



## 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:

A handwritten signature in blue ink, appearing to read "N. Hawkes".

**Name:** Norman Hawkes  
**Position:** Technical Manager  
**Place:** Omega Diagnostics, Omega House, Hillfoots Business Village, Alva, Scotland, United Kingdom, FK12 5DQ  
**Date:** 4<sup>th</sup> 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	<p>AVITEX TURBO CYS – C OD303 – 24 ml</p> <p>AVITEX TURBO CYS – C CALIBRATORS OD313 5 X 2 ml</p> <p>AVITEX TURBO CYS – C CONTROLS OD333 4 X 2 ml</p>
12 01 90 90	Microalbumin	<p>AVITEX TURBO <math>\mu</math>ALB OD373 – 50 ml</p> <p>AVITEX TURBO <math>\mu</math>ALB CALIBRATOR OD393 1 X 1 ml</p> <p>AVITEX TURBO <math>\mu</math>ALB CONTROL OD383 1 X 2 ml</p>
Allergy ( 12 02 )  12 02 01 02 00	Immuglobulin E- Total	<p>PATHOZYME IgE OD417 – 96 Tests</p>



**EC Declaration of Conformity List**

<b>EDMA Classification</b>	<b>Description</b>	<b>Product Product Code - Test Size</b>
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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<b>EDMA Classification</b>	<b>Description</b>	<b>Product Product Code - Test Size</b>
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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<b>EDMA Classification</b>	<b>Description</b>	<b>Product Product Code - Test Size</b>
<p>Rheumatoid Inflammatory Disease Markers ( 12 11 )</p> <p>Rheumatoid Inflammatory Disease Markers (12 11 01 )</p> <p>12 11 01 05 00</p>	<p>Anti-Streptolysin O ( ASO )</p>	<p>AVITEX ASO OD033 – 100 Tests OD033/E - 100 Tests ( Latex only ) OD083 - 50 Tests OD153/A – 25 Tests</p> <p>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</p>



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<b>EDMA Classification</b>	<b>Description</b>	<b>Product Product Code - Test Size</b>
12 11 01 09 00	C-Reactive Protein ( CRP )	<p>AVITEX CRP OD023 – 100 Tests OD023/E - 100 Tests ( Latex only ) OD073 -50 Tests OD143/A – 25 Tests</p> <p>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</p>
12 11 01 10 00  12 11 01 10 00	Rheumatoid Factors ( RF )	<p>AVITEX RF OD013 - 100 Tests OD013/E -100 Tests ( Latex only ) OD063 - 50 Tests OD133/A – 25 Tests</p> <p>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</p> <p>AVITEX ROSE WAALER OD113 – 50 Tests</p>



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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>
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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<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 OD051/T – 100 Tests OD061 – 500 Tests</p> <p>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 )</p>



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



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



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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

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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 CAPTURE OD647 – 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