HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Guide for
Registration of Persons Responsible for Placing 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 medical device organisations and their associated devices.

2 INTRODUCTION

The purpose of this guide is to outline the requirements in relation to registration of medical devices as required by both the Medical Device Directive 93/42/EEC and the Active Implantable Medical Device Directive 90/385/EEC, 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 (AIMDD)
(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 Medical Devices Directives 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 class I or custom made medical devices and place them on the market under your own name, or trading name(s),
- manufacture custom made active implantable medical devices and place them on the market under your own name, or trading name(s),
- fully refurbish class I devices, or label one or more ready-made devices, with a view to placing these on the market under your own name,

- place medical devices bearing the CE marking on the market, under your own name in a system or a procedure pack,
- sterilise, for the purpose of placing on the market under your own name, systems or procedure packs or other CE marked medical devices designed by the manufacturers to be sterilised before use, or
- are the designated authorised representative of a manufacturer.

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.

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 fill in 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' on the 'Publications and Forms' section of www.hpra.ie. The 'fee application form' must also be completed and included in 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). Organisations previously registered with paper-based applications can apply to the HPRA to amend their details from manual to online registrants.

6 INSTRUCTIONS ON HOW TO FILL IN THE ON-LINE APPLICATION FORM

Applications to register an 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, payment has been received and all other relevant documentation has been received, you will be issued with a username and password. These details will allow you access to the registration extranet where you can add new devices or add/amend 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 a medical device organisation. Next, indicate your organisation type, organisation size, date of notification, and the status of your organisation. If you indicate your organisation type as a general medical device organisation you will also be asked to confirm if you sterilise devices (for which you are not the manufacturer) but place them on the market under your own name.

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 terms and 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 Medical Devices on the Market in Accordance with Directive 93/42/EEC and S.I. No. 252 of 1994' 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 you identify the registration status of your organisation:

- if you have not registered your organisation with the HPRA before; tick '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 'Previously registered organisation', provide your organisation registration number and complete section A3.

7.1.2 Section A2 New organisation details

In this section new organisation details are provided to include:

- Organisation type

- Indication if you sterilise devices for which you are not the manufacturer but place on the market under your own name. Please note that if you sterilise CE marked devices on behalf of manufacturers and do not place them on the market under your own name there is no requirement to register.
- Number of employees in your organisation
- Status of your organisation i.e. manufacturer, legal manufacturer, assembler, authorised representative, or importer. If registering as manufacturer, legal manufacturer, or assembler please fill in section B, for all others please fill in both sections B and C.

7.1.3 Section A3 Previously registered organisation

In this section previously registered organisations please select 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 A3 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; please refer to the 'Guide to Fees for Human Products' and the 'Fee Application Form for Human Products' for further information.

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 authorised representative

Provide the authorised 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 10 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 or amend a previously registered device.

New device registrations require sections D2, D3, D4, and D5 to be fully completed.

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

To make an amendment to a previously registered device please provide the device registration number in the space provided and also the amended information in sections D2 to D5 as appropriate. There is no requirement to complete sections which are unchanged.

7.2.2 Section D2 Classification of the concerned device

In this section you identify under which Article of the Directive and S.I. you are registering your device. Please tick the relevant box.

	93/42/EEC	**S.I. No. 252 of 1994**
Class I devices	Article 11(5)	Article 7
Custom-made devices	Article 11(6)	Article 15
System or procedure packs	Article 12	Article 11
Other medical devices	This category is reserved for sterilisation companies who may in addition to the above classes of devices, sterilise other CE marked devices for placing on the market under their own name	

	90/385/EEC	**S.I. No. 253 of 1994**
Custom-made active implantable devices	Article 9(2)	Article 9(1)

7.2.3 Section D3 Device category code

This is the broadest level of the Global Medical Device Nomenclature (GMDN) system. It currently consists of 16 categories representing a basic breakdown of the medical device market. The device to be registered should be assigned to one category to which it is best suited. Non-active implantable devices are not relevant to this application.

01	Active implantable devices
02	Anaesthetic and respiratory devices
03	Dental devices
04	Electro-mechanical medical devices
05	Hospital hardware
06	*In-vitro* diagnostic devices*
07	Non-active implantable devices
08	Ophthalmic and optical devices
09	Reusable devices
10	Single use devices
11	Assistive products for persons with disability
12	Diagnostic and therapeutic radiation devices
13	Complementary therapy devices
14	Biologically-derived devices
15	Healthcare facility products and adaptations
16	Laboratory equipment

* Please note that device category 06 is greyed out on the application form and should not be ticked as there is a separate registration form and guide for *in-vitro* diagnostic devices.

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 and other healthcare products. 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 we ask that you contact the GMDN Agency to request the code. If no GMDN code exists for your device we ask that you 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 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

It is a requirement to have class I general medical devices which are sterile and/or have a measuring function assessed by a Notified Body as per Annex VII of 93/42/EEC. If the device is sterile and/or has a measuring function, tick the box and indicate in the space provided, the identification number of the Notified Body who carried out the conformity assessment on the device.

If you manufacture a custom made device, which is sterile and/or has a measuring function, please tick the relevant box and indicate Notified Body Number as N/A (not applicable).
The 'Generic Name' or 'Name Make' must be provided also. 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.

7.3 Part 3 Declaration

The final part of this form deals with the declaration of conformity with the requirements of the EU Directive and Irish Regulations.

Please ensure that you confirm which class of device you are registering (Class I, custom-made, system and procedure pack, other) by ticking the appropriate box.

If you are registering as an authorised representative please ensure that you have provided evidence that you have been designated by the manufacturer 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 that the receipt of your full application can be verified.

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 'conditions of use' 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:

Class I	
Documentation	EC declaration of conformity and technical documentation
Reference	Directive 93/42/EEC: Article 11(5) and Annex VII part 3 S.I. No. 252 of 1994: Article 7 and Schedule 7

Custom-made general medical device	
Documentation	A statement and documentation allowing an understanding of the design
Reference	Directive 93/42/EEC: Article 11(6) and Annex VIII S.I. No. 252 of 1994: Article 15 and Schedule 8

System or Procedure Packs	
Documentation	EC declaration of conformity and technical documentation
Reference	Directive 93/42/EEC: Article 12 S.I. No. 252 of 1994: Article 11

Custom-made Active Implantable	
Documentation	A statement and documentation allowing an understanding of the design
Reference	Directive 90/385/EEC: Article 9(2) and Annex 6 S.I. No. 254 of 1994: Article (9)1 and Schedule 6

There is no requirement to supply any of these documents when registering. However, these documents must be completed prior to placing medical devices on the market or putting them into service. Furthermore, these documents may be required for inspection at any time by the Competent Authority for a period of at least five years (for devices covered by 93/42/EEC) and 15 years (for devices covered by 90/385/EEC) from the date of manufacture of the last product.

10 THE PROCESS FOR REVIEW AT THE HPRA AND GROUNDS FOR ACCEPTANCE / REJECTION 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/regulatory review is not conducted at the time of registration, as the application is reliant on the declaration from the manufacturer/organisation, of their 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.

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 medical devices or not. If you have any queries in relation to classification, please reference the Directive and related Irish Statutory Instrument. The 'MEDDEV Guideline on Classification of Medical Devices' together with the 'MEDDEV Guideline on Borderline products, drug-delivery products and medical devices incorporating, as an integral part, an ancillary medicinal substance or an ancillary human blood derivative' should also be consulted. These can be viewed through the European Commission website.

If you require clarification, please contact the HPRA at the following address:
Human Products Authorisation and Registration
Health Products Regulatory Authority
Kevin O'Malley House,
Earlsfort Centre
Earlsfort Terrace
Dublin 2
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Information is also available from the HPRA website at www.hpra.ie.