

# Certificate

**mdc medical device certification GmbH**  
certifies that

 **COLTENE**

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

for the scope

**development, manufacturing and distribution of  
dental products**

has introduced and applies a

## Quality Management System

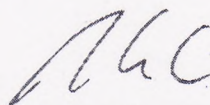
The mdc audit has proven that this quality management system  
meets all requirements of the following standard

### EN ISO 13485

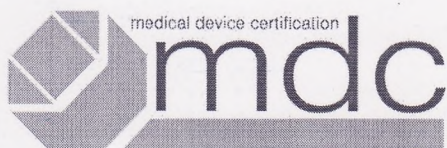
Medical devices – Quality management systems –  
Requirements for regulatory purposes

EN ISO 13485:2016 + AC:2016 - ISO 13485:2016

Valid from	2021-07-27
Valid until	2024-07-26
Registration no.	D1007900066
Report no.	P21-00295-198479
Stuttgart	2021-05-17



Head of Certification Body



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Product Service

# Certificate

No. Q5 029125 0025 Rev. 00

**Holder of Certificate:** **Coltène/Whaledent AG**  
Feldwiesenstrasse 20  
9450 Altstätten  
SWITZERLAND

**Certification Mark:**



**Scope of Certificate:** **Design and development, production and distribution of dental impression materials and accessories, materials for restorative dentistry, burs / polishers for medical use**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). 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:Q5 029125 0025 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:Q5 029125 0025 Rev. 00)

**Report No.:** 713203503

**Valid from:** 2021-03-18

**Valid until:** 2024-03-15

**Date,** 2021-03-18

Christoph Dicks  
Head of Certification/Notified Body





Product Service

# Certificate

No. Q5 029125 0025 Rev. 00

**Applied Standard(s):** EN ISO 13485:2016  
Medical devices - Quality management systems -  
Requirements for regulatory purposes  
(ISO 13485:2016)  
DIN EN ISO 13485:2016

**Facility(ies):** Coltène/Whaledent AG  
Feldwiesenstrasse 20, 9450 Altstätten, SWITZERLAND

See Scope of Certificate

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