



America

CERTIFICATE

No. QS6 107266 0013 Rev. 01

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

REPs Facility ID: F005903

Effective Date: 2023-01-03

Expiry Date: 2026-01-02

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Date of Issue: 2022-12-19

(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

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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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
REPs Facility ID: F005903

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