

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Bio Data Corporation

155 Gibraltar Road
Horsham
Pennsylvania
19044
USA

Holds Certificate Number:

FM 657557

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

The design and development, manufacture, distribution, installation, and service of invitro diagnostic analyzer, reagent, control, test kit medical devices and research use only products for hemostasis.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2016-09-23

Latest Revision Date: 2025-07-29

Effective Date: 2025-09-23

Expiry Date: 2028-09-22

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