Device Group:	P010201 - DENTAL IMPLANTS AND ACCESSORIES
Intended Purpose:	./.
Classification:	Class IIa
Device Group:	Q010101 - DENTAL RESTORATION DEVICES
Intended Purpose:	./.
Classification:	Class IIa
Device Group:	Q010104 - DENTAL PROCEDURE DEVICES - VARIOUS



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Intended Purpose: ./.

Classification: Class IIa
Device Group: Q010105 - RECONSTRUCTION ENDODONTIC PINS
Intended Purpose: ./.

The validity of this certificate depends on conditions and/or is limited to the following: ./.

Revision History:

Rev.	Dated	Report	Description
00	2021-09-29	713210704	-
01	2022-06-24	713226886	-
02	2023-06-30	713226886_IsiEx	Supplemented: Device(s)/group of device(s) added
03	2023-12-07	713226886_SpeEx	Supplemented: Device(s)/group of device(s) added
04	2025-02-21	713226886_BriCri	Supplemented: Device(s)/group of device(s) added