

# EC Certificate

**mdc medical device certification GmbH**

Notified Body 0483  
herewith certifies that

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

for the scope

**root canal filling materials, paper points, aspirator tips,  
medicated gelatin sponges, root canal files,  
dental rotary handpiece with engine**

has introduced and applies a

## Quality System

for the design, manufacture and final inspection.

The mdc audit has proven that this quality system  
meets all requirements according to

**Annex II – excluding Section 4  
of the Council Directive 93/42/EEC**

of 14 June 1993 concerning medical devices.

The surveillance will be held as specified in Annex II, Section 5.

Valid from	2020-08-06
Valid until	2024-05-26
Registration no.	D1007900062
Report no.	P20-01093-182998
Stuttgart	2020-08-06

Head of Certification Body



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