

# 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 No:

**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:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2009-01-07

Latest Revision Date: 2021-10-13

Effective Date: 2020-11-13

Expiry Date: 2023-11-12



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Certificate No: **FM 703929**

Location	Registered Activities
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).
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.

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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.

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Location

Nitinol Devices & Components  
Costa Rica, S. R. L.  
Coyol Free Zone, Buildings B14, B15 and B25  
El Coyol, Alajuela  
20102  
Costa Rica

Registered Activities

Manufacture of Polymer, Chrome-Cobalt and Nitinol based products including guide wires, components and sutures in Buildings B14 and B15.

Contract manufacturer of Percutaneous Transluminal Angioplasty (PTA) Catheters and Stent Delivery Systems (SDS) and other balloon catheters for various applications including Ear-Nose-Throat (ENT) and spine in Building B25.



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