

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

GenWay Biotech, Inc.
7700 Ronson Road
Suite 100
San Diego
California
92111
USA

Holds Certificate No:

FM 569115

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

Design, manufacturing and distribution of mammalian, yeast and E. coli expressed protein used in the detection of infectious disease antibodies and as Medical Device controls.



For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2011-01-24

Latest Revision Date: 2019-12-23

Effective Date: 2020-01-24

Expiry Date: 2023-01-23

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