

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



BSI Group America Inc. is an MDSAP recognised auditing organization

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