

# bsi.



By Royal Charter

## Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2003

This is to certify that:

GenWay Biotech, Inc.  
6777 Nancy Ridge Drive  
San Diego  
California  
92121  
USA

Holds Certificate No:

**FM 569115**

and operates a Quality Management System which complies with the requirements of ISO 13485:2003 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:

Carlos Pitanga, SVP, System Certification and Compliance

Original Registration Date: 01/24/2011

Latest Revision Date: 01/13/2017

Effective Date: 01/24/2017

Expiry Date: 02/28/2019

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This certificate remains the property of BSI and shall be returned immediately upon request.  
An electronic certificate can be authenticated [online](#). Printed copies can be validated at [www.bsigroup.com/ClientDirectory](http://www.bsigroup.com/ClientDirectory)  
To be read in conjunction with the scope above or the attached appendix.

Americas Headquarters: BSI Group America Inc., 12950 Worldgate Drive, Suite 800, Herndon, VA 20170-6007 USA  
A Member of the BSI Group of Companies.