HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Guide to
Applications for Certificates of Free Sale for Medical Devices

AUT-G0026-12
20 DECEMBER 2022
This guide does not purport to be an interpretation of law and/or regulations and is for guidance purposes only.

CONTENTS

1 INTRODUCTION

Certificates of free sale are documents used in the registration of devices in third countries (i.e. countries outside the European Economic Area). They indicate that the devices listed are eligible for sale in the EU market.

2 BACKGROUND

The legislation

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

- Medical devices, including active implantable medical devices
- *In vitro* diagnostic medical devices

The Health Products Regulatory Authority (HPRA) currently issues certificates of free sale under two legal frameworks:

1. The IMB Act which covers devices compliant with the following legislation:
   - Directive 90/385/EEC on active implantable medical devices (AIMDD)
   - Directive 93/42/EEC concerning medical devices (MDD)
   - Directive 98/79/EC on *in vitro* diagnostic medical devices (IVDD)
   - Regulation 2017/745 on medical devices (MDR), specifically for system and procedure packs
   - Medical devices that fall under the MDR transitional provisions (MDR Article 120 (3))
   - *In vitro* diagnostic medical devices that fall under the IVDR transitional provisions (IVDR Article 120(3) and amending Regulation 2022/112)

2. The Medical Devices Regulations which covers medical devices compliant with:
   - Regulation (EU) 2017/745 on medical devices (MDR), as amended
   - Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (IVDR), as amended

It should be noted that while the process for issuing certificates of free sale under each legal framework is similar, each legal framework has a specific application form.

Note: The appropriate legal basis for issuing the certificate of free sale is dependent on the conformity assessment provisions under which the device is originally CE marked, e.g. devices in conformance with the Directives will have a certificate of free sale issued under the IMB Act. Devices in conformity with the MDR/IVDR will have a certificate of free sale issued under the Regulations.

Who can request a certificate of free sale?

Under the framework of the Directives a manufacturer (as defined in the legislation), an authorised representative, system and procedure pack producer or a manufacturing facility which is established in Ireland can apply for a certificate of free sale.

However, under the framework of the Regulations, only manufacturers (as defined in the legislation), or authorised representatives can apply for a certificate of free sale under Article 60 MDR / Article 55 IVDR of the regulations, and they must also be resident in Ireland.
System and procedure pack producers that produce system and procedure packs (SPPs) that are in compliance with the Regulation, can apply to the HPRA for a certificate of free sale; however, this certificate will be issued under the IMB Act, not Article 60 of the MDR.

The following definitions apply:

manufacturer, in the context of medical devices,

a. means-
   i. a person who is responsible for the design, manufacture, packaging and labelling of a medical device before it is placed on the market under his or her own name, regardless of whether these operations are carried out by that person himself or herself or on his or her behalf by a third party, or
   ii. a person who assembles, packages, processes, fully refurbishes or labels one or more ready-made products or assigns to them their intended purpose as a medical device with a view to their being placed on the market under his or her own name, but not including a person who assembles or adapts medical devices already on the market to their intended purpose for an individual patient, or
b. has the meaning assigned to it by-
   i. Article 2(30) of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017, or
   ii. Article 2(23) of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017;

authorised representative

a. means a person established within the European Economic Area who, explicitly designated by the manufacturer, acts for the manufacturer and may be addressed by authorities and bodies in the European Economic Area instead of the manufacturer with respect to the European Communities (Medical Devices) Regulations 1994 (S.I. No. 252 of 1994), the European Communities (Active Implantable Medical Devices) Regulations 1994 (S.I. No. 253 of 2004), or the European Communities (In Vitro Diagnostic Medical Devices) Regulations 2001 (S.I. No. 304 of 2001),
b. has the meaning assigned to it by Article 2(32) of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017,

c. has the meaning assigned to it by Article 2(25) of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017,

manufacturing facility, means a place where an entity, which does not place medical devices on the market under its own name or under its own trademark

a. manufactures a medical device, or
b. manufactures one or more critical components of a medical device to a set of specifications, or
c. carries out packaging activities in relation to a medical device, or
d. carries out labelling activities in relation to a medical device

System and procedure pack producer is the natural or legal person that combines medical devices bearing a CE marking alone or together with other products which are not devices and are compliant with the respective legislation which apply to them, in order to place that combination on the market as either a system or a procedure pack.

Note: Under the Regulation, the HPRA cannot issue a certificate of free sale for manufacturing facilities; however, a letter confirming a site of manufacture can be provided. Such letters can be requested via email from devices@hpra.ie.

Certificate

Each certificate is issued in respect of a specified medical device or devices. The content of each certificate varies depending on the legislative framework and the role of the applicant.

The HPRA can only issue a certificate of free sale:

- where a statement of manufacture for the devices concerned is provided.
- if the manufacturer is certified to manufacture products with a CE mark, where applicable.

Certificates of free sale may be provided for a list of devices that have been assessed by different notified bodies or for a mix of notified body-assessed and self-declared products; however, the devices listed must be under the same legal framework (i.e. either the Directives, Regulation or the IMB Act).

Expiry date

The certificate of free sales, under both legislative frameworks, will be provided with a date of issue. No expiry date will be included on the certificate.

Signature

The HPRA will provide a wet signature and a stamp on the certificates of free sale that are issued.

3 MAKING AN APPLICATION

The applicant must complete one of the following forms to apply for a certificate:
- application for certificates for free sale (MDD, medical devices, system and procedure packs, legacy devices)
- application for certificates for free sale (IVDD medical devices, up-classified and legacy devices[1])
- application for certificates of free sale for medical devices, system and procedure packs compliant with MDR
- application for certificates of free sale for *in vitro* diagnostic medical devices compliant with IVDR

These forms can be downloaded from the 'Publications and Forms' section of www.hpra.ie. The application form must be typed, not handwritten. The applicant must email the completed form to devices@hpra.ie.

Application for certificates for free sale (MDD, medical devices, system and procedure packs, legacy devices) form should be used for:
- devices and system and procedure packs and where the declaration of conformity has been drawn up before 26 May 2021 and the devices are placed on the market before 26 May 2021,
- devices that are in conformance with the Medical Device Directives (MDD or AIMDD) and can continue to be placed on the market until 2024 in accordance Article 120(3) of the MDR,
- devices that are in conformance with the Medical Device Directives (MDD or AIMDD) but will be up classified under the MDR.

Application for certificates for free sale (in vitro diagnostic medical devices, up classified and legacy devices) form should be used for:
- *in vitro* diagnostic medical devices where the declaration of conformity has been drawn up before 26 May 2022 and the devices are placed on the market before 26 May 2022,
- devices that are in conformance with the *In vitro* Diagnostic Medical Devices Directive (IVDD) and that can continue to be made available on the market in accordance Article 110 of the IVDR and Regulation 2022-112,
- *In vitro* diagnostic medical devices that are in conformance with the *In vitro* Diagnostic Medical Devices Directive (IVDD) but will be up classified under the IVDR.

Application for certificates for free sale for medical devices, system and procedure packs compliant with MDR form should be used for:
- devices that are in conformance with the Regulation 2017/745 (MDR),

[1] An *in vitro* diagnostic medical device legacy device is an *in vitro* diagnostic medical device that is in compliance with the *in vitro* diagnostic medical device Directive but can remain on the market under Article 120(3) of the Medical Device Regulation.

- system and procedure packs that are in conformance with the MDR.

Application for certificates for free sale for in vitro *diagnostic medical devices complaint with IVDR* form should be used for:
- devices that are in conformance with the Regulation 2017/746 (IVDR).

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 4.5, part (i) of this guide). 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 FORMS

The forms have seven sections each. **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: Identification of the physical site of manufacture
Section E Service required
Section F: Certificate details
Section G: 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 (MDR/IVDR devices) or a manufacturing facility/physical site of manufacture (MDD/IVD devices). (See the definitions earlier in this guidance.)

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 (as defined in the legislation)

Section B must be completed with details of the manufacturer or the system or procedure pack producer.

4.3 Section C – Identification of the authorised representative

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

4.4 Section D – Identification of the physical site of manufacture (as defined in the legislation)

Section D must be completed.

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

4.5 Section E – Service required

Section E has two parts.

Part (i): 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 are 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 are treated as a new application and will be charged accordingly.

Part (ii): Standard mail will be used for delivery of all certificates 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.

4.6 Section F – Certificate details

This section of the form deals with the information to be included in the certificates of free sale. It consists of one part only:

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:

- Directive 93/42/EEC on Medical Devices
- Medical devices that fall under the transitional provisions (MDR Article 120 (3))
- Directive 98/79/EC on *In Vitro* Diagnostic Medical Devices
- *In vitro* diagnostic medical device that fall under the transitional provisions (IVDR Article 120(3) Regulation 2022 112)
- Directive 90/385/EEC on Active Implantable Medical Devices
  OR
- Regulation (EU) 2017/745 on medical devices (MDR)
- Regulation (EU) 2017/746 on *in vitro diagnostic* medical devices (IVDR)
  OR
- IMB Act for MDR compliant system and procedure packs

<u>*Declaration of conformity and/or manufacturer's statement</u>
When an organisation makes a request for a certificate of free sale the following must accompany the application:
Statement of manufacture
A statement must be provided with the following information:

- name, address and Eudamed Single Registration Number (SRN) (where available) of the manufacturer, authorised representative (if applicable) and manufacturing facility/site (if applicable)
- product class
- list of devices concerned by item number/product code and description, which should appear as follows:
  - Product Code 1 Device name 1
  - Product Code 2 Device name 2
  - Product Code 3 Device name 3
  - Product Code 4 Device name 4

In addition to the above, for certificates of free sale that are issued under the Regulations, device details must include the Basic UDI–DI and the product code, the notified body certificate number and the notified body certificate expiry date.

1. Declaration of conformity

A declaration of conformity should be provided as part of the statement of manufacture and should be included in the application documentation.

**Notified body certificate

When an organisation makes a 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. 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 be included in electronic format in future applications noting the expiry date and relevance to the products listed in the application.

***System and procedure packs

When making a request for a certificate of free sale for a system and procedure pack, documentation (including the declaration of conformity for the pack) should be provided that clearly illustrates the legal framework within which the system and procedure pack applies and the legal framework with which the pack components comply.

4.7 Section G – Device details

This consists of one part only and can be submitted as a separate Word or Excel file with the column headings as outlined in the application forms. The application will not be accepted if this section is incomplete. 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.

Please note that only one type of medical device can appear on a certificate of free sale, e.g. medical devices, *in vitro* diagnostic medical devices or system and procedure packs. Certificates of free sale may be provided for a list of devices that have been assessed by different notified bodies or for a mix of notified body assessed and self-declared products; however, the devices listed must be under the same legal framework (i.e. either the Directives or the Regulation).

When making a request for a certificate of free sale for medical devices or *in vitro* diagnostic medical devices that are in conformance with the Medical Device Directives (MDD, AIMD or IVDD) but now fall under Article 120(3) of the MDR or Article 110(3) of the IVDR, or shall be up classified under the MDR/IVDR, the MDD or IVDD application forms should be used and the required details should be entered in the right column of the device listing table.

For example:

Product code	**Device name**	**Notified body ID**	**Notified body certificate number**	**Notified body certificate expiry date**	**HPRA registration number**	**Article 120 (3) Yes/No**
Xxxxx	**Medical device 1**	**n/a**	**n/a**	**n/a**	**IE……**	**No**

Product code	**Device name**	**Notified body ID**	**Notified body certificate number**	**Notified body certificate expiry date**	**HPRA registration number**	**1. Article 110 (3)** **2. Article 110 (4)** **3. Up-classified *IVDs*** - **Up-classified A (sterile)** - **Up-classified B** - **Up-classified C** - **Up-classified D**
Xxxxx	**IVD 1**	**n/a**	**n/a**	**n/a**	**IE……**	**Art 110 (3)**
Xxxxx	**IVD 2**	**n/a**	**n/a**	**n/a**	**IE……**	**Up-classified A (sterile)**
Xxxxx	**IVD 3**	**n/a**	**n/a**	**n/a**	**IE……**	**Up-classified D**
Xxxxx	**IVD 1**	**n/a**	**n/a**	**n/a**	**IE……**	**Art 110 (4)**

The distinction between these and other devices that are in conformance with MDD/IVDR will be noted on the certificate of free sale.

All relevant notified body certificates must be submitted once they are listed in the application form.

5 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 week and where the requested information/documentation or fee has not been received shall be deemed invalid and shall be returned to the applicant.

6 CONTACT DETAILS

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

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

Telephone: +353-1-6764971
Email: devices@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 the relevant application form and send by email to devices@hpra.ie. or	☐
	b)	If requesting a certificate of free sale that has already been issued, provide the HPRA with the certificate number.	☐
2.		Proof of payment (e.g. cheque, bank draft/transfer credit on account) (see 'Guide to Fees' and the 'Fee Application Form' for more details).	☐
3.		For CE marked products:	
	a)	A copy of the notified body certificates for all CE marked products. or	☐
	b)	The HPRA device registration number for MDD and IVDD devices registered with the HPRA.	☐
4.		Ensure that the accompanying Excel or Word file for device details is ≤30 pages.	☐
5.		The declaration of conformity associated with the devices requested to be included on the certificate.	☐
6.		Listing the devices concerned by item/product code and description, along with the physical site of manufacture.	☐
7.		Ensure all documents are in English, or in Irish and English.	☐