

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003

This is to certify that:

Confluent Medical Technologies, Inc.
47533 Westinghouse Drive
Fremont
California
94539
USA

Holds Certificate No:

FM 539571

and operates a Quality Management System which complies with the requirements of ISO 13485:2003 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.

For and on behalf of BSI:



Carlos Pitanga, SVP, System Certification and Compliance

Original Registration Date: 01/07/2009

Effective Date: 02/08/2017

Expiry Date: 12/09/2017



CMDCAS
Recognized
Registrar



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Certificate No: **FM 539571**

Location	Registered Activities
Confluent Medical Technologies, Inc. 27752 El Lazo Road Laguna Niguel California 92677 USA	The contract manufacture and prototype development of catheter components and subassemblies.
Confluent Medical Technologies, Inc. 27721 La Paz Laguna Niguel California 92677 USA	Extrusion clean room, sales, marketing and supply chain.
Confluent Medical Technologies, Inc. 27722 El Lazo Laguna Niguel California 92677 USA	Balloon clean room; balloons, weld sleeves, and catheters. NPD and engineering.
Confluent Medical Technologies, Inc. 47533 Westinghouse Drive Fremont California 94539 USA	Design and manufacture of Nitinol based products. These products are complemented by technical services including consulting, testing, and analytical support.
Confluent Medical Technologies, Inc. Circuito Int. Norte No. 1820 Parque Ind. Salvarcar Cd. Juarez Chihuahua C.P. 33014 Mexico	Visual Inspection of Nitinol based products.
Nitinol Devices & Components Costa Rica, S. R. L. Coyol Free Zone, Building B14 and B15 El Coyol, Alajuela Costa Rica	Manufacture of Nitinol based products including guide wires.

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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](http://www.bsigroup.com/ClientDirectory). Printed copies can be validated at www.bsigroup.com/ClientDirectory
To be read in conjunction with the scope above or the attached appendix.

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A Member of the BSI Group of Companies.