By Royal Charter

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**

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

Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure
Brazil: RDC ANVISA n. 67/2009, RDC ANVISA n. 665/2022 - Good Manufacturing Practices, RDC ANVISA n. 551/2021
Canada: Medical Devices Regulations - Part 1 - SOR 98/282
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

Please see scope page.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2019-04-29 Effective Date: 2025-04-29 Expiry Date: 2028-04-28

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM
BSI Group America Inc. is an MDSAP recognised auditing organization

...making excellence a habit.™

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.

Original Registration Date: 2019-04-29 Effective Date: 2025-04-29 Expiry Date: 2028-04-28