

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: 27-364-7420

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:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2019-05-03

Effective Date: 2020-11-23

Expiry Date: 2022-05-02



BSI Group America Inc. is an MDSAP authorized auditing organization

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Certificate No: **MDSAP 731502**

Registered Scope:

Design, development, manufacture of in vitro diagnostic medical devices, i.c. reagents, controls, calibrators and analyzers, in the area of haematology, clinical chemistry, immunology, immune-haematology and coagulation, as well as installation and servicing activities.

This certificate is traceable to this company's original registration certificate number FR1 9/81 9943739 dated May 3, 2019 and issued by SGS.



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This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated [online](#). Printed copies can be validated at www.bsigroup.com/ClientDirectory
To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA
A Member of the BSI Group of Companies.