



America

# CERTIFICATE

No. QS6 057633 0026 Rev. 02

**Certificate Holder:** Heraeus Medical GmbH  
Philipp-Reis-Strasse 8/13  
61273 Wehrheim  
GERMANY

**Certification Mark:**



**Scope of Certificate:** Design and Development, Manufacturing and Distribution of Biomaterials for Bone Surgery with and without Drugs and related Equipment for Cementation

**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\\_057633\\_0026\\_Rev.02](http://www.tuvsud.com/ps-cert?q=cert:QS6_057633_0026_Rev.02)

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

**REPs Facility ID:** F001246  
**Report No.:** 713332785  
**Effective Date:** 2024-09-26  
**Expiry Date:** 2027-09-25

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**Date of Issue:** 2024-08-09

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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):

### Heraeus Medical GmbH

Philipp-Reis-Strasse 8/13, 61273 Wehrheim, GERMANY

## Facility Scopes:

Design and Development, Manufacturing and Distribution of Biomaterials for Bone Surgery with and without Drugs and related Equipment for Cementation  
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