



## Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

## HORIBA Instruments Incorporated Also DBA HORIBA Medical Also DBA Pointe brand

Also DBA Pointe Scientific brand Also DBA Clinitox brand 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 Global Regulatory & Quality

Original Registration Date: 2009-12-15 Latest Revision Date: 2024-06-14 Effective Date: 2024-09-11 Expiry Date: 2027-09-10

Page: 1 of 1



...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

Issuing Body: BSI Group The Netherlands B.V., John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands BSI Group The Netherlands B.V. is registered in The Netherlands under number 33264284 | A Member of the BSI Group Holdings B.V. Contact Office: 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA.