



## Certificate of Registration

## OUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

QuinTron Instrument Company, Inc. 2208 S. 38th Street Milwaukee Wisconsin 53215 USA

Facility ID Number: F000369

Holds Certificate No:

**MDSAP 671378** 

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 and service of in-vitro diagnostic analyzer/software device used in the detection of breath gas markers including point-of-care in-vitro diagnostic devices.

jan Congde

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2017-09-28

Effective Date: 2020-07-20

Expiry Date: 2023-07-19

Page: 1 of 1





BSI Group America Inc. is an MDSAP authorized auditing organization

...making excellence a habit."

This certificate remains the property of BSI and shall be returned immediately upon request. An electronic certificate can be authenticated online. Printed copies can be validated at www.bsigroup.com/ClientDirectory To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA A Member of the BSI Group of Companies.