

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

DUNS Number: 34-704-5614

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 [if design controls are part of the certification]; 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, disease status, autoimmune status, cardiovascular risk, protein metabolism, blood analytes, blood components and coagulation.

For and on behalf of BSI:



Carlos Pitanga, Chief Operating Officer Assurance - Americas

Original Registration Date: 2018-10-04

Effective Date: 2018-10-04

Expiry date: 2021-04-10

Page: 1 of 2

...making excellence a habit.™



BSI Group America Inc. is an MDSAP authorized auditing organization

Certificate No:

MDSAP 689555

Location	Registered Activities
The Binding Site Group Ltd 8 Calthorpe Road Edgbaston Birmingham B15 1QT United Kingdom DUNS Number: 34-704-5614	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, 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 DUNS Number: 34-704-5614	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, disease status, autoimmune status, cardiovascular risk, protein metabolism, blood analytes, blood components and coagulation.



Original Registration Date: 2018-10-04

Effective Date: 2018-10-04

Expiry date: 2021-04-10

Page: 2 of 2

This certificate remains the property of BSI and shall be returned immediately upon request.
To be read in conjunction with the scope above or the attached appendix.

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