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 Global Regulatory & Quality

First Issue Date: **2022-07-07**

Current Issue Date: **2024-04-29**

Starting Validity Date: **2024-04-29**

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) IVP 3001 - Agglutination tests	Agglutination assays for the qualitative detection of antibodies to Treponema Pallidum infections from human serum, EDTA plasma or cerebrospinal fluid (CSF).

Class D devices	Intended purpose
PK7400 TP HA Reagent	See EU Technical Documentation Assessment Certificate IVDR 739696
PK7400 TP HA Controls	See EU Technical Documentation Assessment Certificate IVDR 739696

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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
2022-07-07	3328171	Issued
2023-07-20	3886159	Supplemented- The device schedule has been updated to include Class D devices PK7400 TP HA Reagent & PK7400 TP HA Controls
Current	30128701	Supplemented - addition of CSF specimen type to scope of Class C devices W010501 IVP 3001

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