EC Declaration of Conformity (Directive 98/79/EC)

Manufacturer Omega Diagnostics Ltd., Omega House, Hillfoots Business Village, Alva, Scotland, United Kingdom FK12 5DQ

Manufacturer Identification Code: GB / 000072

Competent Authority: Medicines and Healthcare Products Regulatory Agency, Competent Authority GB / CA 01

Product Details: See EC Declaration of Conformity List (attached)

Classification: IVDD, Non Annex II, Self –Declaration

Conformity Assessment Route: Annex III IVDD

We hereby declare the devices named in the EC Declaration of Conformity List (see attached) comply with the requirements of DIRECTIVE 98/79/EC, on in vitro diagnostic medical devices.

Standards Applied: EN ISO 9001:2008, EN ISO 13485:2012, EN ISO 14971:2009, EN ISO 18113-2:2009, EN ISO 15223-1: 2012, EN 13612:2002, EN 23640:2013 and EN 13641:2002.

Signed:

Name: Norman Hawkes
Position: Technical Manager
Place: Omega Diagnostics, Omega House, Hillfoots Business Village, Alva, Scotland, United Kingdom, FK12 5DQ
Date: 4th February 2014

EC Declaration of Conformity List

EDMA Classification	Description	Product Product Code - Test Size
Immunochemistry (12)		
Specific Proteins (12 01)		
Other Specific Proteins (12 01. 90) 12 01 90 09	Cystatin C	AVITEX TURBO CYS – C OD303 – 24 ml AVITEX TURBO CYS – C CALIBRATORS OD313 5 X 2 ml AVITEX TURBO CYS – C CONTROLS OD333 4 X 2 ml
12 01 90 90	Microalbumin	AVITEX TURBO µALB OD373 – 50 ml AVITEX TURBO µALB CALIBRATOR OD393 1 X 1 ml AVITEX TURBO µALB CONTROL OD383 1 X 2 ml
Allergy (12 02) 12 02 01 02 00	Immuglobulin E- Total	PATHOZYME IgE OD417 – 96 Tests

EC Declaration of Conformity List

EDMA Classification	Description	Product Product Code - Test Size
Tumor Markers (12 03) Cancer Antigens (12 03 01)		
12 03 01 02 00	Cancer Antigen 15-3	PATHOZYME BREAST CANCER Ag 15-3 OD297 – 96 Tests
12 03 01 03 00	Cancer Antigen 19-9	PATHOZYME Ag19-9 OD277 – 96 Tests
12 03 01 06 00	Cancer Antigen 125	PATHOZYME Ag 125 OD287 – 96 Tests
12 03 01 31 00	Carcinoembryonic Antigen	PATHOZYME CEA (CARCINOEMBRYONIC Ag) OD317 – 96 Tests
12 03 90 01 00	Alphafetoprotein	PATHOZYME AFP OD307 – 96 Tests

EC Declaration of Conformity List

EDMA Classification	Description	Product Product Code - Test Size
Thyroid Function Hormones (12 04) Thyroid Function Hormones (12 04 01)		
12 04 01 01 00	Free Triidothyronine	PATHOZYME FREE T3(TRIIODOTHYRONINE) OD457 – 96 Tests
12 04 01 02 00	Free Thyroxine	PATHOZYME FREE T4 (THYROXINE) OD467 – 96 Tests
12 04 01 05 00	Triidothyronine	PATHOZYME T3 (TRIIODOTHYRONINE) OD367 – 96 Tests
12 04 01 07 00	Thyroxine	PATHOZYME T4 (THYROXINE) OD377 – 96 Tests
12 04 01 11 00	Thyroid Stimulating Hormone	PATHOZYME TSH OD387 – 96 Tests
12 04 01 11 00		PATHOZYME USTSH OD447 – 96 Tests

EC Declaration of Conformity List

EDMA Classification	Description	Product Product Code - Test Size
Fertility Function Hormones / Proteins (12 05) Fertility Function Hormones / Proteins (12 05 01)		
12 05 01 03 00	Estradiol (E2)	PATHOZYME OESTRADIOL OD477 – 96 Tests
12 05 01 04 00	Follicle Stimulating Hormone (FSH)	PATHOZYME FSH (FOLLICLE STIM. HORMONE) OD337 – 96 Tests
12 05 01 05 00	Luteinising Hormone (LH)	PATHOZYME LH OD357 – 96 Tests
12 05 01 06 00	Progesterone (PRG)	PATHOZYME PROGESTERONE OD487 – 96 Tests
12 05 01 08 00	Prolactin (PRL)	PATHOZYME PROLACTIN OD427 – 96 Tests
12 05 01 10 00	Testosterone	PATHOZYME TESTOSTERONE OD497– 96 Tests

EC Declaration of Conformity List

EDMA Classification	Description	Product Product Code - Test Size
Pregnancy Testing Hormones / Proteins (12 05 02)		
12 05 02 05 00	Human Chorionic Gonadotropin Total (hCG)	BETATEX DIRECT PLUS OD062 – 100 Tests OD072 – 50 Tests
12 05 02 05 00		PATHOZYME hCG OD347 – 96 Tests

EC Declaration of Conformity List

EDMA Classification	Description	Product Product Code - Test Size
Individual Specified Hormones (12 06) Endocrine Hormones and Peptides (12 06 04) 12 06 04 02 00	Human Growth Hormone	PATHOZYME HGH OD437 – 96 Tests
Anemia Related / Vitamin Tests (12 07) Anemia (12 07 01) 12 07 01 02 00	Ferritin	PATHOZYME FERRITIN OD407 – 96 Tests

EC Declaration of Conformity List

EDMA Classification	Description	Product Product Code - Test Size
Auto-Immune Disease Markers (12 10) Autoimmune Connective Tissue Disease (12 10 01) 12 10 01 05 00	dsDNA – Antibodies	AVITEX SLE OD043 – 100 Tests OD093 – 50 Tests OD173/A – 25 Tests

EC Declaration of Conformity List

EDMA Classification	Description	Product Product Code - Test Size
Rheumatoid Inflammatory Disease Markers (12 11) Rheumatoid Inflammatory Disease Markers (12 11 01) 12 11 01 05 00	Anti-Streptolysin O (ASO)	AVITEX ASO OD033 – 100 Tests OD033/E - 100 Tests (Latex only) OD083 - 50 Tests OD153/A – 25 Tests OD343 AVITEX TURBO ASO 50ml OD253 AVITEX TURBO RF/CRP/ASO Low Positive Control 4 x 1ml OD263 AVITEX TURBO RF/CRP/ASO High Positive Control 4 x1ml

EC Declaration of Conformity List

EDMA Classification	Description	Product Product Code - Test Size
12 11 01 09 00	C-Reactive Protein (CRP)	AVITEX CRP OD023 – 100 Tests OD023/E - 100 Tests (Latex only) OD073 -50 Tests OD143/A – 25 Tests OD363 AVITEX TURBO CRP 50ml OD253 AVITEX TURBO RF/CRP/ASO Low Positive Control 4 x 1ml OD263 AVITEX TURBO RF/CRP/ASO High Positive Control 4 x 1ml
12 11 01 10 00 12 11 01 10 00	Rheumatoid Factors (RF)	AVITEX RF OD013 - 100 Tests OD013/E -100 Tests (Latex only) OD063 - 50 Tests OD133/A – 25 Tests OD353 AVITEX TURBO RF 50ml OD253 AVITEX TURBO RF/CRP/ASO Low Positive Control 4 X 1ml OD263 AVITEX TURBO RF/CRP/ASO High Positive Control 4 x 1ml AVITEX ROSE WAALER OD113 – 50 Tests

EC Declaration of Conformity List

EDMA Classification	Description	Product Product Code - Test Size
Rapid Tests Immunochemistry (12 70) Fertility / Pregnancy Rapid Tests (12 70 05)		
12 70 05 02 00	hCG - Rapid Test	VISITECT PREGNANCY OD036 – 25 Tests OD056 – 100 Tests

EC Declaration of Conformity List

EDMA Classification	Description	Product Product Code - Test Size
Microbiology (14) Bacteriology - Identification & Susceptbility Testing (14 02) Immunological Identification (14 02 03)		
14 02 03 02 00	Streptococci	AVIPATH STREP OD014/A - 50 Tests (Latex A only) OD014/B - 50 Tests (Latex B only) OD014/C - 50 Tests (Latex C only) OD014/D - 50 Tests (Latex D only) OD014/F - 50 Tests (Latex F only) OD014/G - 50 Tests (Latex G only) OD014/L - 50 Tests
14 02 03 03 00	Staphylococci	AVIPATH STAPH OD044 – 50 Tests

EC Declaration of Conformity List

EDMA Classification	Description	Product Product Code - Test Size
Parasitology (14 05) Serological Detection and Identification (Parasitology) (14 05 02)		
14 05 02 02 00	Plasmodium falciparum	VISITECT MALARIA Pf OD026 – 25 Tests OD156 – 100 Test
14 05 02 02 00		VISITECT MALARIA COMBO PAN Pf OD206 – 25 Tests

EC Declaration of Conformity List

EDMA Classification	Description	Product Product Code - Test Size
Infectious Immunology (15) Bacteriology (Infectious Immunology) (15 01) Syphilis (Treponema pallidum) (15 01 03)		
15 01 03 03 00	Syphilis Antibody Assays Total	IMMUTREP CARBON ANTIGEN OD031 – 5ml OD041 – 50 ml
15 01 03 03 00		IMMUTREP RPR OD021 – 250 Tests OD051 – 100 Tests OD051/T – 100 Tests OD061 – 500 Tests
15 01 03 03 00		IMMUTREP TPHA OD071 – 200 Tests OD081 – 100 Tests OD211 – 1000 Tests OD221 - 850 Tests OD071/A – 200 Tests (with Plates) OD081/B – 100 Tests (with Plates)

EC Declaration of Conformity List

EDMA Classification	Description	Product Product Code - Test Size
Syphilis (Treponema pallidum) (15 01 03) Continued		
15 01 03 03 00		IMMUTREP USR OD111 – 10 ml OD111/A – 10 ml (with Positive Control)
15 01 03 03 00		IMMUTREP VDRL ANTIGEN ODO11 / 5ml
15 01 03 03 00		PATHOZYME SYPHILIS COMPETITION OD117 – 96 Tests OD157 – 480 Tests
15 01 03 06 00	Syphilis Antibody IgM	PATHOZYME SYPHILIS M CAPTURE OD057 – 96 Tests

EC Declaration of Conformity List

EDMA Classification	Description	Product Product Code - Test Size
Mycobacteria genus + species (15 01 07)		
15 01 07 03 00	Mycobacterial Antibody Assays	PATHOZYME MYCO IgA OD177 – 96 Tests
15 01 07 03 00		PATHOZYME MYCO IgG OD167 – 96 Tests
15 01 07 03 00		PATHOZYME MYCO IgM OD187
15 01 07 03 00		PATHOZYME TB COMPLEX PLUS OD197 – 96 Tests

EC Declaration of Conformity List

EDMA Classification	Description	Product Product Code - Test Size
Salmonella (15 01 10)		
15 01 10 03 00	Salmonella Antibody Assays	MICROPATH Ha OD015 – 100 Tests
15 01 10 03 00		MICROPATH Hb OD025 – 100 Tests
15 01 10 03 00		MICROPATH Hc OD035 –100 Tests
15 01 10 03 00		MICROPATH Hd OD045 – 100 Tests
15 01 10 03 00		MICROPATH OA OD055 – 50 Tests
15 01 10 03 00		MICROPATH OB OD065 – 100 Tests
15 01 10 03 00		MICROPATH OC OD075 – 100 Tests
15 01 10 03 00		MICROPATH OD OD085 – 100 Tests

EC Declaration of Conformity List

EDMA Classification	Description	Product Product Code - Test Size
Salmonella (15 01 10) Continued 15 01 10 03 00		MICROPATH X 4 OD225 – 100 Tests MICROPATH X 6 OD165 – 100 Tests MICROPATH X 6 OD175 – 100 Tests MICROPATH X 8 OD155 – 100 Tests MICROPATH X 10 OD145 – 100 Tests

EC Declaration of Conformity List

EDMA Classification	Description	Product Product Code - Test Size
Other Bacterial Immunoassays (15 01 90)		
15 01 90 01 00	Brucella	MICROPATH BRUCELLA ABORTUS OD095 – 100 Tests
15 01 90 01 00		MICROPATH BRUCELLA MELITENSIS OD105 – 100 Tests
15 01 90 01 00		MICROPATH ROSE BENGAL OD265 – 100 Tests
15 01 90 04 00	Leptospira	VISITECT LEPTO OD146 – 25 Tests
15 01 90 12 00	Proteus	MICROPATH PROTEUS OX19 OD125 – 100 Tests
15 01 90 12 00		MICROPATH PROTEUS OX2 OD115 – 100 Tests
15 01 90 12 00		MICROPATH PROTEUS OXK OD135 – 100 Tests

EC Declaration of Conformity List

EDMA Classification	Description	Product Product Code - Test Size
Epstein Barr Virus (15 04 04)		
15 04 04 90 00	Other EBV Reagents	AVITEX IM OD053 – 100 Tests OD103 – 50 Tests OD163/A – 25 Tests

EDMA Classification	Description	Product Product Code - Test Size
Other Virology Antigen / Antibody Detection (15 04 80)		
15 04 80 06 00	Rotavirus	VIROTECT ROTA OD038 – 50 Tests
15 04 80 11 00	Dengue Virus	PATHOZYME DENGUE IgG OD217 – 96 Tests
15 04 80 11 00		PATHOZYME DENGUE IgM CAPTURE OD647 – 96 Tests
15 04 80 11 00		VISITECT DENGUE OD136 – 25 Tests

EC Declaration of Conformity List

EDMA Classification	Description	Product Product Code - Test Size
Miscellaneous Parasitology (Antibodies) (15 05 10)		
15 05 10 02 00	Chagas	PATHOZYME T CRUZI OD147 – 96 Tests OD247 – 480 Tests

EDMA Classification	Description	Product Product Code - Test Size
Rapid Tests Infectious Immunology (15 70) Bacteriology Rapid Tests (15 70 01)		
15 70 01 05 00	Syphilis - Rapid Test	VISITECT SYPH OD016 –25 Tests
15 70 01 90 00	Other Bacteriology Rapid Tests	VISITECT TB OD126 – 25 Tests