By Royal Charter

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

Facility ID Number: F003415

Holds Certificate No: **MDSAP 705807**

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
USA: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

The design, development, manufacture, and distribution of in-vitro diagnostic reagents, calibrators, controls, and finished test kits used in the detection of analytes, including cancer markers, cardiac markers, and drugs of abuse and utilized for the detection and/or management of various medical conditions including diabetes, endocrine disorders, and protein metabolism. The installation, servicing and distribution of clinical chemistry and hematology analyzers which may be used with the forementioned in vitro diagnostic test kits.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2021-12-02 Effective Date: 2024-09-11 Expiry Date: 2027-09-10

MDSAP MEDICAL DEVICE SINGLE AUDIT PROGRAM
BSI Group America Inc. is an MDSAP recognised auditing organization

...making excellence a habit.™