Certificate US19/819943168

The quality management system of

Argon Medical Devices, Inc.

241 W. Palatine Road, Wheeling, IL, 60090, United States Of America
Facility number: F002562

has been assessed and certified as meeting the requirements of

MDSAP (ISO 13485:2016)

USA: 21 CFR Part 803 - Medical Device Reporting; 21 CFR Part 806 - Reports of Corrections and Removals; 21 CFR Part 807 (Subparts A to D) - Establishment Registration and Device Listing, 21 CFR Part 820 - Quality System Regulation

For the following activities
Contract manufacturer of Angiographic Needles, Soft Tissue Biopsy Needle Products, Hard Tissue Biopsy Needle Products, Anaesthesia Needle Products, Vascular Access Needles, Oncology Needle Products, Catheter sub-assemblies, and re-usable biopsy instruments.

This certificate is valid from Effective date 2024-08-05 until Expiry date 2027-08-05 and remains valid subject to satisfactory surveillance audits.
Issue 6. Certified since 2019-05-08

L. Henderson

Authorised by
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SGS UK LTD is recognised under the Medical Devices Single Audit Program. The validity of this certificate can be verified at www.SGS.com.