

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

Holds Certificate Number:

FM 671377

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

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: 2014-07-22

Latest Revision Date: 2023-06-01

Effective Date: 2023-07-20

Expiry Date: 2026-07-19

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