



America

# CERTIFICATE

No. QS6 015409 0032 Rev. 01

**Certificate Holder:** **VDW GmbH**  
Bayerwaldstraße 15  
81737 München  
GERMANY

**Certification Mark:**



**Scope of Certificate:** See Page 2 for Overall Scope Statement.

**Standard(s):** ISO 13485:2016

**Regulatory Authority(ies):** Australia TGA, Brazil ANVISA, Health Canada, USA FDA, MHLW / PMDA. See attached for listing of specific regulatory requirements.

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website [www.tuvsud.com/ps-cert](http://www.tuvsud.com/ps-cert)  
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

**REPs Facility ID:** F003847

**Effective Date:** 2022-06-09

**Expiry Date:** 2025-04-17

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Date of Issue: 2022-06-16

( Renee Walker )  
Manager, US Certification Body,  
Medical and Health Services

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## Regulatory Requirements: Audit/Certification Criteria

### Australia

Therapeutic Goods (Medical Devices) Regulations 2002  
 - Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

### Brazil

- RDC ANVISA n. 16/2013  
 - RDC ANVISA n. 23/2012  
 - RDC ANVISA n. 67/2009

### Canada

- Medical Device Regulations – Part 1- SOR 98/282

### Japan

- MHLW Ministerial Ordinance 169, Article 4 to Article 68  
 - PMD Act

### United States

- 21 CFR Part 803  
 - 21 CFR Part 806  
 - 21 CFR Part 807 – Subparts A to D  
 - 21 CFR Part 820  
 - 21 CFR Part 821

## Overall Scope Statement:

**Design, Development, Service, Production and Distribution of Dental Instruments, Devices for Root Canal Treatment and Accessories as Sterile Root Canal Instruments for Repeated Use, Lubricant for Endodontic Instruments in the Root Canal Preparation, Rotating Root Canal Instruments, Root Canal Filling Points, Paper Points to Dry the Root Canal, Sterile Root Canal Instruments for Single Use, Device for Root Canal Length Determination, Root Canal Posts, Electronic Powered Motor for Root Canal Root Instruments, Endo Contra Angle, Software as Accessory for Endodontic Equipment, Accessories for the Root Canal Instruments for Diagnosis and Treatment of Acute Cases and Permanent Preservation of Diseased Teeth**

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# CERTIFICATE

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**Facility(ies):** VDW GmbH  
Bayerwaldstraße 15, 81737 München, GERMANY

VDW GmbH  
Hoferstrasse 1, 81737 München, GERMANY

**Facility Scopes:** **VDW GmbH**  
Bayerwaldstraße 15, 81737 München, GERMANY

Design, Development, Service, Production and Distribution of Dental Instruments, Devices for Root Canal Treatment and Accessories as Sterile Root Canal Instruments for Repeated Use, Lubricant for Endodontic Instruments in the Root Canal Preparation, Rotating Root Canal Instruments, Root Canal Filling Points, Paper Points to Dry the Root Canal, Sterile Root Canal Instruments for Single Use, Device for Root Canal Length Determination, Root Canal Posts, Electronic Powered Motor for Root Canal Root Instruments, Endo Contra Angle, Software as Accessory for Endodontic Equipment, Accessories for the Root Canal Instruments for Diagnosis and Treatment of Acute Cases and Permanent Preservation of Diseased Teeth  
REPs Facility ID: F003847

**VDW GmbH**  
Hoferstrasse 1, 81737 München, GERMANY

Service and Distribution of Electronic Powered Motor for Root Canal Root Instruments, Device for Root Canal Length Determination, Endo Contra Angle, Software as Accessory for Endodontic Equipment  
REPs Facility ID: F003847

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