



EC Declaration of Conformity



In vitro diagnostic devices

We hereby declare that the products listed below are manufactured by The Binding Site Group Ltd., 8 Calthorpe Road, Edgbaston, Birmingham B15 1QT, UK, and conform to the requirements for *General In Vitro Diagnostic Devices* under Annex III of the EC Directive on *in vitro* Diagnostic Medical Devices (98/79/EC) which has been transposed into UK law as:

The Medical Device Regulations 2002 (SI.618)

Product code	Product description	GMDN code
BP228	Freelite Panel Sample Set	41431
GT043.3	Human Beta-2 Microglobulin NANORID™ Radial Immunodiffusion Kit	56843
GT073.3	Human Lysozyme 'NL' NANORID™ Radial Immunodiffusion Kit	57364
GT118.3	Human Protein C 'NL' NANORID™ Radial Immunodiffusion Kit	61984
IC050	IgG/RF Stripper	43805
IK050.S	SPAPLUS Weekly Wash Protocol and Bottles	62225
IK077.S	SPAPLUS Cuvette Blank Protocol and bottles (empty)	62225
IK520	SPAPLUS Universal Tube Elevators	62010
IK530	SPAPLUS Calibrator Rack Direct Load	62011
IK540.1	SPAPLUS Control Rack Direct Load QC1	62011
IK540.2	SPAPLUS Control Rack Direct Load QC2	62011
IK707	Optilite Special Wash 1	58236
IK709	Optilite Sample Diluent 1	58237
IK710	Optilite Sample Diluent 2	58237
IK711	Optilite Sample Diluent 3	58237
IK781	Optilite Available on Request (AOR) Reagent Bottles 1	62225
IK782	Optilite Available on Request (AOR) Reagent Bottles 2	62225
IK783	Optilite Available on Request (AOR) Reagent Bottles 3	62225
IK784	Optilite Available on Request (AOR) Reagent Bottles 4	62225
IK785	Optilite Available on Request (AOR) Reagent Bottles 5	62225
IK786	Optilite Available on Request (AOR) Reagent Bottles 6	62225
IK787	Optilite Available on Request (AOR) Reagent Bottles 7	62225
IK788	Optilite Available on Request (AOR) Reagent Bottles 8	62225
IK789	Optilite Available on Request (AOR) Reagent Bottles 9	62225
IK790	Optilite Available on Request (AOR) Reagent Bottles 10	62225
LK001.2TB	Human IgG Subclass Liquid Reagent Kit for use on the Siemens BN™II - Bulk Kit	53787
LK001.P	Human IgG Subclass Liquid Reagent Kits for use on the Siemens BN ProSpec® Analyser	53787
LK003.T	Human IgA Subclass Liquid Latex Reagent Kit for use on the Siemens BN™II	53760
LK008.2TB	Human IgG3 Subclass Liquid Reagent Kit for use on the Siemens BN™II - Bulk Kit	53787
LK008.CB	Human IgG3 Subclass Liquid Reagent Kit for use on the Roche cobas® 6000	53787
LK008.IM	Human IgG3 Subclass Liquid Reagent Kit for use on the Beckman IMMAGE®/IMMAGE®800 Analyser	53787
LK008.OPT	Optilite IgG3 Kit	53787
LK008.S	Human IgG3 Subclass Liquid Reagent Kit for use on the SPAPLUS	53787
LK008.10S	Human IgG3 Subclass Liquid Reagent Kit for use on the SPAPLUS- Bulk Kit	53787
LK008.TB	Human IgG3 Subclass Liquid Reagent Kit for use on the Siemens BN™II	53787
LK009.2TB	Human IgG4 Subclass Liquid Reagent Kit for use on the Siemens BN™II) - Bulk Kit	53787
LK009.CB	Human IgG4 Subclass Liquid Reagent Kit for use on the Roche cobas® 6000	53787
LK009.IM	Human IgG4 Subclass Liquid Reagent Kit for use on the Beckman IMMAGE®/IMMAGE®800 Analyser	53787
LK009.OPT	Optilite IgG4 Kit	53787
LK009.P	Human IgG4 Subclass Liquid Reagent Kits for use on the Siemens BN ProSpec® Analyser	53787
LK009.S	Human IgG4 Subclass Liquid Reagent Kit for use on the SPAPLUS	53787
LK009.10S	Human IgG4 Subclass Liquid Reagent Kit for use on the SPAPLUS- Bulk Kit	53787
LK009.TB	Human IgG4 Subclass Liquid Reagent Kit for use on the Siemens BN™II	53787
LK010.L.OPT	Optilite IgA CSF Kit	53758
LK010.L.S	Human IgA CSF Kit for use on SPAPLUS	53758
LK012.L.OPT	Optilite IgM CSF Kit	53793

Product code	Product description	GMDN code
LK012.L.S	Human IgM CSF Kit for use on SPAPLUS	53793
LK013.OPT	Optilite IgD Kit	53769
LK013.T	Human IgD Liquid Latex Reagent Kit for use on the Siemens BN™II	53769
LK013.S	Human IgD Kit for use on SPAPLUS	53769
LK014.OPT	Optilite IgE Reagent	53778
LK014.S	IgE Kit for use on SPAPLUS	63503
LK016.10.OPT	Optilite® Freelite® Kappa Free Bulk Kit	53799
LK016.10S	Freelite® Human Kappa Free Kit for use on the SPAPLUS – Bulk Kit	53799
LK016.10T	Freelite® Human Kappa Free Kit for use on the Siemens BN™II - Bulk Kit	53799
LK016.CB	Freelite® Human Kappa Free Kit for use on the Roche cobas® systems	53799
LK016.10CB	Freelite® Human Kappa Free Kit for use on the Roche cobas® systems – Bulk kit	53799
LK016.IM	Freelite® Human Kappa Free Kit for use on the Beckman Coulter IMMAGE®/IMMAGE®800	53799
LK016.L.S	Freelite® Human Kappa Free Kit for use on the SPAPLUS	53799
LK016.L.T	Freelite® Human Kappa Free Kit for use on the Siemens BN™II	53799
LK016.OPT	Optilite® Freelite® Kappa Free Kit	53799
LK016.P	Freelite® Human Kappa Free Kit for use on the Siemens BN ProSpec®	53799
LK016.S	Freelite® Human Kappa Free Kit for use on the SPAPLUS	53799
LK016.T	Freelite® Human Kappa Free Kit for use on the Siemens BN™II	53799
LK016.M.OPT	Optilite Freelite Mx™ Kappa Free Kit	53799
LK018.10.OPT	Optilite® Freelite® Kappa Free Bulk Kit	53799
LK018.10S	Freelite® Human Lambda Free Kit for use on the SPAPLUS – Bulk Kit	53799
LK018.10T	Freelite® Human Lambda Free Kit for use on the Siemens BN™II - Bulk Kit	53799
LK018.CB	Freelite® Human Lambda Free Kit for use on the Roche cobas® c systems	53799
LK018.10CB	Freelite® Human Lambda Free Kit for use on the Roche cobas® c systems – Bulk Kit	53799
LK018.IM	Freelite® Human Lambda Free Kit for use on the Beckman Coulter IMMAGE®/IMMAGE®800	53799
LK018.L.S	Freelite® Human Lambda Free Kit for use on the SPAPLUS	53799
LK018.L.T	Freelite® Human Lambda Free Kit for use on the Siemens BN™II	53799
LK018.OPT	Optilite® Freelite® Lambda Free Kit	53799
LK018.P	Freelite® Human Lambda Free Kit for use on the Siemens BN ProSpec®	53799
LK018.S	Freelite® Human Lambda Free Kit for use on the SPAPLUS	53799
LK018.M.OPT	Optilite Freelite Mx™ Lambda Free Kit	53799
LK018.T	Freelite® Human Lambda Free Kit for use on the Siemens BN™II	53799
LK022.S	Human Complement C2 Kit for use on SPAPLUS	64267
LK043.OPT	Optilite® Beta-2 Microglobulin Kit	53927
LK043.L.OPT	Optilite® Beta-2 Microglobulin Urine Kit	53927
LK043.S	Human Beta-2 Microglobulin Kit for use on the SPAPLUS	53927
LK043.U.S	Human Beta-2 Microglobulin Urine Kit for use on the SPAPLUS	53927
LK043.T	Human Beta-2 Microglobulin Latex Enhanced Nephelometric Kit for use on the Siemens BN™II	53927
LK044.L.OPT	Optilite High Sensitivity C-Reactive Protein Kit	53705
LK044.L.S	High Sensitivity C-Reactive Protein Kit for use on SPAPLUS	53705
LK044.S	Full Range C-Reactive Protein Kit for use on SPAPLUS	53705
LK048.S	Human Cystatin C Kit for use on SPAPLUS	48178
LK048.OPT	Optilite Cystatin C Kit	48178
LK055.S	Ferritin Kit for use on SPAPLUS	53718
LK087.IM	Human IgA1 Subclass Liquid Latex Reagent Kit for use on the Beckman IMMAGE®/IMMAGE800® Analyser	53760
LK088.1T	Human IgA2 Subclass Liquid Latex Reagent Kit for use on the Siemens BN™II	53760
LK088.IM	Human IgA2 Subclass Liquid Latex Reagent Kit for use on the Beckman IMMAGE®/IMMAGE800® Analyser	53760
LK088.S	Human IgA2 Kit for use on SPAPLUS	53760
LK088.OPT	Optilite IgA2 kit	53760
LK098.OPT	Optilite Lipoprotein (a) Reagent	53442
LK098.S	Lipoprotein (a) Kit for use on SPAPLUS	53438
LK110.OPT	Anti-Tetanus Toxoid Optilite Kit	64167
LK151.OPT	Optilite Rheumatoid Factor Kit	55111
LK151.S	Rheumatoid Factor Kit for use on SPAPLUS	55111
LK189.S	Human Anti Streptolysin-O kit for use on SPAPLUS	59055
LK189.OPT	Optilite Anti Streptolysin-O kit	59055
LK710.S	Human Anti-Tetanus Toxoid Immunoglobulin Liquid Reagent Kit for use on SPAPLUS	64167
MK010	VaccZyme™ Anti- Tetanus Toxoid IgG Enzyme Immunoassay Kit	50874
MK010.10	VaccZyme™ Anti- Tetanus Toxoid IgG Enzyme Immunoassay Kit	50874
MK010.4	VaccZyme™ Anti-Tetanus Toxoid IgG Enzyme Immunoassay Kit	50874
MK012	VaccZyme™ Anti-PCP IgG Enzyme Immunoassay Kit	51783
MK014	Diphtheria Toxoid IgG Enzyme Immunoassay Kit	50883
MK014.10	Diphtheria Toxoid IgG Enzyme Immunoassay Kit - Bulk kit	50883
MK016	VaccZyme™ Human Anti-Haemophilus Influenzae type b Enzyme Immunoassay Kit	50975
MK091	VaccZyme™ Human anti-Salmonella typhi Vi IgG Enzyme Immunoassay Kit	51572
MK092	VaccZyme™ VZV Glycoprotein IgG Low Level Enzyme Immunoassay Kit	49621
MK114	VaccZyme™ Diphtheria Toxoid IgG Enzyme Immunoassay Kit	50883
MK120	VaccZyme™ Anti-PCP IgA Enzyme Immunoassay Kit	61990
MK121	VaccZyme™ Anti-PCP IgM Enzyme Immunoassay Kit	61991
MK654	Human Anti-IgG/A/M SARS-CoV-2 ELISA	64801
MK654.10	Human Anti-IgG/A/M SARS-CoV-2 ELISA	64801
NC014.OPT	Optilite IgE Calibrator	53777

Product code	Product description	GMDN code
NC044.OPT	Optilite C-Reactive Protein Calibrator	41838
NC061.OPT	Optilite Total Protein Calibrators	53988
NC085.OPT	Optilite Apolipoprotein A-1 Calibrator	41808
NC086.OPT	Optilite Apolipoprotein B Calibrator	41812
NC095.OPT	Optilite CH50 Calibrator	53660
NC095.S	Human CH50 Calibrator set for use on SPAPLUS	53660
NC098.OPT	Optilite Lipoprotein(a) Calibrator	41417
NK001.T	Human IgG Subclass Liquid Reagent Kit for use on the Siemens BN™II Analyser - Bulk Kit	53787
NK004.OPT	Optilite IgG Kit	53785
NK004.S	Human IgG Liquid Reagent Kit for use on the SPAPLUS	53785
NK004.10S	Human IgG Liquid Reagent Kit for use on the SPAPLUS -Bulk Kit	53785
NK004.L.S	Human IgG CSF Kit for use on SPAPLUS	53785
NK004.LL.OPT	Optilite Low Level IgG Kit	53785
NK006.2TB	Human IgG1 Subclass Liquid Reagent Kit for use on the Siemens BN™II - Bulk Kit	53787
NK006.CB	Human IgG1 Subclass Liquid Reagent Kit for use on the Roche cobas® 6000	53787
NK006.IM	Human IgG1 Subclass Liquid Reagent Kit for use on the Beckman IMMAGE®/IMMAGE®800 Analyser	53787
NK006.OPT	Optilite IgG1 Kit	53787
NK006.P	Human IgG1 Subclass Liquid Reagent Kit for use on the Siemens BN ProSpec® Analyser	53787
NK006.S	Human IgG1 Subclass Liquid Reagent Kit for use on the SPAPLUS	53787
NK006.10S	Human IgG1 Subclass Liquid Reagent Kit for use on the SPAPLUS -Bulk Kit	53787
NK006.T	Human IgG1 Subclass Liquid Reagent Kit for use on the Siemens BN™II Analyser	53787
NK006.TB	Human IgG1 Subclass Liquid Reagent Kit for use on the Siemens BN™II	53787
NK007.2TB	Human IgG2 Subclass Liquid Reagent Kit for use on the Siemens BN™II - Bulk Kit	53787
NK007.CB	Human IgG2 Subclass Liquid Reagent Kit for use on the Roche cobas® 6000	53787
NK007.IM	Human IgG2 Subclass Liquid Reagent Kit for use on the Beckman IMMAGE®/IMMAGE®800	53787
NK007.OPT	Optilite IgG2 Kit	53787
NK007.P	Human IgG2 Subclass Liquid Reagent Kit for use on the Siemens BN ProSpec® Analyser	53787
NK007.S	Human IgG2 Subclass Liquid Reagent Kit for use on the SPAPLUS	53787
NK007.10S	Human IgG2 Subclass Liquid Reagent Kit for use on the SPAPLUS- Bulk Kit	53787
NK007.T	Human IgG2 Subclass Liquid Reagent Kit for use on the Siemens BN™II Analyser	53787
NK007.TB	Human IgG2 Subclass Liquid Reagent Kit for use on the Siemens BN™II	53787
NK008.T	Human IgG3 Subclass Liquid Reagent Kit for use on the Siemens BN™II Analyser	53787
NK009.T	Human IgG4 Subclass Liquid Reagent Kit for use on the Siemens BN™II Analyser	53787
NK010.OPT	Optilite IgA Kit	53758
NK010.S	Human IgA Liquid Reagent Kit for use on SPAPLUS	53758
NK010.10S	Human IgA kit for use on SPAPLUS- Bulk Kit	53758
NK012.OPT	Optilite IgM Kit	53793
NK012.S	Human IgM kit for use on SPAPLUS	53793
NK012.10S	Human IgM kit for use on SPAPLUS- Bulk Kit	53793
NK019.OPT	Optilite C1 Inactivator Kit	53676
NK019.S	Human C1 Inactivator Kit for use on SPAPLUS	53676
NK023.OPT	Optilite C3c Kit	53684
NK023.S	Human C3c Kit for use on SPAPLUS	53684
NK025.OPT	Optilite C4 Kit	53691
NK025.S	Human C4 Kit for use on SPAPLUS	53691
NK023.F.S	Human C3c Kit for use on SPAPLUS	53684
NK025.F.S	Human C3c Kit for use on SPAPLUS	53684
NK032.OPT	Optilite Albumin Kit	53596
NK032.L.OPT	Optilite Low Level Albumin Kit	53596
NK032.S	Human Albumin Kit for use on SPAPLUS	53596
NK032.L.S	Human Albumin CSF Kit for use on SPAPLUS	53596
NK032.U.S	Human Microalbumin Kit for use on SPAPLUS	53475
NK034.OPT	Optilite Alpha-1-Antitrypsin Kit	53602
NK034.S	Human alpha 1 antitrypsin Kit for use on SPAPLUS	53602
NK036.U.OPT	Optilite Alpha-1-Microglobulin Kit	53923
NK039.OPT	Optilite Alpha 2 Macroglobulin Kit	53925
NK039.S	Human alpha 2 macroglobulin Kit for use on SPAPLUS	53925
NK039.U.OPT	Optilite® Alpha-2-Macroglobulin Urine Kit	53925
NK044.OPT	Optilite C-Reactive Protein Reagent	53707
NK044.S	C-Reactive Protein kit for use on SPAPLUS	53705
NK045.OPT	Optilite Caeruloplasmin Kit	53632
NK045.S	Human Caeruloplasmin Kit for use on SPAPLUS	53632
NK058.OPT	Optilite Haptoglobin Kit	53737
NK058.S	Human Haptoglobin Kit for use on SPAPLUS	53737
NK061.OPT	Optilite Total Protein Reagent	53989
NK063.OPT	Optilite Alpha-1-Acid Glycoprotein Kit	53606
NK063.S	Human alpha 1 acid glycoprotein Kit for use on SPAPLUS	53606
NK066.OPT	Optilite Prealbumin Kit	53957
NK066.S	Human Prealbumin Kit for use on SPAPLUS	53957
NK070.OPT	Optilite Transferrin Kit	59041
NK070.S	Human Transferrin Kit for use on SPAPLUS	59041
NK070.U.OPT	Optilite Transferrin Urine Kit	59041
NK085.OPT	Optilite Apolipoprotein A-1 Reagent	53444

Product code	Product description	GMDN code
NK085.S	Human Apolipoprotein A-1 (Apo A-1) kit for use on SPAPLUS	53443
NK086.OPT	Optilite Apolipoprotein B Reagent	53448
NK086.S	Human Apolipoprotein B (Apo B) kit for use on SPAPLUS	53447
NK087.1T	Human IgA1 Subclass Liquid Latex Reagent Kit for use on the Siemens BN™II)	53760
NK087.OPT	Optilite IgA1 kit	53760
NK087.S	Human IgA1 Kit for use on SPAPLUS	53760
NK095.OPT	Optilite CH50 Reagent	53662
NK095.S	Human CH50 Reagent pack for use on the SPAPLUS	53662
NK095.F.S	Human CH50 Reagent pack for use on the SPAPLUS	53662
NK621.OPT	Optilite Hevylite® IgG Kappa Kit	53785
NK622.OPT	Optilite Hevylite® IgG Lambda Kit	53785
NK623.OPT	Optilite Hevylite® IgA Kappa Kit	53758
NK624.OPT	Optilite Hevylite® IgA Lambda Kit	53758
NK625.OPT	Optilite Hevylite® IgM Kappa Kit	53793
NK626.OPT	Optilite Hevylite® IgM Lambda Kit	53793
NQ004.OPT	Optilite® IgG Control Pack	41353
NQ004.LL.OPT	Optilite® Low Level IgG Control Pack	41353
NQ004.S	Human IgG Control Pack for use on the SPAPLUS®	41353
NQ006.OPT	Optilite® IgG1 Control Pack	41355
NQ006.S	Human IgG Subclass Control Pack for use on the SPAPLUS®	41355
NQ007.OPT	Optilite® IgG2 Control Pack	41355
NQ008.OPT	Optilite® IgG3 Control Pack	41355
NQ009.OPT	Optilite® IgG4 Control Pack	41355
NQ010.OPT	Optilite® IgA Control Pack	41766
NQ010.L.OPT	Optilite® IgA CSF Control Pack	41769
NQ010.S	Human IgA Control Pack for use on the SPAPLUS®	41766
NQ012.OPT	Optilite® IgM Control Pack	41357
NQ012.L.OPT	Optilite® IgM CSF Control Pack	41357
NQ012.S	Human IgM Control Pack for use on the SPAPLUS®	41357
NQ013.OPT	Optilite® IgD Control Pack	41771
NQ013.S	Human IgD Control Pack for use on the SPAPLUS®	41771
NQ013.T	Human IgD Control Pack for use on the Siemens BN™II	41771
NQ014.OPT	Optilite IgE Controls	37763
NQ016.CB	Freelite® Human Kappa Free Control Pack For use on the Roche Cobas™ c Systems	41431
NQ016.IM	Freelite® Human Kappa Free Control Pack For use on the Beckman Coulter IMMAGE™/IMMAGE™800	41431
NQ016.M.OPT	Optilite® Freelite Mx™ Kappa Free Control Pack	41431
NQ016.OPT	Optilite® Freelite® Kappa Free Control Pack	41431
NQ016.P	Freelite® Human Kappa Free Control Pack for use on the Siemens BN ProSpec™	41431
NQ016.S	Freelite® Human Kappa Free Control Pack for use on the SPAPLUS®	41431
NQ016.T	Freelite® Human Kappa Free Control Pack for use on the Siemens BN™II	41431
NQ018.CB	Freelite® Human Lambda Free Control Pack For use on the Roche Cobas™ c Systems	41431
NQ018.IM	Freelite® Human Lambda Free Control Pack For use on the Beckman Coulter IMMAGE™/IMMAGE™800	41431
NQ018.M.OPT	Optilite® Freelite Mx™ Lambda Free Control Pack	41431
NQ018.OPT	Optilite® Freelite® Lambda Free Control Pack	41431
NQ018.P	Freelite® Human Lambda Free Control Pack for use on the Siemens BN ProSpec™	41431
NQ018.S	Freelite® Human Lambda Free Control Pack for use on the SPAPLUS®	41431
NQ018.T	Freelite® Human Lambda Free Control Pack for use on the Siemens BN™II	41431
NQ019.OPT	Optilite® C1 Inactivator Control Pack	31466
NQ023.OPT	Optilite® C3c Control Pack	31449
NQ023.S	Human C3c Control Pack for use on the SPAPLUS®	31449
NQ025.OPT	Optilite® C4 Control Pack	31471
NQ025.S	Human C4 Control Pack for use on the SPAPLUS®	31471
NQ032.OPT	Optilite® Albumin Control Pack	37721
NQ032.L.OPT	Optilite® Low Level Albumin Control Pack	37721
NQ034.OPT	Optilite® Alpha-1-Antitrypsin Control Pack	41255
NQ036.U.OPT	Optilite® Alpha-1-microglobulin Urine Control Pack	41259
NQ039.OPT	Optilite® Alpha-2-Macroglobulin	41261
NQ039.U.OPT	Optilite® Alpha-2-Macroglobulin Urine Control Pack	41261
NQ043.OPT	Optilite® Beta-2 Microglobulin Control Pack	38214
NQ043.L.OPT	Optilite® Beta-2 Microglobulin Urine Control Pack	38214
NQ043.S	Human Beta-2 Microglobulin Control Pack for use on the SPAPLUS®	38214
NQ044.OPT	Optilite C-Reactive Protein Controls	41839
NQ044.L.OPT	Optilite® High Sensitivity C-Reactive Protein Control Pack	41839
NQ045.OPT	Optilite® Caeruloplasmin Control Pack	41322
NQ048.OPT	Optilite® Cystatin C Control Pack	48175
NQ048.S	Human Cystatin C Control Pack for use on the SPAPLUS®	48175
NQ058.OPT	Optilite® Haptoglobin Control Pack	41406
NQ061.OPT	Optilite Total Protein Controls	53987
NQ063.OPT	Optilite® α1-Acid Glycoprotein Control Pack	33914
NQ066.OPT	Optilite® Prealbumin Control Pack	41388
NQ070.OPT	Optilite® Transferrin Control Pack	41344
NQ070.U.OPT	Optilite® Transferrin Urine Control Pack	41344

Product code	Product description	GMDN code
NQ085.OPT	Optilite Apolipoprotein A-1 Controls	41809
NQ086.OPT	Optilite Apolipoprotein B Controls	41813
NQ087.OPT	Optilite® IgA1 Control Pack	41769
NQ088.OPT	Optilite® IgA2 Control Pack	41769
NQ095.OPT	Optilite CH50 Controls	53661
NQ095.S	Human CH50 controls for use on SPAPLUS	53661
NQ098.OPT	Optilite Lipoprotein(a) Controls	41418
NQ110.OPT	Optilite® Anti-Tetanus Toxoid Immunoglobulin Control Pack	50868
NQ151.OPT	Optilite® Rheumatoid Factor Control Pack	42231
NQ189.OPT	Optilite® Anti-streptolysin O Control Pack	51745
NQ621.OPT	Optilite® Hevylite® IgG Kappa Control Pack	41353
NQ622.OPT	Optilite® Hevylite® IgG Lambda Control Pack	41353
NQ623.OPT	Optilite® Hevylite® IgA Kappa Control Pack	41766
NQ624.OPT	Optilite® Hevylite IgA Lambda Control Pack	41766
NQ625.OPT	Optilite® Hevylite® IgM Kappa Control Pack	41357
NQ626.OPT	Optilite® Hevylite® IgM Lambda Control Pack	41357
PX013	Sheep Anti-Human IgD Immunofixation Grade	57312
PX014	Sheep AntiHuman IgE Immunofixation Grade	57314
PX016	Sheep Anti-Human Kappa Free Light Chains Immunofixation Grade	57325
PX018	Sheep Anti-Human Lambda Free Light Chains Immunofixation Grade	57325
RC001.1	Total Haemolytic Complement	62009
RC001.2	Total Haemolytic Complement	62009
RC001.3	Total Haemolytic Complement	62009
RC002.3	Human C1 Inactivator Functional Activity BINDARID™ Kit	62030
RK002	Human IgG – 'NL' BINDARID™ Radial Immunodiffusion Kit – (COMBI Kit)	57316
	Human IgA – 'NL' BINDARID™ Radial Immunodiffusion Kit	57310
	Human IgM – 'NL' BINDARID™ Radial Immunodiffusion Kit	57318
RK015	Human IgA Subclass NL BINDARID™ Radial Immunodiffusion Kit – Bulk Kit	61985
RK019	Human C1 Inactivator BINDARID™ Radial Immunodiffusion Kit	62030
RK021	Human IgG Subclass Single Dilution BINDARID™ Kit - Bulk Kit	62026
RN004.3	Human IgG - 'NL' BINDARID™ Radial Immunodiffusion Kit	62008
RN010.3	Human IgA - 'NL' BINDARID™ Radial Immunodiffusion Kit	62007
RN012.3	Human IgM - 'NL' BINDARID™ Radial Immunodiffusion Kit	62006
RN013.3	Human Immunoglobulin D BINDARID™ Radial Immunodiffusion Kit	57312
RN019.3	Human C1 Inactivator BINDARID™ Radial Immunodiffusion Kit	62030
RN020.3	Human Complement C1q BINDARID™ Radial Immunodiffusion Kit	57058
RN022.3	Human Complement C2 NL BINDARID™ Radial Immunodiffusion Kit	53679
RN023.3	Human Complement C3 'NL' BINDARID™ Radial Immunodiffusion Kit	57060
RN025.3	Human Complement C4 'NL' BINDARID™ Radial Immunodiffusion Kit	57062
RN027.3	Human Complement C5 BINDARID™ Radial Immunodiffusion Kit	61987
RN029.3	Human Factor B 'NL' BINDARID™ Radial Immunodiffusion Kit	62013
RN032.3	Human Albumin NL BINDARID™ Radial Immunodiffusion Kit	56766
RN034.3	Human Alpha-1 Antitrypsin BINDARID™ Radial Immunodiffusion Kit	62214
RN040.3	Human Antithrombin III BINDARID™ Radial Immunodiffusion Kit	61983
RN045.3	Human Caeruloplasmin NL BINDARID™ Radial Immunodiffusion Kit	61986
RN056.3	Human Fibrinogen BINDARID™ Radial Immunodiffusion Kit	57220
RN058.3	Human Haptoglobin BINDARID™ Radial Immunodiffusion Kit	62012
RN065.3	Human Plasminogen 'NL' BINDARID™ Radial Immunodiffusion Kit	62051
RN070.3	Human Transferrin BINDARID™ Radial Immunodiffusion Kit	57675
RN106.3	Human IgG1 Subclass Single Dilution BINDARID™ Kits	62026
RN107.3	Human IgG2 Subclass Single Dilution BINDARID™ Kits	62026
RN108.3	Human IgG3 Subclass Single Dilution BINDARID™ Kits	62026
RN109.3	Human IgG4 Subclass Single Dilution BINDARID™ Kits	62026
SN080.S	SPAPLUS Sample Diluent Pack	58237
SN107.1	MININEPHPLUS™ On-Board Buffer 1 (1 bottle)	58237
SN107.4	MININEPHPLUS™ On-Board Buffer 1 (4 bottles)	58237
SN114.S	SPAPLUS Sample Diluent 2 Pack	58237
SN119	AUTODIL 100 Sample Diluent	58237
XK001	Immunofixation (IFE) Kit	53967
XK002	Immunofixation (IFE) Kit	53967
XK003	Serum Protein Electrophoresis (SPE) Kit	53967
XK004	Minifix™ Kit	53967
ZK004.R	MININEPH™ Human IgG Kit	53785
ZK006.R	MININEPH™ Human IgG1 Kit	53787
ZK007.R	MININEPH™ Human IgG2 Kit	53787
ZK008.L.R	MININEPH™ Human IgG3 Kit	53787
ZK009.L.R	MININEPH™ Human IgG4 Kit	53787
ZK010.R	MININEPH™ Human IgA Kit	53758
ZK012.R	MININEPH™ Human IgM Kit	53793
ZK023.R	MININEPH™ Human C3 Kit	53684
ZK025.R	MININEPH™ Human C4 Kit	53691
ZK032.R	MININEPH™ Human Albumin Kit	53596
ZK032.U.R	MININEPH™ Human Microalbumin Kit	53475
ZK034.R	MININEPH™ Human A1 Antitrypsin Kit	53602

Product code	Product description	GMDN code
ZK043.L.R	MININEPH™ Human Beta-2 Microglobulin Kit	53927
ZK044.L.R	MININEPH™ Human C-Reactive Protein Kit	53705
ZK045.R	MININEPH™ Human Caeruloplasmin Kit	53632
ZK058.R	MININEPH™ Human Haptoglobin Kit	53737
ZK066.R	MININEPH™ Human Prealbumin Kit	53957
ZK070.R	MININEPH™ Human Transferrin Kit	59041
ZK085.R	MININEPH™ Human Apolipoprotein A1 Kit	53443
ZK086.R	MININEPH™ Human Apolipoprotein B Kit	53447
ZK151.L.R	MININEPH™ Human Rheumatoid Factor Kit	55111
ZK189.L.R	MININEPH™ Human Anti-Streptolysin O Kit	59055
ZK500.R	MININEPH™ Reagent Accessory Pack	58208
ZK502.R	MININEPH™ Sample Diluent Pack	58208

Electronics/Instruments

We hereby declare that the products listed below conform to the requirements of the Electrical Equipment Directive implementing the Low Voltage Directive (2006/95/EC) and the Electromagnetic Compatibility Directive (2004/108/EC), which have been transposed into UK law as:

The Electrical Equipment (Safety) Regulations 1994 (S.I. 1994/3260).

The Electromagnetic Compatibility Regulations 2005 (S.I. 2005, No. 81).

We also hereby declare that the products and integral software, except those marked by an asterisk (*), conform to the requirements for *General In Vitro Diagnostic Devices* under Annex III of the EC Directive on in vitro Diagnostic Medical Devices (98/79/EC) which has been transposed into UK law as:

The Medical Device Regulations 2002 (S.I. 618)

Product code	Product description	EDMA code	GMDN code
AD400	Digital RID Plate Reader	21 02 10 01	No Equivalent GMDN term
AD500.C/D/E	MININEPHPLUS™ Analyser	21 02 10 01	62413
*AD500.2	Barcode Reader	N/A	N/A
IE610	SPAPLUS Analyser	21 02 10 01	62413

For and on behalf of:

**The Binding Site GmbH, Robert-Bosch-Straße 2A, D-68723 Schwetzingen,
Deutschland**

(Authorised Representative)

Signed 

Name Sean O'Dowd

Role Head of Regulatory Affairs

Date 25 March 2021