

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Confluent Medical Technologies
47533 Westinghouse Drive
Fremont
California
94539
USA

Facility ID Number: F003213

Holds Certificate No:

MDSAP 703911

Statement of Conformity: The company listed on this certificate has been audited and found to conform with the following criteria: ISO 13485:2016 and Canada - Medical Devices Regulations - Part 1 - SOR 98/282; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Design, development and manufacture of Nitinol based products including guide wires.

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: 2021-12-24

Effective Date: 2021-12-24

Expiry Date: 2023-11-12



BSI Group America Inc. is an MDSAP authorized auditing organization

Certificate No: **MDSAP 703911**

Location

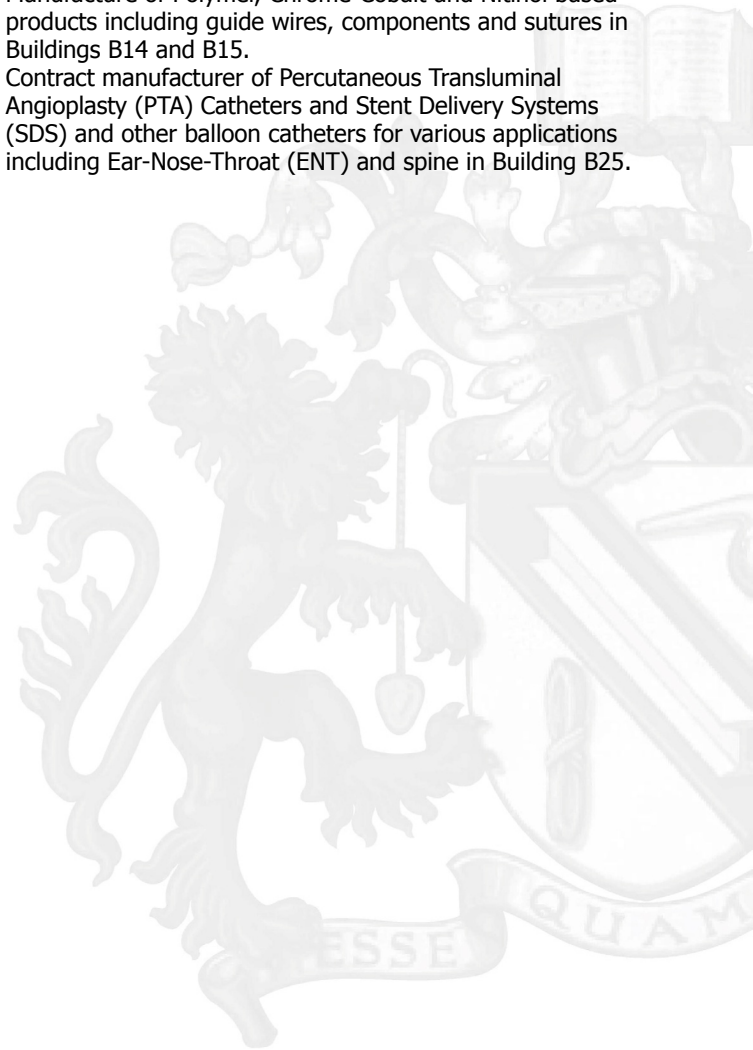
Confluent Medical Technologies
47533 Westinghouse Drive
Fremont
California
94539
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Facility ID Number: F003213

Registered Activities

Design, development and manufacture of Nitinol based products including guide wires.

Nitinol Devices & Components
Costa Rica, S. R. L.
Coyol Free Zone, Buildings B14, B15 and B25
El Coyol, Alajuela
20102
Costa Rica
Facility ID Number: F003268

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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This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated [online](https://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.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA
A Member of the BSI Group of Companies.