

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

DSM Biomedical, Inc.
d.b.a. DSM Biomedical
735 Pennsylvania Drive
Exton
Pennsylvania
19341
USA

Holds Certificate No:

FM 550312

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following 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.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2009-07-01

Latest Revision Date: 2021-06-28

Effective Date: 2021-05-14

Expiry Date: 2024-05-13



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Certificate No: **FM 550312**

Location

Registered Activities

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735 Pennsylvania Drive
Exton
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19341
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DSM Biomedical, Inc
d.b.a. DSM Biomedical
260 Sierra Drive
Exton
Pennsylvania
19341
USA

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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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
To be read in conjunction with the scope above or the attached appendix.