Application for certificates for free sale (IVDD medical devices, up classified and legacy devices\*)

\*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.

Please refer to the ‘*Guide to Applications for Certificates of Free Sale for Medical Devices’* available on the HPRA website at [www.hpra.ie](http://www.hpra.ie/) to ensure that your application is correct and can be validated. 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.

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| Section A: application details |
| i) Date of application:       (Day/Month/Year)ii) Status of organisation making the application: [ ]  Manufacturer (*please fill in section B, C (if applicable) and section D*)[ ]  Authorised Representative (*please fill in sections 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 accountNote: Payment or evidence of payment must accompany your application. |

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| SECTION B: IDENTIFICATION OF THE MANUFACTUREr  |
| 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’*, available at www.hpra.ie). |
| 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: Certificate details |
| Certificate of free sale type:[ ]  *In vitro* diagnostic medical device[ ]  *In vitro* diagnostic medical device that fall under the transitional provisions (IVDR Article 120(3) Regulation 2022 112) Self-declared *in vitro* diagnostic medical devices (other than *in vitro* diagnostic medical device up classified in accordance with the *In vitro* Diagnostic Medical Device Regulation) must have been placed on the market and have a Declaration of Conformity that was drawn up before 26 May 2022 (Article 113(6) IVDR). A declaration to that effect must be provided with the application documentation, otherwise the *in vitro* diagnostic medical device cannot be listed on this application form.  |

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| SECTION G: Device detailsA separate listing of the devices to be stated on the certificate must be provided on an accompanying Excel file or Word document, with the required information about the device(s) as set out below. |
|  | **For notified body certified devices** | **For self-declared devices** | **Transitional provisions / Regulation 2022 -112** |
| **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**
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