Application for Certificates for Free Sale for Medical Devices

The applicant is required to submit specific documents to support the application form. Only information included on the application form and supporting documentation will be reviewed. Data provided outside of the application form and supporting documentation will not be considered. **Please submit one application per email to** [**devicecerts@hpra.ie**](mailto:devicecerts@hpra.ie).

It is the responsibility of the applicant to ensure all information submitted is accurate and complete. Errors noted after issue of a certificate will require a new application to be submitted.

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| SECTION A: APPLICANT DETAILS and DECLARAtion | |
| Applicant name: |  |
| Role/title: |  |
| Email: |  |
| I, **<applicant name>**, on behalf of the **Choose an item.** declare that the information provided in this application form, the device schedule for certificates of free sale and all supporting documentation is current and correct. | |
| Signature and date:  *E-signature preferred* |  |
| *Note: The HPRA reserves the right to refuse issuance of future certificates of free sale to an organisation that has outstanding fees or where the HPRA has been provided with a false declaration, incorrect, invalid or expired documentation for applications.* | |

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| Section B: application details |
| (i) Date of application: **<dd/mm/yyyy>** |
| (ii) Status of organisation making the application:  Manufacturer (*Complete Section C, and fill in Sections D and Section E (if applicable))*  Authorised representative (*Complete Sections C and D, and fill in Section E (if applicable))*  *Note: Only a manufacturer and authorised representative can submit an application. Applications from physical sites of manufacture will not be accepted.* |
| (iii) Payment type *(tick one box only):*  Bank transfer  Credit on account. Please provide your HPRA finance account number from which the fee will be debited:  *Note: Evidence of payment must accompany your application.* |

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| SECTION c: IDENTIFICATION OF THE MANUFACTUREr | |
| Company name, address and country |  |
| SRN: |  |

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| SECTION d: IDENTIFICATION OF THE authorised representative (if Applicable) | |
| Company name, address and country |  |
| SRN: |  |

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| SECTION e: IDENTIFICATION OF THE physical site of manufacture (if Applicable) | |
| Company name, address and country |  |
| Company name, address and country |  |
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| SECTION F: SERVICE REQUIRED |
| Number of copies required:  *Note: 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’, available at* [*www.hpra.ie*](http://www.hpra.ie)*).* |

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| SECTION G: DELIVERY ADDRESS (CERTIFICATES WILL BE SENT TO THIS ADDRESS) | |
| Contact name for delivery: |  |
| Delivery address same as manufacturer address listed in Section C  Delivery address same as authorised representative address listed in Section D | |
| Or provide an alternative company name, address and country for delivery: |  |

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| SECTION h: DELIVERY METHOD |
| *Note: Standard mail will be used for delivery of all certificates of free sale in Ireland unless the applicant wishes to use a courier service.*  *For deliveries outside of Ireland, applicants must arrange a courier for collection of the certificates of free sale.*  *Courier services are at the expense of the applicant. The applicant will be notified when the certificates are ready for collection.* |
| Would you like to arrange a courier to collect these certificates?  Yes  No |

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| SECTION i: Certificate details |
| Certificate of free sale type (*tick one box only*):  **Medical devices**  MDR compliant medical devices  MDD and AIMDD compliant medical devices qualifying under Regulation 2023/607  ***In vitro* diagnostic medical devices (IVDs)**  IVDR compliant IVDs  IVDD compliant IVDs qualifying under Regulation 2024/1860  IVDD compliant IVDs not transitioning to the IVDR  Note: *The applicant* *may only submit an application under one legal framework at a time.* |

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| SECTION j: Device details  A separate listing of the devices to be included on the certificate schedule must be provided on the template ‘Device schedule for certificates of free sale for medical devices AUT-F1074’, with the required supporting documentation for the device(s) specified. A checklist has been provided in Section K below listing the supporting documentation required for the application. |

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| SECTION k: CHECKLIST FOR Supporting documentation requirements  (ALL DOCUMENTATION MUST BE PROVIDED IN ENGLISH) | | |
|  | **Documents required for all devices** | |
|  | Completed application form (AUT-F0124) | |
|  | Completed device schedule (AUT-F1074) | |
|  | Proof of payment | |
|  | *Declaration of Conformity*  Please ensure that the device details provided in the device schedule, AUT-F1074 match the device details on the declaration. | |
|  | *Statement of Manufacture*  Letter stating the address of physical site of manufacture unless provided in the declaration of conformity. | |
|  | **Documents required for devices CE marked under the MDR and IVDR** | **Templates required for devices CE marked under the MDD, AIMDD or IVDD** |
|  | *Notified Body Certificates*  EU quality management system certificate  Where applicable, an EU product certificate (e.g. EU technical documentation assessment certificate, EU type-examination certificate, EU product verification certificate, EU quality assurance certificate)  *Please ensure the notified body certificates have a valid expiry date prior to submitting the application.* | *MD/AIMD*- [Manufacturer’s declaration in relation to Regulation (EU) 2023/607](https://www.medtecheurope.org/resource-library/manufacturers-declaration-in-relation-to-regulation-eu-2023-607/)  *IVD* - [Manufacturer's declaration in relation to Regulation (EU) 2024/1860](https://www.medtecheurope.org/resource-library/manufacturers-declaration-in-relation-to-regulation-eu-2024-1860/) |

Please submit all certificate of free sale applications and queries to [**devicecerts@hpra.ie**](mailto:devicecerts@hpra.ie).