ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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 (MDR)

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

No. G10 029125 0024 Rev. 00

Manufacturer:

Coltène/Whaledent AG
Feldwiesenstrasse 20
9450 Altstätten
SWITZERLAND

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.

Report No.: 713174993

Valid from: 2020-08-11
Valid until: 2025-07-22

Issue date: 2020-08-11

Christoph Dicks
Head of Certification/Notified Body

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No. G10 029125 0024 Rev. 00

Device Group:	Q010201 - DENTAL IMPRESSION MATERIALS, ALGINATES AND OTHERS
Classification:	IIa
Intended Purpose:	
The validity of this certificate depends on conditions and/or is limited to the following:	./.

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