HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Guide to
Registration of Persons Responsible for Placing *In-vitro* Diagnostic Medical Devices on the Market

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This guide does not purport to be an interpretation of law and/or regulations and is for guidance purposes only.

CONTENTS

1 SCOPE

This document relates to the registration of *in vitro* diagnostic medical device organisations and their associated devices.

2 INTRODUCTION

The purpose of this guide is to outline the requirements in relation to registration of *in vitro* diagnostic medical devices (IVDs) as required by the Medical Devices Directive 98/79/EEC and Statutory Instrument (S.I.) No. 304 of 2001, European Communities (*In vitro* Diagnostic Medical Devices) Regulations, as well as to provide guidance on how to complete both the manual and online application forms for registration of these devices.

Manufacturers are advised to consult the relevant legislation relating to medical devices.

Information and assistance can be obtained from the Health Products Regulatory Authority (HPRA); contact details are included below.

3 BACKGROUND

A series of three main EU Directives regulate the safety and marketing of medical devices in the European Community.

(i) Directive 90/385/EEC concerning Active Implantable Medical Devices (AIM DD)
(ii) Directive 93/42/EEC concerning General Medical Devices (MDD)
(iii) Directive 98/79/EC concerning in-vitro Diagnostic Medical Devices (IVDD)

Several amending Directives and implementing measures are also relevant.

4 REQUIREMENTS

The IVD Directive and related Irish Regulations require manufacturers or their nominated authorised representatives or others placing medical device(s) on the Community market to provide certain information to the Competent Authority in the Member State in which they have their registered place of business.

If you have a registered place of business in Ireland, you must register with the HPRA if you:

- manufacture 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 trade name(s), or

- 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, you must designate a single authorised representative in the European Union to act on your behalf.

A manufacturer or other individual subject to the registration requirements outlined above must register with the Competent Authority of the Member State in which they have their registered place of business.

5 MAKING AN APPLICATION

The HPRA operates an online system for the registration of medical devices and related organisations. The registration form can be completed via the HPRA website. Please see the Medical Devices/Regulatory Information section of www.hpra.ie.

Online registration with the HPRA gives user organisations access to their registration details which can be amended online.

Section 6 of this document provides instructions on how to complete the online registration form with further information available in the 'Guide to the Online Registration System for Medical Devices'.

The HPRA also accepts paper-based applications for registration which must be made on the form for the 'Registration of Persons Responsible for Placing *In vitro* Diagnostic Medical Devices on the Market in Accordance with Directive 98/97/EC and S.I. No. 304 of 2001'. This form can be downloaded from 'Publications and Forms' section of www.hpra.ie. Please see section 7 for instructions on how to complete the application form.

The relevant fee should be included for both paper-based and online applications. The registration fees and payment methods are outlined in the 'Guide to Fees for Human Products' and the 'Fee Application Form for Human Products' available on the 'Publications and Forms' section of www.hpra.ie. The fee application form must also be completed and included with every application.

All applications (including the supporting data) must be in English. All applications must be submitted with either the signed declaration (manual applications) or the signed conditions of use (online applications). Additionally, if you are registering as an authorised representative, you must provide evidence of designation by the manufacturer; this is generally in the form of a notarised letter of designation.

If you are a previously registered organisation making a manual application to add to, withdraw from, or amend your registration, you must quote your organisation registration number, and if applicable, the device registration number(s) on the registration form where indicated. These numbers are unique to both your organisation and device(s).

6 INSTRUCTIONS ON HOW TO FILL IN THE ONLINE APPLICATION FORM

Applications to register your organisation can be made online through the HPRA website. Please see the Medical Devices/Regulatory Information section of www.hpra.ie.

Before you can register a device, you must first register your organisation. Once your organisation registration has been approved and payment has been received along with all relevant documentation, you will be issued with a username and password which will allow you to access the registration extranet where you can add new devices or add/amend previously registered devices. For guidance on online device registrations, please see the 'Guide to the Online Registration System for Medical Devices'.

The initial set-up fee covers your first year of use. Thereafter, an annual maintenance fee must be paid for continued access, the cost of which is dependent on the size of your organisation. The registration costs are outlined in the 'Guide to Fees for Human Products' and the 'Fee Application Form for Human Products'.

6.1 Step 1 Organisation details

Register as an in vitro diagnostic medical device organisation. Next, select 'IVD industry' for organisation type and then complete the organisation size, date of notification, and the status of your organisation.

All fields must be completed before proceeding to step 2. If any field is left blank, you will not be able to proceed to step 2. The page will refresh with the missing fields highlighted in red.

6.2 Step 2 Contact details

You will be asked to provide certain contact details depending on the status of your organisation. Authorised representatives are required to provide both their contact details and those of the manufacturer. All others (assemblers, legal manufacturers and manufacturers) need only submit their own contact details.

All fields must be completed before proceeding to step 3. If any field is left blank, you will not be able to proceed to step 3. The page will refresh with the missing fields highlighted in red.

6.3 Step 3 Conditions of use

Before submitting your registration details, you must review your details for accuracy by clicking the 'Review the details you have entered' tab. If at this point you notice any inaccuracies you must start the process again. If all details are correct select the 'print the terms and conditions for signing' tab; a new pop-up window will appear containing the conditions of use which must be printed and signed. The conditions of use should be read and clearly understood before signing. After signing the conditions of use, select the 'submit the form' tab. A confirmation message will appear confirming that you have successfully submitted your application.

7 INSTRUCTIONS ON HOW TO FILL IN THE MANUAL APPLICATION FORM

The application form for the 'Registration of Persons Responsible for Placing In vitro Diagnostic Medical Devices on the Market in Accordance with Directive 98/97/EC and S.I. No. 304 of 2001' is divided into three parts as follows:

- Part 1 Organisation details
- Part 2 Device registration details
- Part 3 Declaration

7.1 Part 1 Organisation details

This part of the form is divided into four sections and deals with the details of your organisation and the type of registration application you wish to make.

Please ensure that both the date of notification and payment details have been completed.

7.1.1 Section A1 Registration status

In this section, identify the registration status of your organisation:

- if you have not registered your organisation with the HPRA before, tick the box 'First registration of organisation' and complete section A2.
- if your organisation has been previously registered and you wish to add to, withdraw from, or amend your registration, tick this box 'Previously registered organisation', provide your organisation registration number and complete section A3.

7.1.2 Section A2 New organisation details

In this section, provide new organisation details:

- Organisation type
- Number of employees in your organisation

- Status of your organisation i.e. manufacturer, assembler, authorised representative, or importer. If registering as a manufacturer or assembler, please complete section B. For all others, please complete both sections B and C.

7.1.3 Section A3 Previously registered organisation

In this section, please select the applicable statement from the following:
- Amend organisation size (amend appropriate part of section A2)
- Change contact details (amend section B and / or C with new details)
- Add/amend/withdraw devices (complete section D)
- Withdraw organisation and all registered devices
- Apply for online registration access (complete section A4)

7.1.4 Section A4 Apply for online registration access

If you are currently registered manually and wish to change to the online system, please read and sign the conditions of use. On receipt of your signed application form you will receive a password and user ID via the e-mail address supplied. Please note that changes to online registration may alter the fee structure under which you are currently charged; for further information please refer to the 'Guide to Fees for Human Products', available on the 'Publications and Forms' section of www.hpra.ie.

7.1.5 Section B Identification of the manufacturer

Provide the manufacturer's name and address as it appears on the device label, outer packaging or the instructions for use. Contact details for the manufacturer should also be provided (phone, e-mail etc.).

7.1.6 Section C Identification of the representative

Provide the representative's name and address as it appears on the device label, outer packaging, or the instruction for use. Contact details for the representative should also be provided (phone, e-mail etc.).

7.2 Part 2 Device registration details

This part of the form is for recording the device registration details. A maximum of ten device registrations can be made per application with each individual device registration requiring Section D to be completed. Therefore, Part 2 may be photocopied up to a maximum of ten times. If you wish to make more than ten registrations, additional application forms are required which also incur additional registration fees.

7.2.1 Section D1 Registration type

This section identifies if you wish to register a new device, withdraw a device or amend a previously registered device.

New IVD registrations require sections D2, D3, D4, D5 and D6 (if applicable) to be fully completed.

To withdraw an IVD, please provide the device registration number in the space provided, no other device details are required.

To make an amendment to a previously registered IVD, please provide the device registration number in the space provided and also the amended information in sections D2 to D6 as appropriate. There is no requirement to complete sections which are unchanged.

7.2.2 Section D2 Classification of the concerned device

The Directive groups IVDs into four categories according to the risk associated with the relative dangers to the public and/or patient treatment by an IVD failing to perform as intended. Tick the classification of your device.

7.2.3 Section D3 Device status

Please indicate the most appropriate device status for your product by ticking only one of the following:

- New product:
  A device is considered 'new' if 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 the procedure involves analytical technology not continuously used on the Community market during the previous three years.

- Performance evaluation:
  If you are registering because you intend to subject the device to one or more performance evaluation studies in laboratories for medical analyses or in other appropriate environments outside your own premises, tick this box. Devices for performance evaluation will not carry a CE mark.

- Neither performance evaluation nor new product:
  If the device you are registering is not a new device or for performance evaluation, tick this box.

7.2.4 Section D4 Nomenclature

The Global Medical Device Nomenclature (GMDN) is an international standardised, controlled nomenclature to accurately describe and catalogue medical devices including IVDs. It is a widely-accepted nomenclature system and provides a standard vocabulary for medical devices in support of the Medical Devices Directive. The HPRA requests that applicants provide an appropriate GMDN code for all devices they wish to register.

If you do not have an appropriate code, please contact the GMDN Agency to request the code. If no GMDN code exists for your device, please submit a proposal for a new GMDN code for your device to the GMDN Agency. Further details can be found on the GMDN Agency website.

You may also use another internationally recognised nomenclature rather than the GMDN.

Please note that since 1 May 2011, device registration applications are only approved by the HPRA once an appropriate GMDN, or other internationally recognised nomenclature code has been provided.

7.2.5 Section D5 Additional device details

The 'Generic Name' or 'Name Make' must be provided. The 'Generic Name' refers to the generic name of the device as assigned by the manufacturer. 'Name Make' refers to the brand name (trademark) under which the medical device is marketed.

An alternative brand name under which the medical device is also marketed may also be provided in the 'Alternative Name-Make' field.

7.2.6 Section D6 Additional information for Annex II and self-testing devices

The following information is required for Annex II and self-testing devices.

- Model: the reference of the device model as assigned by the manufacturer
- Conformity checked by Notified Body: tick this box if a notified body has assessed the device.
- Notified Body identification: each notified body is assigned a unique identification code. Indicate the identification code for the notified body you used to carry out the assessment.
- Conformity with Common Technical Specifications: this only applies to Annex II List A devices. Tick this box if you conform to the Common Technical Specifications. If you do not conform, attach details on how the manufacturer demonstrates compliance with the Essential Requirements to your application form.
- Outcome of performance evaluation.

7.3 Part 3 Declaration

The final part of this form deals with the declaration of conformity with the requirements of the EU Directive and Irish legislation. If you are registering as an authorised representative, please ensure that you have provided evidence that you have been designated by the authorised representative and tick the confirmation box.

A space has also been provided in the footer of each page of the form for pagination. Please indicate the number of pages which comprise the notification and paginate each page in the footer e.g. 1 of 3, 2 of 3 and 3 of 3 so we can verify receipt of your full application.

Please also ensure that all text fields have been completed.

All registration forms must have Part 3 completed to be considered as a valid notification.

8 DOCUMENTATION TO BE SUBMITTED

Additional documentation that needs to accompany your application includes:

- Notarised letter of designation from the manufacturer if you are the authorised representative making the application on behalf of a manufacturer
- Signed terms and conditions if registering online
- Completed fee application form

9 DOCUMENTATION TO BE KEPT AVAILABLE FOR REVIEW BY THE COMPETENT AUTHORITY

The Directive and S.I. requires manufacturers to keep the following documentation available:

General IVDs	
Documentation	EC Declaration of conformity and technical documentation
Reference	Directive 98/79/EC Article 9(1) and Annex III (excl. section 6) S.I. No. 304 of 2001 Regulation 7(1)

A declaration of conformity with the provisions of the Directive and documentation supporting compliance with the applicable essential requirements of the Directive should be available for review by the Competent Authority.

Self-testing IVDs not covered in Annex II	
Documentation	EC Declaration of conformity, technical documentation, EC design-examination certificate
Reference	Directive 98/79/EC Article 9(1) and Annex III (incl. section 6) S.I. No. 304 of 2001 Regulation 7(2)

Self-testing IVDs not covered in Annex II. Prior to making a declaration of conformity with the provision of the Directive, as for General IVDs above, the manufacturer must lodge an application with a notified body for the examination of the design of the product. The examination of the device will include aspects affecting its suitability for non-professional users.

Annex II List A		
Documentation	1	EC declaration of conformity, design dossier, EC design-examination certificate
		or
	2	EC declaration of conformity, EC type-examination certificate, technical documentation
Reference	3	Directive 98/79/EC Article 9-2(a) and Annex IV S.I. No. 304 of 2001 Regulation 7-(3)a
		or
	4	Directive 98/79/EC Article 9-2(b), Annex V and Annex VII S.I. No. 304 of 2001 Regulation 7-(3)b

Annex II and Self-testing IVDs
The manufacturer has to keep available the:

- Data relating to analytical and where appropriate diagnostic parameters as referred to in Section 3 of Part A of Annex I
- Labelling and instruction for use
- Outcome of performance evaluation pursuant to Annex VIII
- Relevant certificates

There is no requirement to supply any of these documents when registering, however these may be inspected at any time by the Competent Authority for a period of at least five years after the last product has been manufactured.

10 PROCESS FOR REVIEW AT THE HPRA AND GROUNDS FOR ACCEPTANCE / REFUSAL OF AN APPLICATION

Application forms are reviewed by the HPRA on receipt to ensure that applications are complete with all relevant signatures, and that documentation and payment have been included.

An application for registration is subject to an administrative review to ensure that the organisation being registered is based within the Member State.

A formal technical or regulatory review is not conducted at the time of registration as the application is reliant on the declaration of the manufacturer/organisation of compliance with the relevant requirements of the devices Directives. In some circumstances at the time of application, the HPRA may request further information relating to the organisation or devices subject to the application. If the products or organisations are deemed by the HPRA not to meet the requirements for registration, they may be withdrawn or refused.

In-vitro diagnostic medical devices registered with the HPRA are subject to ongoing post-market surveillance, with registered organisations subject to a post-market surveillance audit and technical file review.

For a number of products, it may not be clear if they are *in-vitro* diagnostic medical devices or not. If you have any queries in relation to classification, please refer to the Directive and relevant HPRA guides.

If you require clarification, please contact the HPRA at the following address:
Human Products Authorisation and Registration
Health Products Regulatory Authority
Earlsfort Centre
Earlsfort Terrace
Dublin 2
Telephone: +353-1-676 4971
Fax: +353- 1-676 7836
E-mail: deviceregister@hpra.ie

Information is also available from the HPRA website at www.hpra.ie