By Royal Charter

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:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2009-01-07
Latest Revision Date: 2019-01-24

Effective Date: 2018-11-14
Expiry Date: 2020-11-12

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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 1300 White Oaks Rd Campbell California 95008 USA	Contract Design, Development and Manufacturing of Complex Steerable Catheters Including Energy, Sensing, and Flexible Circuit.
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. 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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Location	Registered Activities
Nitinol Devices & Components Costa Rica, S. R. L. Coyol Free Zone, Buildings B14, B15 and B25 El Coyol, Alajuela 20102 Costa Rica	Manufacture of Nitinol based products including guide wires in Buildings B14 and B15. Contract manufacturer of Percutaneous Transluminal Angioplasty (PTA) Catheters and Stent Delivery Systems (SDS) in Building B25.

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