HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

# Guide to
# Applications for Certificates of Free Sale for Medical Devices

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

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## 1 INTRODUCTION

Certificates of free sale are documents used in the registration or renewal of the registration of device products in third countries (i.e. countries outside the European Economic Area) or to accompany a shipment of that product.

## 2 BACKGROUND

An applicant may submit requests for certificates of free sale for export purposes for the following types of medical devices:

- General medical device(s)
- Active implantable medical device(s)
- *In-vitro* diagnostic medical device(s)

Each certificate is issued in respect of a specified medical device product or products. The content of each certificate varies depending on whether the devices are CE marked or non-CE marked and whether the applicant is a manufacturer, authorised representative or legal manufacturer.

The HPRA can only issue a certificate of free sale:
- Where proof of manufacture for the products concerned is provided.
- If the manufacturer is certified to manufacture products with a CE mark, where applicable.
- If the physical site of manufacture, authorised representative or legal manufacturer is located in Ireland.
- In the case of a product which does not bear a CE mark, these must be manufactured in Ireland.

## 3 MAKING AN APPLICATION

The applicant must complete the 'Application for Certificates of Free Sale' form to apply for a certificate. This form can be downloaded from the 'Publications and Forms' section of www.hpra.ie or alternatively is available from the Compliance Department of the HPRA. The application form must be typed, not handwritten. The applicant must email the completed form to exportcerts@hpra.ie. If the legal manufacturer details are to be included on the certificate, this must be requested in the email.

If a request for a certificate of free sale is made which is the same as a previous certificate of free sale issued by HPRA, the HPRA requires the certificate number of the previously issued certificate of free sale, along with the payment and the number of copies required (see Section 4, sub-section 4.4, part iii).

This certificate number can be found on the bottom left corner of a certificate of free sale. Applicants should also submit their current notified body certificates or applicable HPRA registration numbers. The HPRA will then issue a new certificate based on this certificate number.

All application forms and supporting documentation for a certificate of free sale must be in English. The HPRA will send the certificate of free sale to the Irish-based organisation stated on the application form. If the issued certificates are to be sent to a different location, the postal details must be included in the original email.

There is a page limit of 30 pages for the application form for a certificate of free sale. An application which exceeds this limit will not be accepted.

## 4 INSTRUCTIONS ON HOW TO FILL IN THE APPLICATION FORM

The 'Application for Certificate of Free Sale' form has six sections. **The applicant must fill in all the sections unless instructed differently as outlined below**. The sections of the form are as follows:

Section A: Application details
Section B: Identification of the manufacturer
Section C: Identification of the authorised representative
Section D: Service required (the urgent service is no longer available so only standard service is applicable at this time)
Section E: Certificate details
Section F: Device details

### 4.1 Section A – Application Details

Section A has the following three parts:

Part (i): Date of application

This is the date when the applicant applies for the certificate of free sale.

Part (ii): Status of organisation making the application

This section indicates if the organisation making the request is a manufacturer or an authorised representative.

- If a manufacturer is making the request, tick this box and complete Section B only.
- If the organisation making the request is an authorised representative, tick this box and complete Sections B and C.

Part (iii): Payment details

This indicates which type of payment is to be used for the certificates of free sale, e.g. if paying by cheque, then tick this box. Please refer to the 'Guide to Fees' and the 'Fee Application Form', available on the 'Publications and Forms' section of www.hpra.ie, for more information regarding payment. The HPRA accepts payment by cheque, bank draft, bank transfer or by via credit on account.

### 4.2 Section B – Identification of the manufacturer (site of manufacture)

Section B must be completed. Only state the details of the manufacturer (site of manufacture) in this section. The legal manufacturer's details *(see note below)* must **not** be entered in Section B. The manufacturer details provided will appear on the Certificate of Free Sale.

### 4.3 Section C – Identification of authorised representative

Section C must be completed if the authorised representative details are required to appear on the certificate of free sale.

**Note: if an applicant requires the legal manufacturer's details to appear on a certificate of free sale, they must state the full name and address of the legal manufacturer in the email accompanying the application.**

### 4.4 Section D – Service requested

Section D has three parts.

Part (i): Standard service

- Please tick this box. A standard service is when the certificate of free sale is issued within the standard processing timeframe from receipt of the application form in the HPRA. **Please note that the timeline only starts once all the correct information, documentation and payment have been received**.

Part (ii): Number of copies required

The number of copies required should be stated in the box provided. A minimum of four copies of a certificate of free sale is issued for each request. Additional copies of the certificate are available at the time of the initial request at an extra cost. Additional copies which are requested after the initial request must be applied for by way of a new application and will be charged accordingly.

Part (iii): Delivery of a certificate of free sale

The HPRA uses standard surface mail for delivery of all certificates unless otherwise requested. If an applicant wishes to organise a courier to collect the certificates of free sale at their **own expense** from the HPRA, they must indicate this by ticking the box. The applicant will be contacted once the certificates are completed to arrange a courier. If the box is not ticked, standard mail will be used.

### 4.5 Section E – Certificate details

This section of the form deals with the information to be included in the certificates of free sale. It consists of two parts:

Part (i): Certificate of free sale type

This indicates which type of device is to be included in the certificate of free sale. The types of the medical devices are:

- General medical devices
- Active implantable medical devices
- *In-vitro* diagnostic medical devices

Part (ii): CE mark on device(s)

If there is a CE mark on the device(s) to be included in the certificate of free sale, tick the box 'Yes'. The applicant should attach the following:

- Proof of manufacture in the form of a declaration of conformity and/or manufacturers statement *(see note below*)* including the product listing, **and**

- A copy of a current notified body certificate *(see note below**)* for the relevant device(s), or the HPRA device registration number.

If there is no CE mark on the device(s) to be included in the certificate of free sale, tick the box 'No'. The applicant should submit the following to the HPRA:

- Proof of manufacture in the form of a manufacturers statement *(see note below*)* including the product listing.

Please note that a combination of CE marked products and non-CE marked products cannot be requested on the same application.

*Declaration of conformity and/or manufacturers statement

When an organisation makes a request for a certificate of free sale, proof of manufacture must accompany the application. A manufacturer's statement showing the physical site of manufacture is acceptable provided it also includes the following information:

- Name and address of the manufacturer, authorised representative (if applicable) and legal manufacturer (if applicable)
- Product Class
- List of devices concerned by item number/product code and description, which should appear as follows:
  - Product Code 1 Description 1
  - Product Code 2 Description 2
  - Product Code 3 Description 3
  - Product Code 4 Description 4

A declaration of conformity may also be used as proof of manufacture provided the information above is also included in the application documentation. A designated representative within your organisation should notify the HPRA of any changes to this listing such as the addition and withdrawal of a device(s). These changes must be submitted to the HPRA by post/email on the organisation's letterhead paper and signed by the designated representative.

**Notified body certificate

When an organisation makes the first request for a certificate of free sale, a copy of a current notified body certificate for the relevant device(s) must accompany the application. The organisation should forward updated versions of the current notified body certificates or new notified body certificates for new devices to the HPRA. This document must list the sites of manufacture and the address of the relevant European authorised representative. Design Examination Certificates for Class III devices must also be attached if applicable. These certificates must have at least six months' validity remaining after submission.

These certificates should routinely be included in electronic format in future applications noting the expiry date and relevance to the products listed in the application.

Please note that the notified body certificates for quality management systems (ISO) are not sufficient.

The HPRA device registration number for the product(s) which are to appear on the certificate of free sale must be stated, if the applicant manufactures any of the following devices:

- Class 1 devices
- Custom-made devices
- Systems and procedure packs
- Other medical devices (This category is reserved for sterilisation companies who may in addition to the above categories of device sterilise other CE-marked devices for placing on the market under their own name.)

Applications for Class I devices pending registration must not be submitted.

### 4.6 Section F – Device details

This consists of one part only. The application will not be accepted if this section is incomplete. The HPRA will not accept separate documents attached to the email with the product codes and descriptions. If the HPRA does not accept an application, the organisation will be contacted. The maximum size of an application cannot exceed 30 pages in total and product descriptions should ideally be kept to a single line of text.

Part (i): List of medical devices included on the certificate of free sale

Please note that only one type of medical device can appear on a certificate of free sale, e.g. either general medical devices or active implantable medical devices or in-vitro diagnostic medical devices. Further to this, a combination of CE marked devices and non-CE marked devices cannot appear on the certificate of free sale. In these cases, a separate application must be made and the HPRA will issue a separate certificate.

The applicant must fill in the item/product number and a brief description for each device which is to be included on the certificate. If there is more than one item/product number per description, the description should be repeated for each item/product number. For example: if there are four product codes to one description, it should be stated as follows:

- Product Code 1 Description 1
- Product Code 2 Description 1
- Product Code 3 Description 1
- Product Code 4 Description 1

## 5 DOCUMENTATION TO BE SUBMITTED

Please refer to the checklist in appendix 1.

Additionally, applicants may be required to submit the following upon request:

- Copies of the label, packaging and instructions of use (in all languages requested by the countries where the device is marketed).
- If applicable, the MDD agreement/contract between the manufacturer and European authorised representative which should include reference to responsibility for post market surveillance process and data, vigilance reports and complaints, processes and data.

## 6 THE PROCESS FOR REVIEW AT THE HPRA

Application forms are reviewed by the HPRA on receipt to ensure that all the information required has been provided and that the fee has been paid. If all the required information and documentation has not been received and/or the fee has not been paid, the applicant will be requested to provide the missing information/ documentation and/or fee. The application will be put on hold until all the relevant information/documentation and/or fee is received. Applications which have been on hold for one month and where the requested information/documentation or fee has not been received shall be deemed to be invalid and shall be returned to the applicant.

## 7 DURATION OF VALIDITY OF THE CERTIFICATE

Certificates of free sale have a validity period of five years from date of issue. Note that where a certificate of free sale has been issued and device registration is not continued for whatever reason, the potential remains for the free sale certificate to be used in non-EU markets up to its expiry date. It is the responsibility of the organisation to which the certificate is issued to have a system in place to withdraw certificates which list such devices from circulation.

## 8 CONTACT DETAILS

For general enquiries regarding applications for certificates of free sale, please contact:

Compliance Department
Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2
D02 XP77

Telephone: +353-1-6764971
Fax: +353-1-6344033
Email: exportcerts@hpra.ie

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

## APPENDIX 1 CERTIFICATE OF FREE SALE CHECKLIST

| What needs to be submitted to the HPRA | | | Completed |
|---|---|---|---|
| 1. | a) | Complete relevant sections of the application form and send by email to exportcerts@hpra.ie<br>or | ☐ |
| | b) | If requesting a certificate of free sale that has already been issued, please notify the HPRA of the certificate number and a new certificate will be issued based on this number | ☐ |
| 2. | | Ensure only one type of device is specified on the application form, e.g. GMD, AIMD or IVD | ☐ |
| 3. | | Ensure that there is not a combination of CE marked or non-CE marked products specified on the application form | ☐ |
| 4. | | Ensure that payment accompanies the application form (e.g. cheque, bank draft/transfer) or has been paid in advance (credit on account) (see 'Guide to Fees' and the 'Fee Application Form' for more details) | ☐ |
| 5. | | For CE marked products: | |
| | a) | Send a copy of the notified body certificates for all CE marked products to the HPRA<br>or | ☐ |
| | b) | Inform the HPRA of the device registration number if the device is registered with the HPRA | ☐ |
| 6. | | Ensure that the application form is under 30 pages | ☐ |
| 7. | | Copy of the Companies Registration Office (CRO) certificate issued to the company | ☐ |
| 8. | | Declaration of conformity or proof of manufacture listing the devices concerned by item/product code and description along with the physical site of manufacture | ☐ |
| 9. | | Ensure all documents are in English | ☐ |