



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, adapters for aspirator tips, medicated gelatine sponges, retraction cords, root canal files, sterile sleeve for tubes, dental rolls, compression caps, dental pellets, cold spray, articulating paper, occlusion testing material 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

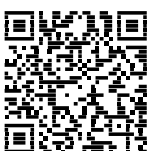
including applicable country-specific regulatory requirements, as indicated below the scope (full references of abbreviations are listed in the annex)

Certificate registration no.	290077 MDSAP16
Certificate unique ID	1000258135
Effective date	2025-07-14
Expiry date	2027-06-28
Frankfurt am Main	2025-07-14



DQS Medizinprodukte GmbH

Heinrich von Mettenheim
Managing Director



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

Visit <https://www.dqs.de/en/customer-database/> to validate this certificate.

The validity of the certification can only be verified by the QR-code.



Annex to certificate
Certificate registration No.: 290077 MDSAP16
Certificate unique ID: 1000258135
Effective date: 2025-07-14

Coltène/Whaledent GmbH & Co. KG

Raiffeisenstraße 30
89129 Langenau
Germany

Audited site

533184
Coltène/Whaledent GmbH & Co. KG
Raiffeisenstraße 30
89129 Langenau
Germany

533185
Coltène/Whaledent GmbH & Co. KG
Raiffeisenstraße 28
89129 Langenau
Germany

REPs FEI No.: site scope and country-specific requirements

Design, manufacturing, servicing and distribution of root canal filling material, paper points, surgical aspirator tips, aspirator tips, adapters for aspirator tips, medicated gelatine sponges, retraction cords, root canal files, sterile sleeve for tubes, dental rolls, compression caps, dental pellets, cold spray, articulating paper, occlusion testing material and steel separating strips
-AUS (a), BRA, CND, JPN, USA (a,b,c,d)
REPs FEI No.: F000623

Design, manufacturing, servicing and distribution of root canal filling material, paper points, surgical aspirator tips, aspirator tips, adapters for aspirator tips, medicated gelatine sponges, retraction cords, root canal files, sterile sleeve for tubes, dental rolls, compression caps, dental pellets, cold spray, articulating paper, occlusion testing material 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. 665/2022 RDC ANVISA n. 551/2021 RDC ANVISA n. 67/2009
CND	Canada	Medical Devices Regulations – Part 1- SOR 98/282 Medical Devices Regulations – Part 1.1 – SOR 98/282 (as applicable)
JPN	Japan	MHLW Ministerial Ordinance 169, Article 4 to Article 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