

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

OSARTIS GmbH
Lagerstraße 11 – 15
Dieburg
64807
Germany

DUNS Number: 34-426-1631

Holds Certificate No:

MDSAP 699421

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure; Brasil - RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009; Canada - Medical Devices Regulations - Part 1 - SOR 98/282; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Design and Development, Production and Distribution of Bone Cements, Mixing and Delivery Devices (including Application Aids) and Bone Substitute Materials (Including Application Devices) and Collagen Products.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2019-08-02

Effective Date: 2019-08-02

Expiry Date: 2022-08-01



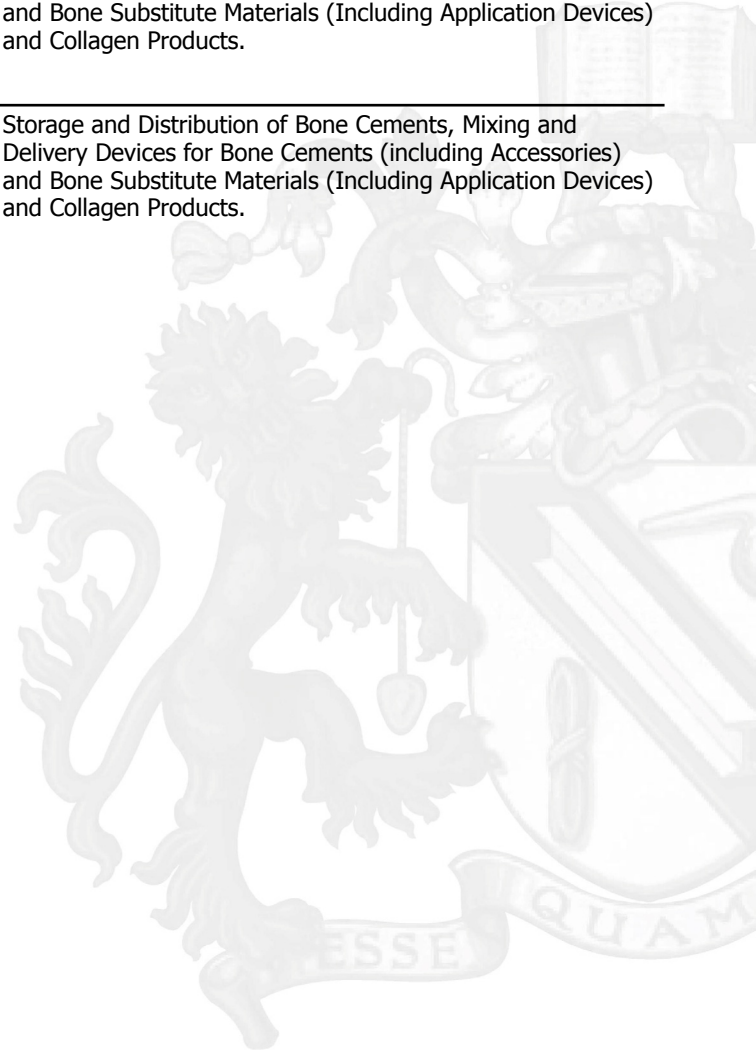
BSI Group America Inc. is an MDSAP authorized auditing organization

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Certificate No: **MDSAP 699421**

Location	Registered Activities
OSARTIS GmbH Lagerstraße 11 – 15 Dieburg 64807 Germany DUNS Number: 34-426-1631	Design and Development, Production and Distribution of Bone Cements, Mixing and Delivery Devices (including Application Aids) and Bone Substitute Materials (Including Application Devices) and Collagen Products.
OSARTIS GmbH Nordring 29 Dieburg 64807 Germany	Production and Distribution of Bone Cements, Mixing and Delivery Devices for Bone Cements (including Accessories) and Bone Substitute Materials (Including Application Devices) and Collagen Products.
OSARTIS GmbH Benzstraße 4 Dieburg 64807 Germany	Storage and Distribution of Bone Cements, Mixing and Delivery Devices for Bone Cements (including Accessories) and Bone Substitute Materials (Including Application Devices) and Collagen Products.



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This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated [online](http://www.bsigroup.com/ClientDirectory). Printed copies can be validated at www.bsigroup.com/ClientDirectory
To be read in conjunction with the scope above or the attached appendix.

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