

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: 2020-09-25

Effective Date: 2018-11-14

Expiry Date: 2020-11-12

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...making excellence a habit.™

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 Inc 1300 White Oaks Rd Campbell California 95008 USA | Contract 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, development and manufacture of Nitinol based products including guide wires. These products are complemented by technical services including consulting, testing, and analytical support. |

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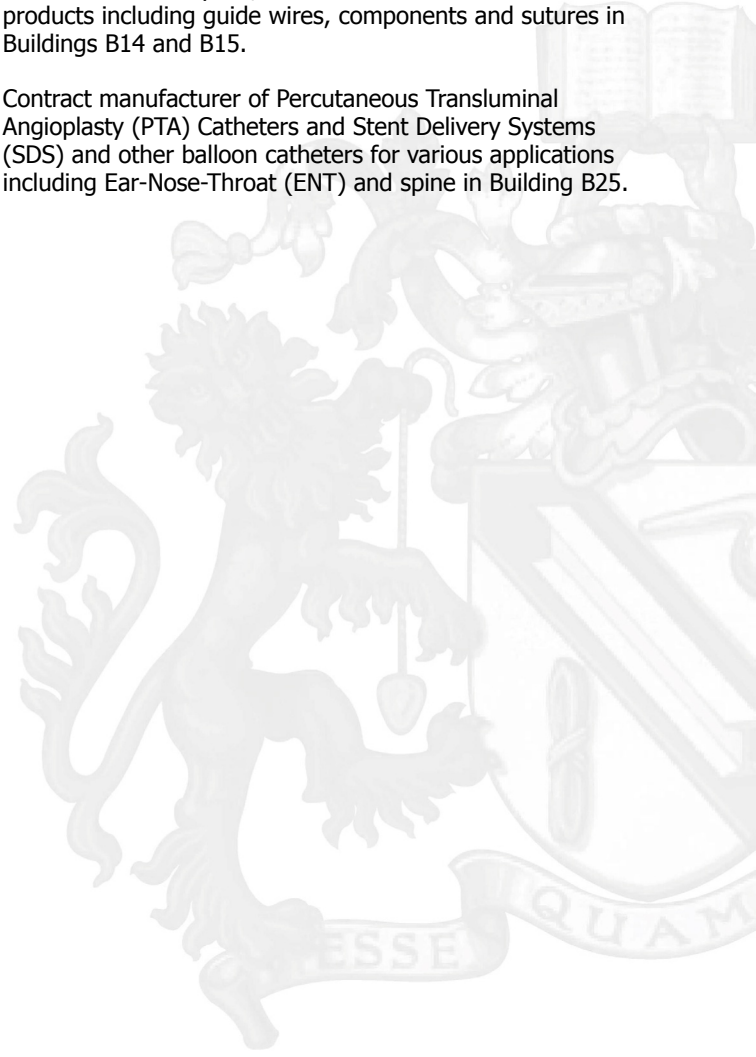
Expiry Date: 2020-11-12

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To be read in conjunction with the scope above or the attached appendix.

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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 and B25 El Coyol, Alajuela 20102 Costa Rica | 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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