

Safeguarding public health

Our Ref: IVD000072

Mr Norman Hawkes,
Omega Diagnostics Ltd
Hillfoots Business Village
Alva
FK12 5DQ
United Kingdom

18 February 2010

Dear Mr Norman Hawkes,

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 your company's details and for supplying the medical device information in regards to the change to the original notification dated 2 April 2003.

The change(s) to registration has been recorded based on your declaration that you have determined that the device(s) fall within the definition of "in vitro diagnostic 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 reagents, reagent products, calibration and control materials:
group by common technological characteristics and/or analytes**

New products: None

For performance evaluation: None

Neither:

Syphilis Antibody Assays Total
Syphilis Antibody IgM
Immunoglobulin E - Total (Allergy Screening)
Cancer Antigen 15-3
Cancer Antigen 19-9
Cancer Antigen 125
Carcinoembryonic Antigen
Free Triiodothyronine
Free Thyroxine
Triiodothyronine
Thyroxine
Thyroid Stimulating Hormone
Estradiol
Follicle Stimulating Hormone
Luteinising Hormone
Progesterone
Prolactin
Testosterone (with Dehydro and Free Testosterone)
Human Chorionic Gonadotropin Total
Human Growth Hormone
ds DNA - Antibodies
Systemic Lupus Erythematosus
Anti-Streptolysin/Anti-Streptolysin O (qualitative)
C-Reactive Protein
Rheumatoid Factors
HCG - Rapid Test
Streptococci
Staphylococci
Plasmodium falciparum
Mycobacterial Antibody Assays
Salmonella Antibody Assays
Brucella
Leptospira
HSV 1 IgG
HSV 1 IgM
HSV2 IgG Antibodies
HSV2 IgM
Other EBV Reagents
Rotavirus
Chagas
Syphilis - Rapid Test
Other Bacteriology Rapid Tests
Alphafetoprotein
Dengue Virus
Proteus

For other IVDs, group by appropriate indications

New products: None

For performance evaluation: None

Neither: None

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

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

New products: None

For performance evaluation: None

Neither:

Fluorotect Chlamydia

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



Sean Williams
Regulatory Affairs Administrator

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