EU Quality Management System Certificate

mdc medical device certification GmbH

Kriegerstr. 6, 70191 Stuttgart, Germany
Notified body (identification number 0483)

hereby certifies that the company (SRN: DE-MF-000005717)

Coltène/Whaledent GmbH + Co. KG

Raiffeisenstraße 30
89129 Langenau
Germany

has implemented and applies a quality management system in accordance with Annex IX, Chapter I of Regulation (EU) 2017/745 for conformity assessment of the devices listed on the following pages.

An audit by mdc has proven that this quality management system fulfils the following requirements:

Annex IX - Chapter I (Quality Management System)

of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices

Surveillance is carried out in accordance with Annex IX, Section 3 of Regulation (EU) 2017/745.

This certificate consists of 3 pages. Details of the devices affected by this certificate as well as further information and conditions are included on the following pages.

Valid from:	2022-07-11	Registration No.	D1007900068
Valid until:	2027-03-29	Evaluation Report No.	242069

Stuttgart, 2022-07-11

Head of Notified Body

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-098

Devices:

Product: Aspirator tips
Intended purpose: Aspirator tips are intended for low volume aspiration of liquid and solid substances during non-surgical dental procedures in the oral cavity.
Risk class: IIa

Product: Surgitip
Intended purpose: Surgitips are intended for low volume aspiration of liquid and solid substances during dental surgical procedures in the oral cavity.
Risk class: IIa

Product: Surgitip-micro
Intended purpose: Surgitip-micro is intended for low volume aspiration of liquid and solid substances during dental surgical and micro-surgical procedures in the oral cavity.
Risk class: IIa

Product: Surgitip-endo
Intended purpose: Surgitip-endo are intended for aspiration during endodontic treatments and in specific for drying of the root canal.
Risk class: IIa

Product: VacuSoft
Intended purpose: VacuSoft universal aspirator cannula is used for large volume evacuation of liquid and solid substances during the dental treatment, e.g. water, aersole, saliva, blood, filling material. It keeps away tongue and cheeks to allow an unrestricted view of the treatment field.
Risk class: IIa

Product: Guttapercha Points
Intended purpose: Guttapercha Points are used as a filling material (permanent use) of the cleaned tooth root canals to fill the root canal of a prepared tooth, in strict accordance with internationally recognized standards
Risk class: IIa

Product: GuttaFlow 2
Intended purpose: Guttaflow is a cold flowable filling system for root canals, combining sealer and gutta-percha in one product. It is used during a root canal treatment for filling the root canal of a prepared tooth, in strict accordance with internationally recognized standards.
Risk class: IIa

Product: GuttaFlow bioseal
Intended purpose: Guttaflow is a cold flowable filling system for root canals, combining sealer and gutta-percha in one product. It is used during a root canal treatment for filling the root canal of a prepared tooth, in strict accordance with internationally recognized standards.
Risk class: IIa

Notes:

The certificate is based on the previous certificate D1007900067 dated 30.03.2022 with the following changes:
Supplemented by the products Guttapercha Points, GuttaFlow 2, GuttaFlow bioseal