

# Certificate



Certificate No.: MD 740977 163587-20  
Manufacturer: **Vascular Technology, Inc.**  
12 Murphy Drive  
Nashua, NH 03062  
USA

D-U-N-S No.: 16-198-9343

Certification criteria: ISO 13485:2016  
Australia Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure  
Canada Medical Devices Regulations – Part 1 – SOR 98/282  
Japan MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act  
United States 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 – Subparts A to D

Scope: Design and Development, Manufacture, Distribution and Service of the Doppler Ultrasound Systems, Oxygen Monitors, and Remotely Operated Suction Irrigation Systems

TUV Rheinland of North America, Inc., an MDSAP recognized Auditing Organization, certifies that the quality management system of the Manufacturer has been audited against and found to conform the Certification criteria for the Scope contained in this certificate. The quality management system is subject to annual surveillance audit(s).

Project No.: 31793161.002  
Issue Date: 2019-10-22  
Effective Date: 2019-10-22  
Expiry Date: 2022-03-06



A handwritten signature in blue ink that reads "Songqi".

Certification officer: S. Liu  
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified by calling 1-888-743-4652.