



America

# CERTIFICATE

No. QS6 033098 0047 Rev. 04

**Certificate Holder:**

**Kettenbach GmbH & Co. KG**  
Im Heerfeld 7  
35713 Eschenburg  
GERMANY

**Certification Mark:**



**Scope of Certificate:**

**Design and Development, Production and Distribution of Dental Products (Denture Soft Liner, Dental Impression Materials, Adhesives for Impression Materials, Bite Registration Materials, Dental Restoration Materials for Crowns and Bridges, Dual-Curing Build-Up Materials, Cavity Cleaning Liquids, Cavity Varnishes);**

**Production and Distribution of Dental Products (Mixing Units for Dental Products (Non-Active Medical Devices), Impression Trays**

**Standard(s):**

**ISO 13485:2016**

**Regulatory Authority(ies):**

**Australia TGA, Brazil ANVISA, Health Canada, Japan MHLW / PMDA, USA FDA. 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. For details and certificate validity see:

[www.tuvsud.com/ps-cert?q=cert:QS6\\_033098\\_0047\\_Rev.04](http://www.tuvsud.com/ps-cert?q=cert:QS6_033098_0047_Rev.04)

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

**REPs Facility ID:**

**F001258**

**Report No.:**

**713345188**

**Effective Date:**

**2025-01-29**

**Expiry Date:**

**2028-01-28**

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Date of Issue: 2025-01-13

( Renee Walker )  
Director, US Certification Body, MHS

# C E R T I F I C A T E

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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. 665/2022 - Good Manufacturing Practices  
- RDC ANVISA n. 551/2021  
- RDC ANVISA n. 67/2009 - Vigilance

### Canada

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

### Japan

- MHLW Ministerial Ordinance No. 169 (2004), as amended by MHLW Ministerial Ordinance No.60 (2021)  
- Japan PMD Act (as applicable)

### United States

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

## Facility(ies):

### Kettenbach GmbH & Co. KG

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