Safeguarding public health

MHRA

Our Ref: IVD 000045

Dr Julie Reeve,
Genesis Diagnostics Ltd
8 Henry Crabb Road
Ely
CB6 ISE
UK

15 August 2008

Dear Dr Julie Reeve,

MEDICAL DEVICES REGULATIONS 2002: REGULATION 44
Registration of Persons Placing In vitro Diagnostic Medical Devices on the Market

Thank you for informing the Competent Authority of the company's details and for supplying the medical device information.

Your registration has been recorded based on your declaration that you have determined that the device(s) fall within the definition of "in vitro diagnositc medical device", and that you have classified it/them correctly taking into account the intended purpose(s) and mode(s) of action. In accepting your registration, I should make clear that the Competent Authority does not examine each individual notification and therefore cannot and does not necessarily endorse these determinations. Neither does this letter represent any form of accreditation or approval by the UK Competent Authority.

Your registration is based upon your declaration on the RG3 form and means that you should now be operating under the In Vitro Diagnostic Medical Devices Directive and the 2002 Regulations for the products you asked us to register, by fully complying with the essential requirements, CE marking those products or labelling them as such.

If you stop placing devices on the market or if you are not complying with the Regulations you should inform us as required by the Regulations. You should be aware that it is an offence to place on the market CE marked devices that do not comply with the Regulations.

The information you provided has been recorded against the reference number shown at the top of this letter, which we ask you to quote in all future correspondence and communications.

Please inform us of any changes to:

- the company information
- additional generic groups of devices or, for Annex II or Self-Test devices, additional devices
- discontinuation of a generic group of devices or, for Annex II or Self-Test devices, discontinuation of devices

Please use RG3, the Registration form, to tell us about any of these changes. A fee of £70 is payable for each change or set of changes notified.

Thank you for registering the following generic groups of devices

Part 5: IVDs which are not Annex II and not self-test devices

For reagnets, reagent products, calibration and control materials: group by common technological characteristics and/or analytes

New products:

Other Allergy Tests

For performance evaluation:

None

Neither:

MPO ANCA
PR3 ANCA
Parietal Cell Antibodies
Other Other Auto-Immune Disease Tests
Thyroglobulin
Serological Identification of Yeasts and Fungi
H. Pylori Antibody Assays
ANA Screening
ds DNA - Antibodies
Thyroglobulin Autoantibody
Thyroid Peroxydase Antibodies
Anti-Cardiolipin Antibodies
Gliadin Antibodies
Goodpasture Antibodies
ss DNA - Antibodies
ENA Screening
Jo-1
Scl-70
Sm
SS-A
SS-B
Other ANA / ENA
LKM1 and Related Proteins Antibodies
Other Rheumatoid Factors
Anti-ß2-Glycoprotein I Antibodies
Immunoglobulin E - Total (Allergy Screening)
Other Allergy Tests
Pseudomonas Aeruginosa Antibody IgG
Other Pseudomonas Aeruginosa Reagents
Rheumatoid/Autoimmune Controls
Other Controls Immunochemistry
Rheumatoid Factors
Candida albicans
Aspergillus
Other H. Pylori Reagents
Intrinsic Factor (Blocking Antibody)
Allergen Specific IgG
Tissue Transglutaminase Antibodies
Other HSV Reagents
Anti-centromere Antibodies
U1-snRNP - Antibodies
HSV 1 Antibodies - Total
HSV 2 Antibodies - Total

For other IVDs, group by appropriate indications

New products:
Diagnostics & Clinical Interpretation Supporting Software

For performance evaluation:
None

Neither:
None

Part 6: IVDs which are Annex II or self-test devices

For reagnets, reagent products, calibration and control materials: group by common technological characteristics and/or analytes

New products:
None

For performance evaluation:
None

Neither:
None

For other IVDs, group by appropriate indications

New products:
None

For performance evaluation:
None

Neither:
None

If you have any queries regarding your registration, please do not hesitate to contact us.

Yours sincerely

Mr Sean Williams
(on behalf of the Competent Authority, UK)

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