

**Declaration of Conformity in accordance with the In Vitro  
Diagnostic Directive 98/79/EC**

<b>1. Manufacturer and or Authorised Representatives Details</b>
Leica Biosystems Newcastle Ltd Balliol Business Park West Benton Lane Newcastle upon Tyne NE12 8EW  Tel: 0191 215 0567 Fax: 0191 215 1152
<b>2. The following Devices, classified as 'all other IVD Medical Devices', conform to the relevant provisions of the IVD Directive 98/79/EC and are CE marked in accordance with Annex III.</b>
See attached appendix.
<b>3. Description of the device</b>
Novocastra™ lyophilised, liquid and Ready-to-Use primary antibodies for immunohistochemistry.
<b>4. Signed on behalf of the manufacturer by</b>
Signed:  Date: 11/11/06 Dr Ian Milton Managing Director

## Appendix I

### List of Primary Antibodies for the Declaration of Conformity in accordance with the In Vitro Diagnostic Directive 98/79/EC

NCL-5D3 NCL-L-5D3 RTU-5D3	NCL-CD4-1F6 NCL-L-CD4-1F6 RTU-CD4-1F6	NCL-CD79a-225 NCL-L-CD79a-225
NCL-AE1/AE3 NCL-L-AE1/AE3 RTU-AE1/AE3	NCL-CD5-4C7 NCL-L-CD5-4C7 RTU-CD5-4C7	NCL-CD117 NCL-L-CD117 RTU-CD117
NCL-ALK	NCL-CD7-272 NCL-L-CD7-272 RTU-CD7-272	NCL-CD138
NCL-AR-318		NCL-CD143-510
NCL-a-SARC NCL-L-a-SARC	NCL-L-CD7-580	NCL-CHROM-430
NCL-bcl-2 NCL-L-bcl-2 RTU-bcl-2	NCL-CD8-295 NCL-L-CD8-295 RTU-CD8-295	NCL-c-erbB-2-316  NCL-CK20 NCL-L-CK20 RTU-CK20
NCL-Bcl-6-564	NCL-CD8-4B11	NCL-CK20-543
NCL-b-DG	NCL-CD10-270 NCL-L-CD10-270 RTU-CD10-270	NCL-L-CK20-561
NCL-b-SARC NCL-L-b-SARC	NCL-L-CD11c-563	NCL-CK34BE12 RTU-CK34BE12
NCL-CA125 NCL-L-CA125 RTU-CA125	NCL-CD15 NCL-L-CD15 RTU-CD15	NCL-CK5 NCL-L-CK5 RTU-CK5
NCL-CALRETININ NCL-L-CALRETININ RTU-CALRETININ	NCL-CD20-L26 NCL-L-CD20-L26 RTU-CD20-L26	NCL-CK7-OVTL NCL-L-CK7-OVTL RTU-CK7-OVTL
NCL-L-CALRET-566	NCL-CD21-2G9 NCL-L-CD21-2G9	NCL-L-CK7-560
NCL-CB11 NCL-L-CB11 RTU-CB11	NCL-CD23-1B12 NCL-L-CD23-1B12 RTU-CD23-1B12	NCL-CYCLIN D1-GM NCL-L-CYCLIN D1-GM RTU-CYCLIN D1-GM
NCL-CBE-356 NCL-L-CBE-356 RTU-CBE-356	NCL-CD30 NCL-L-CD30 RTU-CD30	NCL-d-SARC  NCL-DES-DERII NCL-L-DES-DERII RTU-DES-DERII
NCL-CD1a-235 NCL-L-CD1a-235 RTU-CD1a-235	NCL-CD31-1A10	NCL-L-DOG-1
NCL-CD2-271 NCL-L-CD2-271 RTU-CD2-271	NCL-L-CD33  NCL-CD38-290 NCL-L-CD38-290	NCL-DRP2
NCL-CD3-PS1 NCL-L-CD3-PS1 RTU-CD3-PS1 NCL-L-CD3-565	NCL-CD56-1B6 NCL-L-CD56-1B6 RTU-CD56-1B6	NCL-DYS1 NCL-DYS1/2 NCL-DYS1/2/3 NCL-DYS2 NCL-DYS3 NCL-EBV-CS1-4

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NCL-E-CAD RTU-E-CAD	NCL-HHV8-LNA	NCL-OCT2
NCL-EGFR NCL-L-EGFR	NCL-HMB45 NCL-L-IgD	NCL-p16-432 NCL-L-p16-432 RTU-p16-432
NCL-EGFR-384 NCL-L-EGFR-384 RTU-EGFR-384	NCL-L-IgM NCL-DYS1/2 NCL-DYS1/2/3	NCL-p53-CM1 NCL-p53-DO7 NCL-L-p53-DO7 RTU-p53-DO7
NCL-EMA NCL-L-EMA RTU-EMA	NCL-Ki67-MM1 NCL-L-Ki67-MM1 RTU-Ki67-MM1	NCL-PGP9.5 NCL-L-PGP9.5 RTU-PGP9.5
NCL-EMERIN	NCL-Ki67p	NCL-PGR NCL-PGR/2 NCL-L-PGR RTU-PGR
NCL-END NCL-L-END RTU-END	NCL-LCA	NCL-PGR-AB NCL-L-PGR-AB RTU-PGR-AB
NCL-ER-6F11 NCL-ER-6F11/2 NCL-L-ER-6F11 NCL-L-ER-6F11/2 RTU-ER-6F11	NCL-LL002 NCL-L-LL002 RTU-LL002 NCL-MAPSIN	NCL-PGR-B NCL-L-PGR-B RTU-PGR-B
NCL-ER-PGR-312d/1	NCL-MelanA NCL-L-MelanA RTU-MelanA	NCL-PGR-312 NCL-PGR-312/2 NCL-L-PGR-312 NCL-L-PGR-312/2 RTU-PGR-312
NCL-ER/PGRd	NCL-MEROSIN	NCL-PLAP-8A9 NCL-L-PLAP-8A9 RTU-PLAP-8A9
NCL-ER-PGRd/1	NCL-MESO NCL-L-MESO RTU-MESO	NCL-RCC
NCL-ESA RTU-ESA	NCL-L-MSH6	NCL-SMA RTU-SMA
NCL-L-EZH2	NCL-L-MLH1	NCL-SPEC1
NCL-g-SARC	NCL-MUC-1	NCL-SYNAP-299 NCL-L-SYNAP-299 RTU-SYNAP-299
NCL-GAL3	NCL-MUC-2	NCL-TdT-339 NCL-L-TdT-339 RTU-TdT-339
NCL-GAL7	NCL-MUC-5AC	NCL-TTF1 NCL-L-TTF1
NCL-GCDFP15 NCL-L-GCDFP15 RTU-GCDFP15	NCL-MUC-6	NCL-L-TPO
NCL-L-GEMININ	NCL-MSH2	
NCL-GRAN-B NCL-L-GRAN-B RTU-GRAN-B	NCL-Myf-4 NCL-L-Myf-4	
NCL-L-Granulysin NCL-Hamlet	NCL-L-Napsin A	
NCL-Hamlet-2	NCL-NK1 RTU-L-NK1 NCL-L-NSE-435	

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NCL-L-TRAF-1

NCL-TYROS  
NCL-L-TYROS  
RTU-TYROS

NCL-L-VE-CAD

NCL-VIM-V9  
NCL-L-VIM-V9  
RTU-VIM-V9

NCL-L-VIM-572

NCL-L-VMAT1

NCL-L-WT1-562

NCL-L-ZAP-70