

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:

Design, development and manufacture of Nitinol based products including guide wires. These products are complemented by technical services including consulting, testing, and analytical support. The contract manufacture and prototype development of catheter components and subassemblies. Contract manufacturer of Percutaneous Transluminal Angioplasty (PTA) Catheters and Stent Delivery Systems (SDS).

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2009-01-07

Latest Revision Date: 2023-02-28

Effective Date: 2020-11-13

Expiry Date: 2023-11-12



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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] Laguna Niguel California 92677 USA	The contract manufacture and prototype development of catheter components and subassemblies.
Confluent Medical Technologies, Inc. 27721 La Paz [Bldg 3] Laguna Niguel California 92677 USA	Extrusion clean room, sales, marketing and supply chain.
Confluent Medical Technologies, Inc. 27721 La Paz [Bldg. 2] Laguna Niguel California 92677 USA	Balloon clean room; balloons, weld sleeves, and catheters. New Product Design and Development.
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	Design, development and manufacture of Nitinol based products including guide wires. These products are complemented by technical services including consulting, testing, and analytical support. The contract manufacture and prototype development of catheter components and subassemblies. Contract manufacturer of Percutaneous Transluminal Angioplasty (PTA) Catheters and Stent Delivery Systems (SDS).

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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	Registered Activities
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	Manufacture of polymer, chrome-cobalt and Nitinol based products including guidewires, components and sutures in B14 and B15. Contract manufacturer of percutaneous transluminal angioplasty (PTA) catheters and stent delivery systems (SDS) and other balloon catheter for various applications including Ear-Nose-Throat (ENT) and spine in building B25 and B28.
Confluent Medical Technologies 6 Riverside Lane Chattanooga Tennessee 37406 USA	Film casting and braiding manufacture.
Confluent Medical Technologies 9208 Waterford Center Boulevard, Suite 140 Austin Texas 78758 USA	Pilot manufacturing and design and development.

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