By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

HORIBA ABX SAS
Parc Euromédecine
Rue du Caducée – BP 7290
Montpellier cedex 4
34184
France

Facility ID Number: F006173

Holds Certificate No: **MDSAP 731502**

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure; Brasil - RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009; Canada - Medical Devices Regulations - Part 1 - SOR 98/282; Japan - MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Please see scope page.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2019-05-03 Effective Date: 2022-05-03 Expiry Date: 2025-05-02

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

...making excellence a habit.™

Certificate No: **MDSAP 731502**

Registered Scope:

The design and development and manufacture in-vitro diagnostic medical devices, in vitro diagnostic reagents, in-vitro diagnostic test kits used in the diagnosis and management of disease status, blood analytes, blood components, coagulation.

The design and development and manufacture, installation, and servicing of in-vitro diagnostic analyzers used in the diagnosis and management of disease status, blood analytes, blood components, coagulation.

Original Registration Date: 2019-05-03 Effective Date: 2022-05-03 Expiry Date: 2025-05-02