Application for Certificates of Free Sale for *in vitro* diagnostic medical devices compliant with IVDR

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. Documents to support the claims made in this application form must be submitted with the application. Incomplete applications will be returned to the applicant. 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 section B, C and 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:  |       |
| SRN: |       |

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

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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 |
| [ ]  *in vitro* diagnostic medical devices compliant with Regulation 2017/746 |

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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 Excel file or Word document, which must contain the required information about the device(s), as set out below. |
| **Basic UDI-DI** | **Product code**  | **Device name/product name** | **Notified body certificate number** | **Notified body certificate expiry date** |