

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Confluent Medical Technologies, Inc.

47533 Westinghouse Drive
Fremont
California
94539
USA

Holds Certificate Number:

FM 703929

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

The design and development, and manufacture of nitinol-based products including guide wires for peripheral vascular applications.

The contract manufacture of plastic and metal-based products including components and sutures; and percutaneous transluminal angioplasty catheters, stent delivery systems and other balloon catheters for various applications.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2009-01-07

Latest Revision Date: 2023-11-07

Effective Date: 2023-11-13

Expiry Date: 2026-11-12

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...making excellence a habit.™

Certificate No: FM 703929

Location	Registered Activities
Confluent Medical Technologies, Inc. 20 Commerce Drive Warwick Rhode Island 02886 USA	Contract manufacturing of Medical Textile and Composite Materials for the Biomedical, Biosurgical and Tissue Engineering Markets.
Confluent Medical Technologies, Inc. 27721 La Paz Road [Bldg. 1, 2 & 3] Laguna Niguel California 92677 USA	Contract manufacture and New Product Design and Development for extrusion, balloons and catheter components and subassemblies.
Confluent Medical Technologies, Inc. 60 Commerce Drive Warwick Rhode Island 02886 USA	Contract Manufacturing of Medical Textile and Composite Materials for the Biomedical, Biosurgical and Tissue Engineering Markets.
Confluent Medical Technologies 47533 Westinghouse Drive Fremont California 94539 USA	The design and development, and manufacture of nitinol-based products including guide wires for peripheral vascular applications.
Confluent Medical Technologies, Inc. Calle Jumanos #937 Suite B Col. Heroes De Mexico Cd. Juarez Chihuahua C.P. 32599 Mexico	Visual Inspection of Nitinol based products.
Nitinol Devices & Components Costa Rica, S. R. L. Coyol Free Zone, Buildings B14, B15, B25 and B28 El Coyol, Alajuela 20102 Costa Rica	The manufacture of nitinol-based products including guide wires for peripheral vascular applications. The contract manufacture of plastic and metal-based products including components and sutures; and percutaneous transluminal angioplasty catheters, stent delivery systems and other balloon catheters for various applications.

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An electronic certificate can be authenticated [online](#).

Printed copies can be validated at www.bsigroup.com/ClientDirectory

Issuing Body: BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands

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

Contact Office: 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA.

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Location

Confluent Medical Technologies
6 Riverside Lane
Chattanooga
Tennessee
37406
USA

Registered Activities

Film casting and braiding manufacture.

Confluent Medical Technologies
9208 Waterford Center Boulevard, Suite 150
Austin
Texas
78758
USA

Pilot manufacturing and design and development.



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