



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

Manufacturer Omega Diagnostics, 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 IV IVDD, Full Quality Assurance

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 13485:2003, EN ISO 14971:2007, EN 375:2001, EN 591:2001, EN 980:2008, EN 13612:2002, EN 13640:2002, & 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 November 2009



EC Declaration of Conformity List

EDMA Classification	Description	Product Product Code - Test Size
Immunochemistry (12)		
Allergy (12 02) 12 02 01 02 00	Immuglobulin E- Total	PATHOZYME IgE OD417 – 96 Tests
Tumor Markers (12 03) Cancer Antigens (12 03 01) 12 03 01 02 00 12 03 01 03 00 12 03 01 06 00 12 03 01 31 00 12 03 90 01 00	Cancer Antigen 15-3 Cancer Antigen 19-9 Cancer Antigen 125 Carcinoembryonic Antigen Alphafetoprotein	PATHOZYME BREAST CANCER Ag 15-3 OD297 – 96 Tests PATHOZYME Ag19-9 OD277 – 96 Tests PATHOZYME Ag 125 OD287 – 96 Tests PATHOZYME CEA (CARCINOEMBRYONIC Ag) OD317 – 96 Tests PATHOZYME AFP OD307 – 96 Tests



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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 Triiodothyronine	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	Triiodothyronine	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



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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



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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



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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



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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
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
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
12 11 01 10 00		AVITEX ROSE WAALER OD113 – 50 Tests



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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



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EDMA Classification	Description	Product Product Code - Test Size
<p>Microbiology (14)</p> <p>Bacteriology - Identification & Susceptibility Testing (14 02)</p> <p>Immunological Identification (14 02 03)</p> <p>14 02 03 02 00</p> <p>14 02 03 03 00</p>	<p>Streptococci</p> <p>Staphylococci</p>	<p>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</p> <p>AVIPATH STAPH OD044 – 50 Tests</p>



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



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



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



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



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EDMA Classification	Description	Product Product Code - Test Size
Salmonella (15 01 10)	Salmonella Antibody Assays	
15 01 10 03 00		MICROPATH SAL H-A OD015 – 100 Tests
15 01 10 03 00		MICROPATH SAL H-B OD025 – 100 Tests
15 01 10 03 00		MICROPATH SAL H-C OD035 – 100 Tests
15 01 10 03 00		MICROPATH SAL H-D OD045 – 100 Tests
15 01 10 03 00		MICROPATH SAL O-A OD055 – 50 Tests
15 01 10 03 00		MICROPATH SAL O-B OD065 – 100 Tests
15 01 10 03 00		MICROPATH SAL O-C OD075 – 100 Tests
15 01 10 03 00		MICROPATH SAL O-D OD085 – 100 Tests



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



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



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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 OD227 – 96 Tests
15 04 80 11 00		VISITECT DENGUE OD136 – 25 Tests



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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