ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 015409 0032 Rev. 00

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

Certification Mark:

Scope of Certificate: **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**

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 https://www.tuev-sued.de/product-testing/certificates

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

DUNS No: **31-613-8895**

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(Arie Henkin)
Manager, Certification Body MHS

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Regulatory Requirements: **Audit/Certification Criteria**

Australia
Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1

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

Canada
- Medical Device Regulations SOR/98-282, Part 1

United States
- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807
- 21 CFR Part 820
- 21 CFR Part 821

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

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

Facility Scopes: 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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