

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003

This is to certify that:

DSM Biomedical, Inc.
d.b.a. DSM Biomedical
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 13485:2003 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 4 - Production Quality Assurance Procedure [if design controls are excluded from 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

The design, development and manufacture of bioresorbable implants fabricated alone or from combinations of synthetic resorbable polymers, bioceramics and collagen; and associated instrumentation. The design, development and manufacture of autologous blood and tissue processing systems. The manufacture and distribution of medical devices to customer specifications.

For and on behalf of BSI:

Carlos Pitanga, SVP, System Certification and Compliance

Original Registration Date: 2017-08-09

Effective Date: 2017-12-21

Expiry Date: 2019-02-28



BSI Group America Inc. is an MDSAP authorized auditing organization

Certificate No: **MDSAP 669973**

Location

DSM Biomedical, Inc.
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735 Pennsylvania Drive
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DUNS Number: 13-110-7757

Registered Activities

The design, development and manufacture of bioresorbable implants fabricated alone or from combinations of synthetic resorbable polymers, bioceramics and collagen; and associated instrumentation. The design, development and manufacture of autologous blood and tissue processing systems. The manufacture and distribution of medical devices to customer specifications.

DSM Biomedical, Inc.
d.b.a. DSM Biomedical
640 Rice Blvd.
Exton
Pennsylvania
19341
USA
DUNS Number: 13-110-7757

The design, development and manufacture of bioresorbable implants fabricated alone or from combinations of synthetic resorbable polymers, bioceramics and collagen; and associated instrumentation. The design, development and manufacture of autologous blood and tissue processing systems. The manufacture and distribution of medical devices to customer specifications.



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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.

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