

# EU Quality Management System Certificate

Regulation (EU) 2017/746, Annex IX Chapter I and III

## IVDR 744391 R000

**Manufacturer:** The Binding Site Group Ltd

**Address:**

8 Calthorpe Road  
Edgbaston  
Birmingham  
B15 1QT  
United Kingdom

**Single Registration Number:** Not Available

**EU Authorised Representative:** The Binding Site Ireland Limited

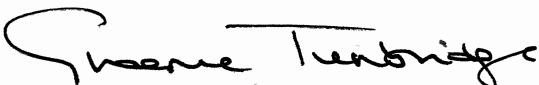
**Address:**

First floor, 43-49 Sir John Rogerson's Quay  
Dublin 2  
Ireland

**Scope:** See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/746, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class D devices, and self-test, near-patient test and companion diagnostic devices an Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):



Graeme Tunbridge, Senior Vice President Medical Devices

First Issue Date: **2023-05-04**

Current Issue Date: **2023-05-04**

Starting Validity Date: **2023-05-04**

Expiry Date: **2028-05-03**

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### Device Schedule: Class D, C and B devices

#### Class C devices

W0102 - Immunochemistry (Immunology)  
 IVP 3007 - In vitro diagnostic devices which require knowledge regarding immunoassays

#### Intended purpose

Immunochemistry (Immunology) devices for in vitro detection of proteins as an aid in diagnosis and monitoring of monoclonal gammopathies, inflammatory conditions, kidney disease and haematological malignancies.

#### Class B devices

IVR 0608 – Devices intended to be used for screening, determination or monitoring of physiological markers.

#### Intended purpose

Immunochemistry (Immunology) devices intended to be used for screening, determination or monitoring of physiological markers

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### Certificate History

*(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)*

Date	Reference Number	Action
Current	3387963	Issued



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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.  
This certificate was issued electronically and is bound by the conditions of the contract.