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COMPETENT AUTHORITY (UK)

EC MEDICAL DEVICES DIRECTIVES

**GUIDANCE NOTES
FOR THE REGISTRATION OF
PERSONS RESPONSIBLE FOR
PLACING IN-VITRO DIAGNOSTIC
MEDICAL DEVICES ON THE MARKET
(THE MEDICAL DEVICES
REGULATIONS 2002)**

Amended February 2006

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WHY NOTIFY

The In Vitro Diagnostic Medical Devices Directive 98/79/EC requires manufacturers of their authorised representatives or others placing in vitro diagnostic medical devices(s) on the Community market to provide certain information to a Competent Authority in a Member State where they have a registered place of business.

These notes explain who should and how to provide the information to the Competent Authority (UK).

WHO SHOULD NOTIFY

You must register with one Competent Authority in a Member State in which you have your registered place of business if you:

- manufacture in vitro diagnostic medical devices (IVDs) and place them on the market under your own name, or trading name(s);
- manufacture IVDs for performance evaluation and make them available under your own name, or trading name(s);
- are the authorised representative of a manufacturer who does not have a registered place of business in the Community.

If you do not have a registered place of business in a Member State and you wish to place IVDs on the European market then you must designate a person established in the Community to act on your behalf as your Authorised Representative.

NOTIFICATIONS BY MANUFACTURERS OR AUTHORISED REPRESENTATIVES WHO ARE NOT BASED IN THE UK

Until the European Databank referred to in Article 12 of the Directive has been established, the Directive additionally requires manufacturers or Authorised Representatives who are not based in the UK and who place IVDs on the UK market to provide the same information to the Competent Authority (UK) as those who are based in the UK.

Such notifications are not covered by this Guidance and further advice to non-UK manufacturers may be found on the MHRA website at <http://www.mhra.gov.uk>

WHEN TO NOTIFY?

The Medical Devices Regulations 2002 came into force on 13 June 2002. For *in vitro* diagnostic there is a transitional period until 7 December 2003 in respect of a device placed on the market and a transitional period until 7 December 2005 in respect of a device put into service, during which a manufacturer can choose either to follow existing national regulations to apply the CE mark. You must inform the Competent

Authority when you first apply the CE marking to your IVDs. If you have a number of products (outside annex II and not self-test) which you intend to CE mark over a period, you may inform the UK Competent Authority of all device groups when informing of the first CE marking. Please give the dates when you anticipate CE marking the various products.

WHOM TO NOTIFY?

If you have a registered business in the UK you may inform the UK Competent Authority at the address given at the end of these guidance notes. If you also have businesses in other Member States you may choose to inform one of them and not the UK, but you must inform one Competent Authority in which you have a registered place of business.

If your business is registered in another Member State and not the UK you should seek information from the Competent Authority in that Member State on how to submit the required information.

HOW TO NOTIFY?

The UK Competent Authority has a designated form (Form RG3) which is available from MHRA or on our website at <http://www.mhra.gov.uk>

HOW MUCH WILL IT COST?

There is a fee of £70 for each registration or change in registration, and this must be sent at the same time as the information. One registration and/or change in registration may cover several products or groups of products.

WHAT HAPPENS TO MY NOTIFICATION?

The Medicines & Healthcare products Regulatory Agency aims to acknowledge your notification within five working days of its receipt. We will also send you a receipt and invoice for the registration fee (which the Regulations require to be submitted with your notification). If we require any further information we will ask for it, otherwise we will confirm that we have accepted your notification and allocate you a reference number. This number will cover all devices notified by the person responsible. It does not imply any form of approval by the Competent Authority. Finally, relevant data on your devices will be entered into the European databank, Eudamed, in accordance with Article 12 of the in vitro diagnostic Directive.

CHANGES TO REGISTERED DETAILS?

After we register your notification, you must use form RG3 to tell us about any changes or additions to the registered details. Additionally, we may periodically review our records and request confirmation of the registered information.

FORM RG3

The following is guidance on how to fill in the form. RG3 must be used for all notifications or changes to notifications.

PART 1

Identification of the registration

Question 6200

Date of registration is the date on which the form is sent to the Medicines & Healthcare products Agency. Please also confirm that the relevant fee is enclosed. Cheques should be made payable to the Medicines & Healthcare products Regulatory Agency.

Question 6220 & 6230

If this is your first notification to the UK Competent Authority for IVDs you should indicate this here. Otherwise if it is a change of address or significant change of product, or a discontinuation of a product, tick the appropriate box and provide the previously allocated reference number. A significant change of product is one which affects the information given in a previous registration. This could include a change in product name for Annex II devices or an additional product that does not fall within the descriptions/generic device group code previously given for other devices that you have already registered.

Question 6240

You should indicate if you are the manufacturer, or the authorised representative for a manufacturer located outside of the EC. The term manufacturer also include "Own Branders". More information on Own Brand Labelling may be found in Bulletin 19.

PARTS 2 & 3

Identification of Manufacturer and Authorised Representative

Parts 2 and 3 require the name and address details of the manufacturer or authorised representative located in the UK. If you are the manufacturer, you should fill in Part 2. If you are the authorised representative, you should fill in Part 3, and provide the

details of the manufacturer that you are representing in Part 2. Only fill in the address lines indicated.

PART 4

Declaration

The declaration must be signed by or on behalf of the manufacturer, if based in the UK. In the case of the manufacturer being based outside the UK, the declaration must be signed by or on behalf of the authorised representative. In signing the form please note:

1. that Authorised Representative should provide evidence of their status, for example in the form of a letter of designation from the manufacturer whom they present:
2. for Annex II or self-test devices, you are undertaking to keep available data relating to analytical and where appropriate diagnostic parameters as referred to in Section 3 of Part A of Annex 1 of the Directive, together with their labelling and instructions for use. Such data may from time to time be requested by the Competent Authority.

PARTS 5 & 6

For Annex II and self-testing devices please fill in part 6. For other devices please fill in part 5.

PART 5

IVDs which are not Annex II of self-test

Question 6445

You should indicate in the boxes provided whether any of the devices are either “new” products as defined in the Regulations, or devices for performance evaluation, or neither of these two. If your devices cover more than one of these categories could you please ensure that a separate page is used for each category by photocopying the original page. Please also keep discontinuations separate.

The Regulations define a “new” product as follows:

- *either “there has been no such device continuously available on the Community market during the previous three years for the relevant analyte or other parameter, or*
- *use of the device involves analytical technology not continuously used in connection with a given analyte or other parameter on the Community market during the previous three years”.*

The Regulations define a device for performance evaluation as:

“a product which is intended by its manufacturer to be subject to one or more performance evaluation studies in laboratories for medical analysis or in other appropriate environments outside his own premises”.

Questions 64550, 6490, 6550, 6565 and 6590

The Regulations require IVDs to be grouped together for the purposes of registration – please refer to the attached list of device groups and instructions.

PART 6

IVDs which are Annex II or self-test devices

The Regulations require each individual Annex II or self-test product or model to be identified separately. Therefore Part 6 requires one page for each product notified.

Question 6605 Product name

The product name is the name given by the manufacturers to the make model of device, including model number if any.

Questions 6450, 6465, 6490, 65550, 6565 and 6590

The Regulations also require the individual products to be assigned to a group or family for the purposes of registration, and so you should specify the group to which each individual product belongs – please refer to the attached list of device groups and instructions.



Further Information

For general enquiries on the Directive please contact:

European and Regulatory Affairs,
Medicines & Healthcare products Regulatory Agency,
Market Towers,
1 Nine Elms Lane,
London,
SW8 5NQ

Tel: 020 7084 3300

Fax: 020 7084 3112

E-mail: ERA@mhra.gsi.gov.uk

For enquiries about registration, please contact MHRA at the above address or telephone:

Tel: 020 7084 3318

Fax: 020 7084 3107

Completed RG3 forms should be returned to the Registration Scheme Officer at the above address.