

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Argon Medical Devices, Inc.
1445 Flat Creek Road
Athens
Texas
75751
USA

Facility ID Number: F000045

Holds Certificate No:

MDSAP 694618

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure; Brasil - RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009; Canada - Medical Devices Regulations - Part 1 - SOR 98/282; Japan - MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Please see scope page.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2019-04-29

Effective Date: 2022-04-29

Expiry Date: 2023-04-28



BSI Group America Inc. is an MDSAP authorized auditing organization

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Certificate No: **MDSAP 694618**

Registered Scope:

Design, manufacture, servicing and contract manufacture and distribution of sterile and non- sterile disposable and reusable medical devices consisting of single and multi- lumen central venous catheterization, endovascular snares, drainage catheters and collection devices, hystero-salpingography catheters, dialysis catheters, fluid management systems, IV lines, manifolds, prostate seeding needles and stabilization devices, biopsy and access needles, breast biopsy site markers, syringes, hemostatic wound dressing, guidewires, biopsy instruments and tray, introducer kits, trays and accessories, scalpels, arterial line kits, procedure drapes, equipment covers, high pressure lines, monitoring lines, stopcocks, adapters and plugs, vascular and non- vascular care products for cardiology, interventional radiology and critical care procedures, thrombectomy devices and vena cava filter systems.



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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](#). Printed copies can be validated at www.bsigroup.com/ClientDirectory
To be read in conjunction with the scope above or the attached appendix.

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A Member of the BSI Group of Companies.