



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

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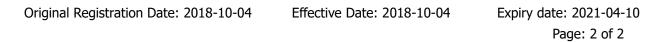
...making excellence a habit."



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.

Certificate No: MDSAP 689555

Location	Registered Activities
The Binding Site Group Ltd	The design, development, manufacture, service and distribution of
8 Calthorpe Road	in-vitro test kits, reagents, analysers and software used in the
Edgbaston	diagnosis and management of cancer, immune status, disease status,
Birmingham	autoimmune status, cardiovascular risk, protein metabolism, blood
B15 1QT	analytes, blood components and coagulation.
United Kingdom	
DUNS Number: 34-704-5614	
The Binding Site Group Ltd	The design, development, manufacture, service and distribution of
Unit 27, Sovereign Road	in-vitro test kits, reagents, analysers and software used in the
Kings Norton Business Centre	diagnosis and management of cancer, immune status, disease status,
Kings Norton	autoimmune status, cardiovascular risk, protein metabolism, blood
Birmingham	analytes, blood components and coagulation.
B30 3HN	
United Kingdom	
DUNS Number: 34-704-5614	



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