EU DECLARATION OF CONFORMITY

Product:	Newbio TPHA
Product Codes:	NB007, NB008, NB009

Intended Purpose:

Intended for the qualitative detection of Treponema pallidum IgG and IgM antibodies to syphilis in human serum, EDTA plasma, or CSF. The intended use population is patients with a suspected syphilis infection or at elevated risk of syphilis infection who attend STI clinics or other healthcare settings. This assay is not intended for automated use. This assay is not intended for blood screening or as a confirmatory assay on donor samples.

Basic UDI-DI:	506051514 TPHA 7L
Risk Class:	Class C - Annex VIII Rule 3(a)
Common Specification:	Not applicable
Manufacturer:	Newmarket Biomedical Ltd, Unit 1, Lanwades Business Park, Kentford, Suffolk, CB8 7PN, UK
SRN:	GB-MF-000025155
EU Authorised Representative:	Medical Device Safety Service, Schiffgraben 41, 30175 Hannover, Germany
Notified Body:	BSI Group The Netherlands B.V. Say Building John M. Keynesplein 9 1066 EP Amsterdam The Netherlands
Notified Body No.:	2797
Conformity assessment procedure:	Annex IX Chapters I and III under Regulation 2017/746
IVDR Certificate(s) issued:	IVDR 739694 Quality Management System Certificate

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I declare the above-named product complies with the requirements of Regulation (EU) 2017/746, on *in vitro* diagnostic medical devices. This Declaration of Conformity is issued under the sole responsibility of the manufacturer.

Signed: **Date:** 3 May 2024

Name: Mark Bates **Title:** Chief Operating Officer

Place of signature: Unit 1, Lanwades Business Park, Kentford, Suffolk, CB8 7PN

For and on behalf of Newmarket Biomedical Ltd.