

Certificate of Registration

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

This is to certify that:

Agena Bioscience, Inc.
4755 Eastgate Mall
San Diego
California
92121
USA

Holds Certificate Number:

MD 600665

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, installation and servicing of diagnostic products, reagents, and instruments for genetic analysis.

For and on behalf of BSI:



Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2013-08-21

Latest Revision Date: 2025-05-28

Effective Date: 2025-08-21

Expiry Date: 2028-08-20

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