

# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

DSM Biomedical, Inc.  
Also dba DSM Biomedical  
735 Pennsylvania Drive  
Exton  
Pennsylvania  
19341  
USA

Facility ID Number: F000252

Holds Certificate No:

**MDSAP 669973**

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

**Australia:** Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure

**Brazil:** RDC ANVISA n. 67/2009, RDC ANVISA n. 665/2022 - Good Manufacturing Practices, RDC ANVISA n. 551/2021

**Canada:** Medical Devices Regulations - Part 1 - SOR 98/282

**Japan:** MHLW MO No 169 (2004), as amended by MHLW MO No 60 (2021), 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:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2017-08-09

Effective Date: 2024-05-14

Expiry Date: 2027-05-13



BSI Group America Inc. is an MDSAP recognised 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.



Original Registration Date: 2017-08-09

Effective Date: 2024-05-14

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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](#). Printed copies can be validated at [www.bsigroup.com/ClientDirectory](http://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.

Certificate No: **MDSAP 669973**

Location

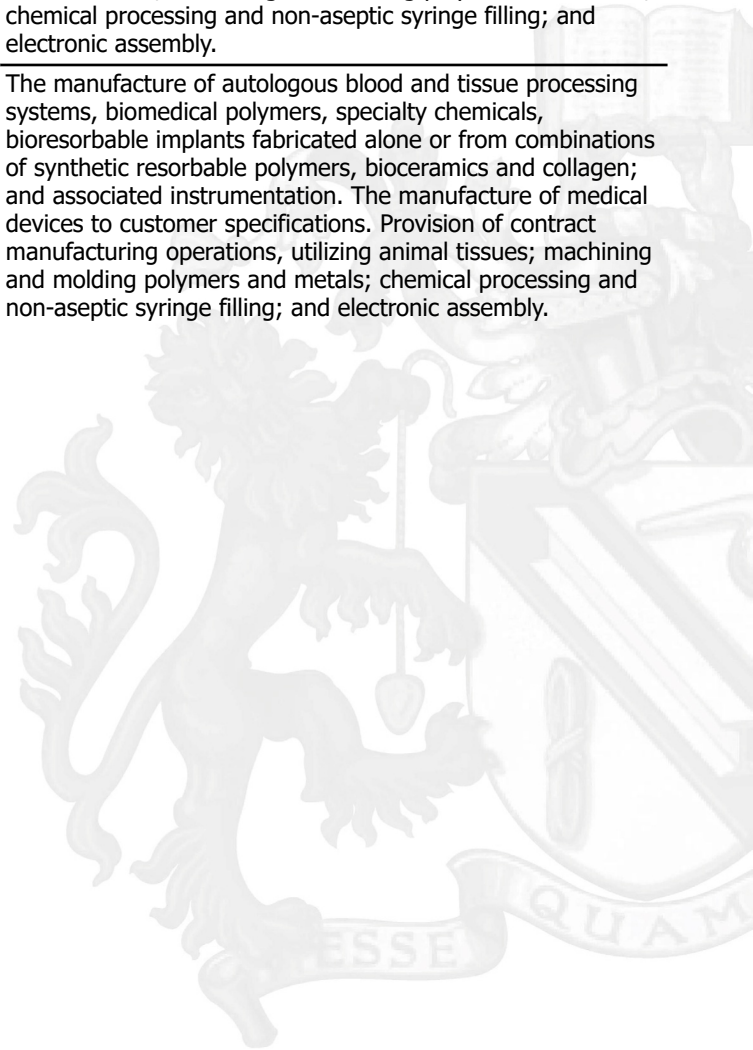
Registered Activities

DSM Biomedical, Inc.  
Also dba DSM Biomedical  
735 Pennsylvania Drive  
Exton  
Pennsylvania  
19341  
USA  
Facility ID Number: F000252

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. 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.

DSM Biomedical, Inc  
Also dba DSM Biomedical  
260 Sierra Drive  
Exton  
Pennsylvania  
19341  
USA  
Facility ID Number: F000252

The 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 of medical devices to customer specifications. Provision of contract manufacturing operations, utilizing animal tissues; machining and molding polymers and metals; chemical processing and non-aseptic syringe filling; and electronic assembly.



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