

EU Quality Management System Certificate

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

IVDR 739694 R000

Manufacturer: Newmarket Biomedical Ltd

Address:

Unit 1
Lanwades Business Park
Kentford
Suffolk
CB8 7PN
United Kingdom

Single Registration Number: GB-MF-000025155

EU Authorised Representative: Medical Device Safety Service GmbH (MDSS)

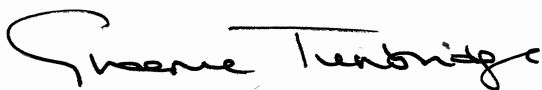
Address:

Schiffgraben 41
30175 Hannover
Germany

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 Issued: **2022-07-07**

Date: **2022-07-07**

Expiry Date: **2027-07-06**

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Device Schedule: Class D, C and B devices

Class C devices	Intended purpose
W010501 - Bacteriology (infect. Immunology)	Agglutination assays for the qualitative detection of antibodies to Treponema Pallidum infections from human serum or EDTA plasma.
IVP 3001 - Agglutination tests	



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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	3328171	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.