



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

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

Holds Certificate No:

MDSAP 813922

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

Brazil: RDC ANVISA n. 67/2009, RDC ANVISA n. 665/2022 - Good Manufacturing Practices **Japan:** MHLW MO No 169 (2004), as amended by MHLW MO No 60 (2021), PMD Act **USA:** 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Contract manufacture of plastic and metal-based products including components, sutures, guide wires, 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 Global Regulatory & Quality

Original Registration Date: 2024-11-21

Effective Date: 2024-11-21

Expiry Date: 2026-11-12

Page: 1 of 1





...making excellence a habit."

This certificate remains the property of BSI and shall be returned immediately upon request. An electronic certificate can be authenticated <u>online</u>. 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.