Application for Certificates for Free Sale (Medical Device Directives: Medical Devices / System and Procedure Packs / Legacy Devices\*) for Devices Qualifying under Regulation 2023/607

**Certificates of free sale for products in this form will be issued in accordance with the IMB Act 1995 as amended, and not under Article 60 of Regulation 2017/745 on medical devices (MDR).**

\*A legacy device is a medical device that is in compliance with the Medical Devices Directives and can remain on the market under Article 120 of the MDR as amended by Regulation 2023/607.

You are required to submit specific documents to support the claims made in this application form. All applications must be prepaid and proof of payment of the required fee must accompany the application at time of submission. Please submit the completed application form and relevant documents to [devices@hpra.ie](mailto:devices@hpra.ie).

The following documents must be submitted as part of this application:

* A completed version of this application form
* Declaration of conformity
* [Manufacturer self-declaration letter](https://www.medtecheurope.org/resource-library/manufacturers-declaration-in-relation-to-regulation-eu-2023-607/)
* Proof of payment
* Device schedule
* Unless otherwise stated in the declaration of conformity, a letter confirming the physical site of manufacture.

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| Section A: application details |
| i) Date of application: dd/mm/yyyy  ii) Status of organisation making the application:  Manufacturer / System and procedure pack producer (*please fill in Section B, C (if applicable) and Section D*)  Authorised Representative (*please fill in Section B, C and D*)  Physical site of manufacture (*please fill in Section B and C (if applicable) and Section D*)  iii) Payment made by: (*tick one box only*)  Cheque  Bank transfer  Bank draft  Credit on account  Note: Payment or evidence of payment must accompany the application. |

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| SECTION B: IDENTIFICATION OF THE MANUFACTUREr / SYSTEM AND PROCEDURE PACK PRODUCER | |
| Name: |  |
| Address: |  |

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| SECTION C: IDENTIFICATION OF THE authorised representative (if Applicable) | |
| Name: |  |
| Address: |  |

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| SECTION D: IDENTIFICATION OF THE physical site of manufacture | |
| Name: |  |
| Address: |  |

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| SECTION E: SERVICE REQUIRED |
| i) Number of copies required:  Four copies of each certificate will be supplied as standard. Additional copies can be supplied at an extra cost (please refer to the [Guide to Fees for Human Products](https://www.hpra.ie/homepage/about-us/publications-forms/guidance-documents/item?id=3860f925-9782-6eee-9b55-ff00008c97d0&t=/docs/default-source/publications-forms/guidance-documents/fin-g0002-guide-to-fees-for-human-products-v30)). |
| ii) Standard mail will be used for delivery of all certificates of free sale. However, you may organise a courier at your own expense for more urgent receipt of certificates of free sale.  Please tick this box  if you are organising a courier. Otherwise, standard mail will be used. |

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| SECTION F: contact details of the applicant | |
| Name: |  |
| Email address: |  |
| Position: |  |
| Signature: | *E-signature preferable* |

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| SECTION G: Device details  A separate listing of the devices to be stated on the certificate must be provided on an accompanying Word or Excel document, with the required information about the device(s) as set out below. | | | | |
|  | | **For notified body certified devices** | | **For self-declared devices** |
| **Product code** | **Device name** | **Notified body ID** | **Notified body certificate number** | **HPRA registration number** |