



Certificate Number US19/819943168

The quality management system of

Argon Medical Devices, Inc.

241 W. Palatine Road, Wheeling, IL, 60090, United States

Facility identification number: F002562

has been audited against the criteria stated below and found to conform to those criteria for the scope contained in this certificate



MDSAP(ISO 13485:2016)

Canada:

Medical Devices Regulations – Part 1 SOR 98/282

United States:

21 CFR 820 / 21 CFR 803 / 21 CFR 806 / 21 CFR 807 – Subparts A to D



For the following activities and devices

Design and manufacture of sterile and non-sterile Angiographic Needles, Soft Tissue Biopsy Needle Products, Hard Tissue Biopsy Needle Products, Anesthesia Needle Products, Vascular Access Needles, and Oncology Needle Products. Design and Manufacture of sterile and non-sterile catheter sub-assemblies. The manufacture and service of re-usable, non-sterile biopsy instruments.

This certificate is valid from

Effective Date: 2022-05-08 until Expiry Date: 2025-03-19 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 2024-06-22

Issue 4 Certified since 2019-05-08

Authorised by LHenderson
Business Manager

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