



America

# CERTIFICATE

No. QS6 107266 0013 Rev. 00

**Certificate Holder:** OSARTIS GmbH  
Auf der Beune 101  
64839 Münster  
GERMANY

**Certification Mark:**



**Scope of Certificate:** Design and Development, Production and Distribution of Bone Cements, Mixing and Delivery Devices (including Application Aids) and Bone Substitution Materials (including Application Devices) and Collagen Products

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

**Regulatory Authority(ies):** Australia TGA, Brazil ANVISA, Health Canada, 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. 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:** F005903

**Effective Date:** 2022-01-03

**Expiry Date:** 2023-01-02

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**Date of Issue:** 2022-01-07

( Michael Ogunleye )  
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

**United States**

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

**Facility(ies):**

OSARTIS GmbH  
Auf der Beune 101, 64839 Münster, GERMANY

OSARTIS GmbH  
Lagerstraße 11-15, 64807 Dieburg, GERMANY

OSARTIS GmbH  
Nordring 29, 64807 Dieburg, GERMANY

OSARTIS GmbH  
Benzstraße 4, 64807 Dieburg, GERMANY

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# CERTIFICATE

No. QS6 107266 0013 Rev. 00

**Facility Scopes:**

**OSARTIS GmbH**

Auf der Beune 101, 64839 Münster, GERMANY

Design and Development, Production and Distribution of Bone Cements, Mixing and Delivery Devices (including Application Aids), Cementing Technique, and Bone Substitute Materials (including Application Devices) and Collagen Products  
REPs Facility ID: F005903

**OSARTIS GmbH**

Lagerstraße 11-15, 64807 Dieburg, GERMANY

Design and Development, Production and Distribution of Bone Cements, Mixing and Delivery Devices (including Application Aids), Cementing Technique, and Bone Substitute Materials (including Application Devices) and Collagen Products  
REPs Facility ID: F005903

**OSARTIS GmbH**

Nordring 29, 64807 Dieburg, GERMANY

Production and Distribution of Bone Cements, Mixing and Delivery Devices (including Application Aids), Cementing Technique, and Bone Substitute Materials (including Application Devices) and Collagen Products  
REPs Facility ID: F005903

**OSARTIS GmbH**

Benzstraße 4, 64807 Dieburg, GERMANY

Storage and Distribution of Bone Cements, Mixing and Delivery Devices (including Application Aids), Cementing Technique, and Bone Substitute Materials (including Application Devices) and Collagen Products  
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