

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 Number:

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:


Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2009-07-01

Latest Revision Date: 2026-02-10

Effective Date: 2024-05-14

Expiry Date: 2027-05-13

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BSI Group The Netherlands B.V. is registered in The Netherlands under number 33264284 | A Member of the BSI Group Holdings B.V.

America Headquarters: BSI Group America Inc. 1950 Opportunity Way, Suite 900, Reston, VA 20190.

Certificate No: FM 550312

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