


EC Declaration of Conformity

Version	Released	Amendments
1	30/04/2013	First Q-Pulse Entry
2	14/04/2014	Update Harmonised Standards
3	04/03/2015	Amend manufacturer's address to be the same format as printed on kit boxes.
4	09/06/2015	Removal of <i>Pseudomonas aeruginosa</i> products
5		

We, Genesis Diagnostics Ltd, hereby declare that the devices named within have been designed to comply with the essential requirements of the DIRECTIVE 98/79/EC, on in vitro diagnostic medical devices.

Authorised By:

Signed
Name
Role
Place
Date


Matthew Bennett
Quality Manager
Genesis Diagnostics Ltd
10/06/2015

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1 Manufacturer

Genesis Diagnostics Ltd.
Eden Research Park
Henry Crabb Road
Littleport
Cambridgeshire
CB6 1SE
England
United Kingdom

2 Manufacturer Identification Code

GB / 000045

3 Competent Authority

Medicines & Healthcare products Regulatory Agency (MHRA)
51 Buckingham Palace Road
Victoria
London,
SW1W 9SZ

4 Conformity Assessment Route

IVDD 98/79/EC, ANNEX III Section 6.1, Table 1

5 Standards Applied

EN ISO 9001:2008
BE EN ISO 14971:2012
BS EN ISO 18113:2011

EN ISO 13485:2003
BS EN 13641:2002
BS EN 13640:2013

6 Product Details & Conformity Assessment Route

6.1 Table 1: Conformity Assessment Route, IVDD 98/79/EC, ANNEX III

EDMA Classification	Description	Product Product Code
12 02 01 09	Allergen Specific IgG	93 Food IgG GD014
		93 Food IgG Bulk (×10 plates) GD014/10
		Mediterranean Foods IgG GD014M
		Mediterranean Foods IgG Bulk (×10 plates) GD014M/10
		40 Food IgG GD015
		Beta-Lactoglobulin IgG GD039
		Ovalbumin IgG GD041
		Casein IgG GD043
		Soya IgG GD045
		Alpha Lactalbumin IgG GD051
5 Food IgG GD109		
Genarrayt® Microarray 200+ Food GD201, GD201-4, GD201-1 GD202, GD202-4, GD202-1		

EDMA Classification	Description	Product Product Code
12 02 01 08	Allergen Specific IgA	Beta-Lactoglobulin IgA GD036 Ovanlbumin IgA GD040 Casein IgA GD042 Soya IgA GD044 Alpha Lactalbumin IgA GD050
12 10 90 09	MPO ANCA	MPO Antibodies GD002
12 10 90 10	PR3 ANCA	PR3 Antibodies GD003
12 10 90 07	Goodpasture Antibodies	GBM Antibodies GD004 (96 Test) GD004/A (48 Test)
12 02 01 02	Immunoglobulin E Total	Total IgE GD009
12 10 01 05	dsDNA Antibodies	dsDNA GD010 High Avidity dsDNA IgG Gd128
12 10 01 06	ssDNA Antibodies	ssDNA GD012
15 06 01 01	Aspergillus	Aspergillus IgG GD029

EDMA Classification	Description	Product Product Code
12 10 90 06	Gliadin Antibodies	Gliadin IgG GD016 Gliadin IgA GD017
12 10 01 01	ANA Screening	ANA Ease (Screen)
12 11 01 10	Rheumatoid Factors	Rheumatoid Factor Total GD006 Rheumatoid Factor IgM GD023 Rheumatoid Factor IgA GD024 Rheumatoid Factor IgG GD037
12 11 01 11	Anti-Cyclic Citrullinated Peptide	Citrullinated Protein Antibodies GD110
12 10 90 90	Other, Other Auto-Immune Disease Tests	Intrinsic Factor IgG GD035 Prothrombin IgG GD076 LC1 Antibodies GD108
14 03 05 01	Serological Identification of Yeasts and Fungi	Candida IgA GD019 Candida IgM GD020 Candida IgG GD022

EDMA Classification	Description	Product Product Code
12 10 90 01	Anti-Cardiolipin Antibodies	Cardiolipin IgA GD025 Cardiolipin IgG GD026 Cardiolipin IgM GD027 Cardiolipin Total GD028
12 10 03 01	Thyroid Peroxidase (incl. Microsomal) Antibodies	TPO IgG GD049
15 01 04 03	H. Pylori Antibody Assays	HpG-Screen GD001 H pylori IgA GD008 CagA IgG GD033 H pylori IgM GD124
12 10 90 11	Parietal Cell Antibodies	Gastric Parietal Cell Antibodies GD036
12 10 03 04	Thyroglobulin Autoantibody	Thyroglobulin Antibodies GD048
12 10 01 02	ENA Screening	ENA Six Screen GD060
12 10 01 08	Jo-1	Jo-1 Antibodies GD061
12 10 01 12	SSA	SSA/Ro Antibodies GD062
12 10 01 11	Sm	Sm Antibodies GD063
12 10 01 90	Other ANA/ENA	Sm/RNP Antibodies GD064

EDMA Classification	Description	Product Product Code
12 10 01 13	SSB	SSB/La Antibodies GD066
12 10 90 04	Anti-β2-Glycoprotein I Antibodies	Beta 2 Glycoprotein IgA GD030 Beta 2 Glycoprotein IgG GD031 Beta 2 Glycoprotein IgM GD032
12 10 90 19	Saccharomyces cerevisiae Antibodies	ASCA IgA GD078 ASCA IgG GD079
12 04 01 08	Thyroglobulin	Thyroglobulin Antigen GD101
12 10 01 15	Anti-Centromere Antibodies	Centromere B IgG GD104
12 10 90 08	LKM-1 and Related Proteins Antibodies	LKM-1 Antibodies GD107
12 10 01 14	U1-snRNP small nucleoprotein antibody	U1-RNP Antibodies GD125
12 10 90 21	Tissue Transglutaminase Antibodies	Tissue transglutaminase IgA (Recom) GD071N Tissue transglutaminase IgG (Recom) GD072N
12 10 01 10	Scl-70	Scl-70 Antibodies GD065

EDMA Classification	Description	Product Product Code
12 50 01 14	Rheumatoid/Autoimmune Controls	Rheumatoid Factor IgM GDA01M
		Rheumatoid Factor IgA GDA01A
		Rheumatoid Factor IgG GDA01G
		Proteinase -3 Antibodies GDA02
		Myeloperoxidase Antibodies GDA03
		dsDNA Antibodies GDA04
		SSA/RO and SSB/La Antibodies GDA05
		Jo-1 Antibodies GDA06
		Centromere B Antibodies GDA07
		TPO/Tg Antibodies GDA08
		Cardiolipin IgG/IgM GDA09
		B2 Glycoprotein-1 Antibodies GDA10
		Prothrombin Antibodies GDA11
		LKM-1/LC1 Antibodies GDA12
Gliadin IgG/IgA Antibodies GDA14		

EDMA Classification	Description	Product Product Code
12 50 01 14 (cont.)	Rheumatoid/Autoimmune Controls (cont.)	Intrinsic Factor/GPC Antibodies GDA15 GBM Antibodies GDA17 Scl-70 Antibodies GDA18 Sm/Sm RNP Antibodies GDA19 Acetylcholine Receptor Antibodies GDA20 Transglutaminase IgA Antibodies GDA21 U1 RNP Antibodies GDA22 Citrullinated Protein Antibodies GDA23 Transglutaminase IgG Antibodies GDA24