

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: Trasonic Systems Inc.
34 Dutch Mill Road
Ithaca
New York
14850
USA

Facility ID Number: F003151

Holds Certificate No: **MDSAP 703653**

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and 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; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

The design, manufacture, service and distribution of ultrasonic flowmeters, Indicator Dilution Flow Meters, tissue perfusion monitors, sterile and non-sterile probes, Fluid Warmer, Blood Pump and sterile catheters.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2020-11-09

Effective Date: 2020-11-09

Expiry Date: 2023-06-19



BSI Group America Inc. is an MDSAP authorized auditing organization

Page: 1 of 1

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