



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485: 2003

This is to certify that:

**Spire Biomedical, Inc.
One Patriots Park
Bedford
Massachusetts
01730
USA**

Holds Certificate No: **FM 511930**

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

Design, development, manufacturing, and distribution of hemodialysis catheters, catheterization kits, vascular dilators, guidewires, tunnelers and repair kits. Contract provider of medical device surface treatment processing.

This certificate is traceable to this company's original certificate 74 500 2274 dated September 06, 2006 and issued by TUV.

For and on behalf of BSI:

President, BSI America, Inc.

Originally Registered: **10/09/2006**

Effective Date: **08/27/2009**

Expiry Date: **08/26/2012**



**CMDCAS
Recognized
Registrar**

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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: 12110 Sunset Hills Road, Suite 200, Reston, VA 20190, USA.

