



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485: 2003

This is to certify that:

Nitinol Devices and Components, Inc.
47533 Westinghouse Drive
Fremont
California
94539
USA

Holds Certificate No: **FM 539571**

and operates a Quality Management System which complies with the requirements of ISO 13485: 2003 for the following scope:

Design, development and manufacture of Nitinol based products including endovascular guide wires. These products are complemented by technical services including consulting, testing, and analytical support.

For and on behalf of BSI:

VP Regulatory Affairs, BSI Group America Inc.

Originally Registered: **01/07/2009**

Effective Date: **01/03/2012**

Expiry Date: **01/02/2015**



CMDCAS
Recognized
Registrar



Page: 1 of 2

This certificate remains the property of BSI and shall be returned immediately upon request. An electronic certificate can be authenticated [online](#). 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., 12110 Sunset Hills Road, Suite 200, Reston, VA 20190, USA.
A Member of the BSI Group of Companies.



Certificate No: **FM 539571**

Location

Registered Activities

Nitinol Devices and Components, Inc.
47533 Westinghouse Drive
Fremont
California
94539
USA

Design and manufacture of Nitinol based products.
These products are complemented by technical
services including consulting, testing, and analytical
support.

Nitinol Devices and Components Inc.
Circuito Int. Norte No. 1820
Parque Ind. Salvarcar
Cd. Juarez
Chihuahua
C.P. 33014
Mexico

Visual Inspection of Nitinol based products.

Nitinol Devices & Components
Costa Rica, S. R. L.
Coyol Free Zone, Building B15
El Coyol, Alajuela
Costa Rica

Manufacture of guide wires.

Originally Registered: **01/07/2009**

Effective Date: **01/03/2012**

Expiry Date: **01/02/2015**

Page: 2 of 2

This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated [online](#). 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., 12110 Sunset Hills Road, Suite 200, Reston, VA 20190, USA.
A Member of the BSI Group of Companies.