By Royal Charter

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	Intended purpose
W0102 - Immunochemistry (Immunology) IVP 3007 - In vitro diagnostic devices which require knowledge regarding immunoassays	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	Intended purpose
IVR 0608 – Devices intended to be used for screening, determination or monitoring of physiological markers.	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.

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Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.
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