

# 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**

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

**Australia:** Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure

**Brazil:** RDC ANVISA n. 67/2009, RDC ANVISA n. 665/2022 - Good Manufacturing Practices, RDC ANVISA n. 551/2021

**Canada:** Medical Devices Regulations - Part 1 - SOR 98/282

**Japan:** MHLW MO No 169 (2004), as amended by MHLW MO No 60 (2021), PMD Act

**USA:** 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Please see scope page.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2018-10-04

Effective Date: 2024-04-11

Expiry Date: 2027-04-10



BSI Group America Inc. is an MDSAP recognised auditing organization

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Certificate No: **MDSAP 689555**

## Registered Scope:

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: 2024-04-11

Expiry Date: 2027-04-10

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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.

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 27-29 & 31-33, 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.



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