



## Certificate of Registration

## QUALITY 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** 

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

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 MO No 169 (2004), as amended by MHLW MO No 60 (2021), 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.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2017-09-28

Effective Date: 2023-07-20

Expiry Date: 2026-07-19

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...making excellence a habit."

This certificate remains the property of BSI and shall be returned immediately upon request. An electronic certificate can be authenticated <u>online</u>. 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.