By Royal Charter

EC Certificate - Full Quality Assurance

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV, excluding Sections 4 and 6

No. **CE 595831**

Issued To: **Leica Biosystems Newcastle Ltd**
Balliol Business Park West
Benton Lane
Newcastle upon Tyne
NE12 8EW
United Kingdom

In respect of:

Design, development and manufacture of in-vitro diagnostic reagents for PSA and cytomegalovirus for use in Immunohistochemical staining and in-situ hybridisation.

on the basis of our examination under the requirements of Council Directive 98/79/EC, Annex IV, the quality system was found to meet the requirements of 98/79/EC Annex IV.

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

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2013-05-20** Date: **2020-11-13** Expiry Date: **2024-05-26**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive. For the placing on the market of List A devices covered by this certificate, an EC Design-Examination Certificate according to 98/79/EC Annex IV Section 4 is required and a letter releasing each batch according to Annex IV Section 6.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

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Supplementary Information to CE 595831

Issued To:

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Number	Device Name	Catalogue Number	Intended purpose per IFU
Annex II	**List B**		
IVD 0307	Bond Ready-to-Use Primary Antibody Prostate Specific Antigen (35H9)	PA0431	Prostate Specific Antigen (35H9) monoclonal antibody is intended to be used for the qualitative identification by light microscopy of human prostate specific antigen in formalin-fixed, paraffin-embedded tissue by immunohistochemical staining using the automated BOND system (includes Leica BOND-MAX system and Leica BOND-III system). The clinical interpretation of any staining or its absence should be complemented by morphological studies and proper controls and should be evaluated within the context of the patient's clinical history and other diagnostic tests by a qualified pathologist.

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Number	Device Name	Catalogue Number	Intended purpose per IFU
Annex II	**List B**		
IVD 0307	Novocastra Liquid Mouse Monoclonal Antibody Prostate Specific Antigen	NCL-L-PSA-431	NCL-L-PSA-431 is intended for the qualitative identification by light microscopy of human prostate specific antigen in paraffin sections. The clinical interpretation of any staining or its absence should be complemented by morphological studies using proper controls and should be evaluated within the context of the patient's clinical history and other diagnostic tests by a qualified pathologist.

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Number	Device Name	Catalogue Number	Intended purpose per IFU
Annex II	**List B**		
IVD 0305	BOND Ready-to-Use ISH CMV Probe	PB0614	CMV Probe is intended to be used for the qualitative identification of human cytomegalovirus early gene RNA transcript, in formalin-fixed, paraffin-embedded tissue by in situ hybridization (ISH) using the automated BOND system (includes Leica BOND-MAX system and Leica BOND-III system). The clinical interpretation of any staining or its absence should be complemented by morphological studies and proper controls and should be evaluated within the context of the patient's clinical history and other diagnostic tests by a qualified pathologist.

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List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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Date:	**2020-11-13**
Issued To:	**Leica Biosystems Newcastle Ltd** **Balliol Business Park West** **Benton Lane** **Newcastle upon Tyne** **NE12 8EW** **United Kingdom**

Subcontractor:	**Service(s) supplied**
CEpartner4U B.V. Esdoornlaan 13 3951 DB Maarn The Netherlands	**EU Representative**

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EC Certificate - Full Quality Assurance Certificate History

Certificate No: **CE 595831**
Date: **2020-11-13**
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Date	Reference Number	Action
20 May 2013	7947178	First Issue.
20 May 2014	8108562	Certificate renewal.
22 February 2019	8133480	Traceable to NB 0086.
28 May 2019	9739754	Certificate renewal.
Current	3308267	Addition of subcontractor as EU Rep