

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

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

Holds Certificate Number:

MD 730428

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Design, development, manufacture, distribution and sales of in vitro test kits, in vitro diagnostic reagents, in vitro diagnostic analyzers and accessories used in the diagnosis and management of disease status, blood analytes, blood components, hemostasis.
Installation and servicing activities of in vitro diagnostic analyzers.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2021-01-15

Latest Revision Date: 2022-01-27

Effective Date: 2021-10-18

Expiry Date: 2024-10-17

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