



# CERTIFICATE



This is to certify that the company

## Coltène/Whaledent GmbH & Co. KG

Raiffeisenstraße 30  
89129 Langenau  
Germany

with the organizational units/sites as listed in the annex

has implemented and maintains a **Quality Management System**.

### Scope of certification:

Design, manufacturing, servicing and distribution of root canal filling material, paper points, surgical aspirator tips, aspirator tips, medicated gelatine sponges, retraction cords, dental rotary handpiece with engine, root canal files, sterile covers, sterile sleeve for tubes, dental rolls, compression caps, dental pellets, dental dams, cold spray, articulating paper, occlusion testing material, tweezers, instrument organizer, accessories of dental syringes, dental bibs and steel separating strips

– **AUS (a), BRA, CND, JPN, USA (a, b, c, d)**

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

## ISO 13485 : 2016

including applicable country-specific regulatory requirements, as indicated below the scope (full references of abbreviations are listed in the annex)

Certificate registration no. 290077 MDSAP16

Certificate unique ID 170774284

Effective date 2021-06-29

Expiry date 2024-06-28

Frankfurt am Main 2021-06-29



## DQS Medizinprodukte GmbH

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**DQS Medizinprodukte GmbH is recognized under the Medical Devices Single Audit Program.**

Visit <https://www.mydqs.com/en/customers/customer-database.html> to validate this certificate.



## Annex to certificate

**Certificate registration No.: 290077 MDSAP16**

**Certificate unique ID: 170774284**

**Effective date: 2021-06-29**

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### Audited site

#### **Coltène/Whaledent GmbH & Co. KG**

Raiffeisenstraße 30  
89129 Langenau  
Germany

#### **Coltène/Whaledent GmbH & Co. KG**

Raiffeisenstraße 28  
89129 Langenau  
Germany

### **DUNS No., site scope and country-specific requirements**

Design, manufacturing, servicing and distribution of root canal filling material, paper points, surgical aspirator tips, aspirator tips, medicated gelatine sponges, retraction cords, dental rotary handpiece with engine, root canal files, sterile covers, sterile sleeve for tubes, dental rolls, compression caps, dental pellets, dental dams, cold spray, articulating paper, occlusion testing material, tweezers, instrument organizer, accessories of dental syringes, dental bibs and steel separating strips

**– AUS (a), BRA, CND, JPN, USA (a, b, c, d)  
DUNS No.: 315494443**

Design, manufacturing, servicing and distribution of root canal filling material, paper points, surgical aspirator tips, aspirator tips, medicated gelatine sponges, retraction cords, dental rotary handpiece with engine, root canal files, sterile covers, sterile sleeve for tubes, dental rolls, compression caps, dental pellets, dental dams, cold spray, articulating paper, occlusion testing material, tweezers, instrument organizer, accessories of dental syringes, dental bibs and steel separating strips

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### Full references of country-specific requirements of MDSAP participating Regulatory Authorities

Abbreviation	Jurisdiction	Reference
AUS	Australia	(a) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 – Full Quality Assurance Procedure (b) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 4 – Production Quality Assurance Procedure
BRA	Brazil	RDC ANVISA n. 16/2013 RDC ANVISA n. 23/2012 RDC ANVISA n. 67/2009
CND	Canada	Medical Device Regulations SOR/98-282, Part 1
JPN	Japan	MHLW Ministerial Ordinance No. 169 (2004) as amended by MHLW Ordinance No. 128 (2014), Articles 4 to 68 Japan PMD Act (as applicable)
USA	United States	(a) 21 CFR Part 803 (b) 21 CFR Part 806 (c) 21 CFR Part 807 (d) 21 CFR Part 820 (e) 21 CFR Part 821