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

\*A legacy device is a medical device that is in compliance with the Medical Devices Directives 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 / 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 your 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’*, 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 (*tick one box only*)  Medical device  Active implantable medical device  Medical devices that fall under the transitional provisions (MDR Article 120(3))  Class 1 medical devices and system and procedure packs which are self-declared (other than devices up classified in accordance with the Medical Device Regulation) must have been placed on the market and have a Declaration of Conformity that was drawn up before 26 May 2021. A declaration to that effect must be provided with the application documentation otherwise the devices cannot be listed on this application form. |

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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, with the required information about the device(s) as set out below. | | | | | | |
|  | | **For notified body certified devices** | | | **For self-declared devices** | **Transitions Provisions**  **MDR Article 120(3) or up classified Class 1 devices** |
| **Product code** | **Device name** | **Notified body ID** | **Notified body certificate number** | **Notified body certificate expiry date** | **HPRA registration number** | **YES / NO** |