By Royal Charter

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

The design and development, and manufacture of nitinol-based products including guide wires for peripheral vascular applications.

The contract manufacture of plastic and metal-based products including components and sutures; and percutaneous transluminal angioplasty catheters, stent delivery systems and other balloon catheters for various applications.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2021-12-24 Effective Date: 2023-11-13 Expiry Date: 2026-11-12

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM
BSI Group America Inc. is an MDSAP recognised auditing organization

...making excellence a habit.™

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	The manufacture of nitinol-based products including guide wires for peripheral vascular applications. The contract manufacture of plastic and metal-based products including components and sutures; and percutaneous transluminal angioplasty catheters, stent delivery systems and other balloon catheters for various applications.

Original Registration Date: 2021-12-24 Effective Date: 2023-11-13 Expiry Date: 2026-11-12