

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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