

# EU Quality Management System Certificate

We hereby certify the company

**Coltène/Whaledent GmbH + Co. KG**  
**Raiffeisenstraße 30**  
**89129 Langenau**  
**Germany**

the introduction and application of a quality management system in accordance with Annex IX, Chapter I and III of Regulation (EU) 2017/745 for conformity assessment.

An audit by mdc has proven that this quality management system meets 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 from mdc medical device certification GmbH (Notified Body 0483) consists of 3 pages. Details about the devices covered as well as further information and conditions are contained on the following pages.

Valid from 2025-12-01  
Valid until 2027-03-29

Registration No. D1007900076  
Report No. P24-00500-296187

Stuttgart, 2025-12-01



Notified Body



## Devices:

---

HyFlex Rotary Files

Risk class: IIa

---

Aspirator tips

Risk class: IIa

---

Surgitip-micro

Risk class: IIa

---

Surgitip-endo

Risk class: IIa

---

Guttapercha Points

Risk class: IIa

---

GuttaFlow 2

Risk class: IIa

---

Paper Points

Risk class: IIa

---

Steri-sleeve

Risk class: I (sterile)

---

GuttaFlow bioseal

Risk class: IIa

---

Surgitip

Risk class: IIa

---

### Notes:

For class I devices placed on the market in sterile condition the involvement of mdc is limited to the aspects relating to establishing, securing and maintaining sterile conditions.

### The certificate is based on the previous certificate

D1007900067 (2022-03-30)  
D1007900068 (2022-07-11)  
D1007900073 (2024-05-27)  
D1007900075 (2025-09-15)

with the following changes to D1007900075:  
Supplemented by: HyFlex Rotary Files