

# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

The Binding Site Group Ltd  
8 Calthorpe Road  
Edgbaston  
Birmingham  
B15 1QT  
United Kingdom

Facility ID Number: F000449

Holds Certificate No:

**MDSAP 689555**

Statement of Conformity: The company listed on this certificate has been audited to and found to conform with the following criteria: ISO 13485:2016 and Australia - Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure; Brasil - RDC ANVISA n. 16/2013, RDC ANVISA n. 23/2012, RDC ANVISA n. 67/2009; Canada - Medical Devices Regulations - Part 1 - SOR 98/282; Japan - MHLW Ministerial Ordinance 169, Article 4 to Article 68, PMD Act; USA - 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

The design, development, manufacture, service and distribution of in-vitro test kits, reagents, analysers and software used in the diagnosis and management of cancer, immune status, infectious disease status, autoimmune status, cardiovascular risk, protein metabolism, blood analytes, blood components and coagulation.



For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2018-10-04

Effective Date: 2021-04-11

Expiry Date: 2024-04-10



BSI Group America Inc. is an MDSAP authorized auditing organization

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Certificate No: **MDSAP 689555**

Location	Registered Activities
The Binding Site Group Ltd 8 Calthorpe Road Edgbaston Birmingham B15 1QT United Kingdom Facility ID Number: F000449	The design, development, manufacture, service and distribution of in-vitro test kits, reagents, analysers and software used in the diagnosis and management of cancer, immune status, infectious disease status, autoimmune status, cardiovascular risk, protein metabolism, blood analytes, blood components and coagulation.
The Binding Site Group Ltd Unit 27, Sovereign Road Kings Norton Business Centre Kings Norton Birmingham B30 3HN United Kingdom Facility ID Number: F000449	The design, development, manufacture, service and distribution of in-vitro test kits, reagents, analysers and software used in the diagnosis and management of cancer, immune status, infectious disease status, autoimmune status, cardiovascular risk, protein metabolism, blood analytes, blood components and coagulation.



Original Registration Date: 2018-10-04      Effective Date: 2021-04-11      Expiry Date: 2024-04-10

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](#)  
To be read in conjunction with the scope above or the attached appendix.