

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

Holds Certificate Number:

FM 700791

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Design, manufacture, servicing and contract manufacturing 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.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2010-09-03

Latest Revision Date: 2022-09-15

Effective Date: 2022-04-29

Expiry Date: 2022-10-28

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