

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Azure Biosystems, Inc.
6747 Sierra Court Ste A-B
Dublin
California
94568
USA

Holds Certificate Number:

MD 750616

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

The design, development and manufacture of in-vitro diagnostic analyzers and software used in the diagnosis, management and detection of transmissible agents, sexually transmissible agents and for genetic testing with in-vitro diagnostic devices.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2022-04-21

Latest Revision Date: 2022-04-21

Effective Date: 2022-04-21

Expiry Date: 2025-04-20

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