

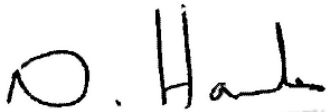
## EU Declaration of Conformity

Omega Diagnostics  
Omega House  
Hillfoots Business Village  
Alva  
Scotland  
United Kingdom  
FK12 5DQ  
Manufacturer Identification Code GB / 000072

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

Herewith declare that the attached listed products meet the applicable provisions of the EU Directive 98 / 79 / EEC on in – vitro diagnostic medical devices for IVD's which are not Annex II or self-testing devices by self conformity assessment and carry the CE mark accordingly.

Alva, 28th January 2008



Norman Hawkes

Technical Manager

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<b>EDMA Classification</b>	<b>Description</b>	<b>Product Product Code - Test Size</b>
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	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

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

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<b>EDMA Classification</b>	<b>Description</b>	<b>Product Product Code - Test Size</b>
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

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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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<b>EDMA Classification</b>	<b>Description</b>	<b>Product Product Code - Test Size</b>
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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<b>EDMA Classification</b>	<b>Description</b>	<b>Product Product Code - Test Size</b>
<p>Microbiology ( 14 )</p> <p>Bacteriology - Identification &amp; 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</p> <p>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 - 50 Tests</p> <p>AVIPATH STAPH OD044 – 50 Tests</p>

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<b>EDMA Classification</b>	<b>Description</b>	<b>Product Product Code - Test Size</b>
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 OD026 – 25 Tests

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<b>EDMA Classification</b>	<b>Description</b>	<b>Product Product Code - Test Size</b>
<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 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 ) OD211/C – 1000 Tests ( with Plates )</p>

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

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

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<b>EDMA Classification</b>	<b>Description</b>	<b>Product Product Code - Test Size</b>
Salmonella ( 15 01 10 )		
15 01 10 03 00	Salmonella Antibody Assays	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 OD155 – 8 X 100 Tests OD145 – 10 X 100 Tests



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

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<b>EDMA Classification</b>	<b>Description</b>	<b>Product Product Code - Test Size</b>
<p>Herpes Simplex Virus ( 15 04 03 )</p> <p>15 04 03 11 00</p>	<p>HSV 2 IgG</p>	<p>PATHOZYME HSV-2 VIRO IgG OD697 – 96 Tests</p>

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<b>EDMA Classification</b>	<b>Description</b>	<b>Product Product Code - Test Size</b>
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

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

<b>EDMA Classification</b>	<b>Description</b>	<b>Product Product Code - Test Size</b>
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