

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



BSI Group America Inc. is an MDSAP authorized auditing organization

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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.



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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](https://www.bsigroup.com/ClientDirectory). Printed copies can be validated at www.bsigroup.com/ClientDirectory
To be read in conjunction with the scope above or the attached appendix.

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A Member of the BSI Group of Companies.