

Certificate of Registration

QUALITY MANAGEMENT SYSTEM – ISO 13485:2016

This is to certify that:

DSM Biomedical, Inc.
d.b.a. DSM Biomedical
d.b.a. Actamax Surgical Materials, LLC
735 Pennsylvania Drive
Exton
Pennsylvania
19341
USA

DUNS Number: 13-110-7757

Holds certificate No:

MDSAP 669973

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 [if design controls are part of the certification]; 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; Japan - MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D

Please see scope page.

For and on behalf of BSI:



Carlos Pitanga, Chief Operating Officer Assurance - Americas

Original Registration Date: 2017-08-09

Effective Date: 2018-11-08

Expiry date: 2021-05-13

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BSI Group America Inc. is an MDSAP authorized auditing organization

Certificate No:

MDSAP 669973

Registered Scope:

The design, development and manufacture of autologous blood and tissue processing systems, biomedical polymers, specialty chemicals, bioresorbable implants fabricated alone or from combinations of synthetic resorbable polymers, bioceramics and collagen; and associated instrumentation. The manufacture and distribution of medical devices to customer specifications. Provision of contract manufacturing operations, including distribution, utilizing animal tissues; machining and molding polymers and metals; chemical processing and non-aseptic syringe filling; and electronic assembly.



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This certificate remains the property of BSI and shall be returned immediately upon request.
To be read in conjunction with the scope above or the attached appendix.

Managed by: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA
A Member of the BSI Group of Companies.