



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: HORIBA Instruments Incorporated

Also DBA: HORIBA Medical, Pointe, Pointe Scientific, and Clinitox Brands

5449 Research Drive

Canton Michigan 48188 USA

Holds Certificate Number: FM 548355

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

The design, manufacture and distribution of clinical chemistry in-vitro diagnostics products and distribution and service instruments.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2009-12-15

Latest Revision Date: 2022-09-15

Effective Date: 2021-09-11 Expiry Date: 2024-09-10

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...making excellence a habit."





This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract. An electronic certificate can be authenticated <u>online</u>.

Printed copies can be validated at www.bsigroup.com/ClientDirectory