



EU Quality Assurance Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex XI Part A
(Class IIa Devices)

No. G20 090341 0017 Rev. 00

Manufacturer:

Candolor AG

Boulevard Lilienthal 8
8152 Glattpark (Opfikon)
SWITZERLAND

SRN Manufacturer - CH-MF-000015795

Authorized Representative:

Candolor Dental GmbH
Am Riederngraben 6, 78239 Rielasingen-Worblingen, 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. The Notified Body confirms that the class IIa devices in question conform to the technical documentation and meet the requirements of this Regulation which apply to them. 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 XI Part A 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 assurance 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 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:G20_090341_0017_Rev.00

Report No.: 713253246

Valid from: 2023-11-03

Valid until: 2028-11-02

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2023-11-03



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



Product Service

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 (Class IIa Devices)

No. G20 090341 0017 Rev. 00

Classification: Class IIa
Device Group: Q010699 - MATERIALS FOR THE PREPARATION OF CUSTOM-
 MADE DENTAL DEVICES - OTHER

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

Revision History:

Rev.	Dated	Report	Description
00	2023-11-03	713253246	Initial issuance