

GENESIS DIAGNOSTICS LTD		
Written By: Dr. J. G. Reeve	Form 21-06a	Rev. No. 09
Approved By: Mr. A. Shepherd	Effective Date: 26 June 2009	Page 1 of 2

EC Declaration of Conformity
In accordance with Directive 98/79/EC

We, Genesis Diagnostics Ltd. of Eden Research Park, Henry Crabb Road, Littleport, Ely, Cambridgeshire, UK declare that:

Product names: Rheumatoid Factor-IgA Control Serum, Rheumatoid Factor-IgG Control Serum, Rheumatoid Factor-IgM Control Serum, Proteinase-3 (PR3) Abs Control Serum, Myeloperoxidase (MPO) Abs Control Serum, dsDNA Abs Control Serum, SSA/SSB Abs Control Serum, Jo-1Abs Control Serum, Centromere B Abs Control Serum, TPO/Tg Abs Control Serum, Cardiolipin IgG/IgM Control Serum , B2-GP-1 IgG Control Serum , Prothrombin IgG Control Serum, LKM-1/LC-1 IgG Control Serum , Gliadin IgG/IgA Control Serum , Intrinsic Factor/GPC Antibodies Control Serum , GAD Abs Control Serum , GBM Abs Control Serum , Scl 70 Abs Control Serum , Sm/Sm RNP Abs Control Serum , Acetylcholine Receptor Abs Control Serum , Transglutaminase IgA Antibodies Control Serum , U1-Sm RNP Control Serum , Citrullinated Peptide antibodies Control Serum , HpG-Screen ELISA Kit, Hp-Screen ELISA Kit (10 pack), MPO Antibodies ELISA Kit, PR3 Antibodies ELISA Kit, GBM Antibodies ELISA Kit, GBM Antibodies ELISA Kit (48 well), Rheumatoid Factor Screen ELISA Kit, *Pseudomonas aeruginosa* IgG ELISA Kit, *H. pylori* IgA ELISA Kit, Total IgE ELISA Kit, dsDNA Antibodies ELISA Kit, ss-DNA Antibodies ELISA Kit, Food IgG (93 Foods) ELISA Kit, 93 Food IgG Screen ELISA Kit (10 Pack), 109 Food IgG Mediterranean ELISA Kit, 109 Food IgG Mediterranean ELISA Kit (10 Pack), 40 Food IgG Screen ELISA Kit (4 tests), 40 Food IgG Screen ELISA Kit (10 pack), Gliadin IgG ELISA Kit, Gliadin IgA ELISA Kit, *Pseudomonas aeruginosa* IgA ELISA Kit, Candida IgA ELISA Kit, Candida IgM ELISA Kit, Candida IgG ELISA, Rheumatoid Factor IgM ELISA Kit, Rheumatoid Factor IgA ELISA Kit, Cardiolipin IgA ELISA Kit, Cardiolipin IgG ELISA, Cardiolipin IgM ELISA, Total Anti-Cardiolipin Screen ELISA, Aspergillus IgG ELISA Kit, β 2-Glycoprotein I IgA ELISA Kit, β 2-glycoprotein I IgG ELISA Kit, β 2-glycoprotein I IgM ELISA Kit, CagA IgG ELISA Kit, Intrinsic Factor IgG ELISA Kit, GPC Antibodies ELISA Kit, Rheumatoid Factor IgG ELISA Kit, β -Lactoglobulin IgA ELISA Kit, β -Lactoglobulin IgG ELISA Kit, Ovalbumin IgA ELISA Kit, Ovalbumin IgG ELISA Kit, Casein IgA ELISA Kit, Casein IgG ELISA Kit, Soya IgA ELISA Kit, Soya IgG ELISA Kit, Thyroglobulin IgG ELISA Kit, Thyroid Peroxidase Antibodies ELISA Kit, α -lactalbumin IgA ELISA Kit, α -lactalbumin IgG ELISA Kit, ENA-Six Screen ELISA Kit, Jo-1 Antibodies ELISA Kit, SSA/Ro Antibodies ELISA Kit, Smith (Sm) Antibodies ELISA Kit, RNP/Sm Antibodies ELISA Kit, Scl-70 Antibodies ELISA Kit, SSB/La Antibodies ELISA Kit, Transglutaminase IgA (Guinea Pig) ELISA KIT, Transglutaminase IgA (Recom) ELISA KIT, Transglutaminase IgA (Recom) ELISA KIT (10 pack), Transglutaminase IgG (Recom) ELISA Kit, ANA Ease ELISA Kit, Prothrombin (Factor II) IgG ELISA Kit, Gliadin IgG/IgA Combined ELISA Kit, ASCA IgG ELISA Kit (Saccaromyces), ASCA IgA ELISA Kit (Saccaromyces), Toxoplasma IgG ELISA Kit, Toxoplasma IgM ELISA Kit, Rubella IgG ELISA Kit, Rubella IgM ELISA Kit, CMV IgG ELISA Kit, CMV IgM ELISA Kit, HSV-1 IgG ELISA Kit, HSV-2 ELISA Kit, HSV-1/-2IgM ELISA Kit, Tg-AGT ELISA Kit, Centromere B IgG ELISA Kit, LKM-1 IgG ELISA Kit, LC1 IgG ELISA Kit, 5 Food IgG ELISA Kit, Citrullinated Protein Antibodies IgG ELISA Kit, Glia-chek G ELISA Kit, Glia-chek A ELISA Kit, Gliadin IgG ELISA Kit, Gliadin IgA ELISA Kit, Tissue Transglutaminase IgA ELISA Kit, Tissue Transglutaminase IgG ELISA Kit, *H. pylori* IgM ELISA Kit, U1RNP IgG ELISA Kit, Intrinsic Factor IgG (recombinant) ELISA Kit, High Avidity dsDNA IgG ELISA, Genarrayt Microarray 200+ food IgG 64 pt, Genarrayt Microarray 200+ food IgG 4 pt, Genarrayt Microarray 200+ food IgG 16 pt.

Product numbers: GDA01A, GDA01G, GDA01M, GDA02, GDA03, GDA04, GDA05, GDA06, GDA07, GDA08, GDA09, GDA10, GDA11, GDA12, GDA14, GDA15, GDA16, GDA17, GDA18, GDA19, GDA20, GDA21, GDA22, GDA23, GD01, GD01/10, GD02, GD03, GD04, GD04A, GD06, GD07, GD08, GD09, GD10, GD12, GD14, GD14/10, GD14M, GD14M/10, GD15, GD15/10, GD16, GD17, GD18, GD19, GD20, GD22, GD23, GD24, GD25, GD26, GD27, GD28, GD29, GD30, GD31, GD32, GD33, GD35, GD36, GD37, GD38, GD39, GD40, GD41, GD42, GD43, GD44, GD45, GD48, GD49, GD50, GD51, GD60, GD61, GD62, GD63, GD64, GD65, GD66, GD70, GD71, GD71/10, GD72, GD74, GD76, GD77, GD78, GD79, GD80, GD81, GD82, GD83, GD84, GD85, GD86, GD87, GD88, GD101, GD104, GD107, GD108, GD109, GD110, GD111, GD112, GD113, GD114, GD116, GD117, GD124, GD125, GD126, GD128, GD201, GD201-1, GD201-4.

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in accordance with the following Directive:

98/79/EC The In Vitro Diagnostic Medical Devices Directive
have been designed and manufactured to the following specifications:

- BE EN ISO 14971:2001 Medical Devices – Application of risk management to medical devices
- BS EN 375:2001 Information supplied by the manufacturer with in vitro diagnostic reagents for professional use
- BS EN ISO 9001:2000 Quality systems – Model for quality assurance in design/development, production, installation and servicing
- BS EN ISO 13485: 2003 Quality Systems – Medical Devices – Particular requirements for the application of ISO 9001
- BS EN 13641:2002 Elimination or reduction of risk of infection related to in vitro diagnostic reagents
- BS EN 13640:2002 Stability testing of in vitro diagnostic reagents

I hereby declare that the devices named above have been designed to comply with the relevant sections of the above referenced specifications. The devices comply with all essential requirements of the Directive.

Signed by:



Name: Geoff Gower
Position: Managing Director
Place: Genesis Diagnostics Ltd
Date: 26 June 2009