

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

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

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:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2021-12-24

Effective Date: 2023-05-15

Expiry Date: 2023-11-12



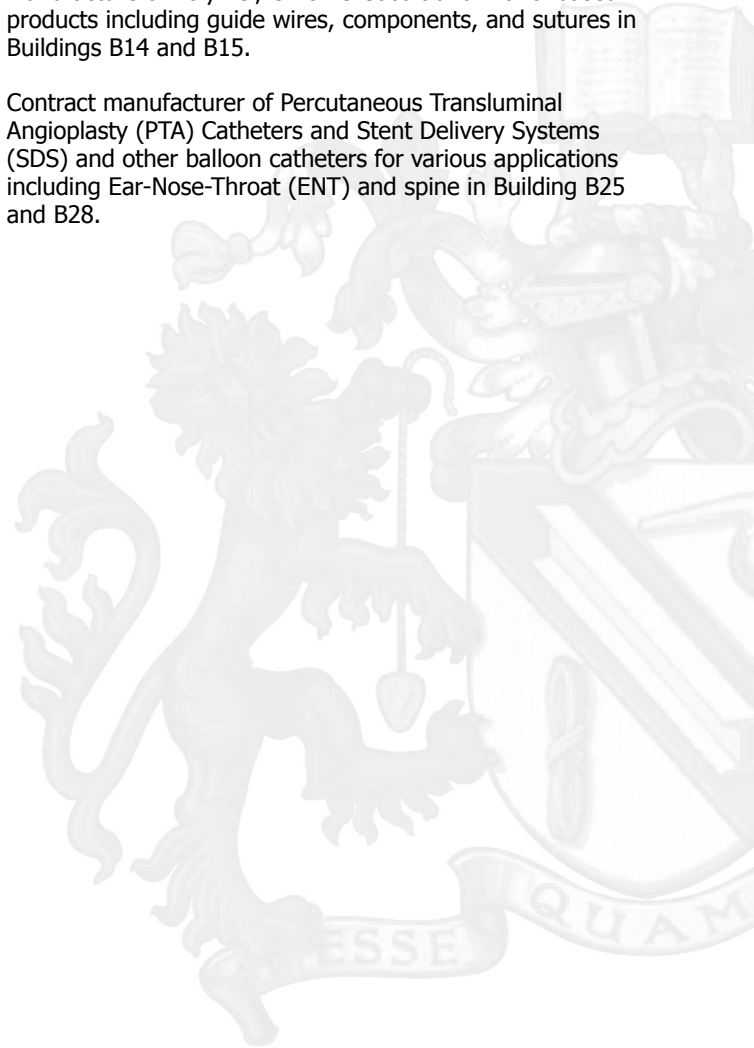
BSI Group America Inc. is an MDSAP recognised auditing organization

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Certificate No: **MDSAP 703911**

Location	Registered Activities
Confluent Medical Technologies 47533 Westinghouse Drive Fremont California 94539 USA Facility ID Number: F003213	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, B25 and B28 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 and B28.



Original Registration Date: 2021-12-24 Effective Date: 2023-05-15 Expiry Date: 2023-11-12

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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.

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