|  |  |  |
| --- | --- | --- |
|  |  | Medical devices notification form |

|  |  |
| --- | --- |
| A Administrative data | |
| Type of notification | |
| First notification | |
| Change of information | |
| Previous notification number (in case of change) | Date |
| Enter text | Date picker |

|  |
| --- |
| **B Information on submitter** |
| Status of submitter  Manufacturer |
| Authorized representative |
| Other (identify the role): |
| Enter text |

|  |  |
| --- | --- |
| C Manufacturer information | |
| Name | |
| Enter text | |
| Contact name | |
| Enter text | |
| Address | |
| Enter text | |
| Post code | City |
| Enter text | Enter text |
| Phone | Fax |
| Enter text | Enter text |
| E-mail | Country |
| Enter text | Enter text |

|  |  |
| --- | --- |
| D Authorized representative information | |
| Name | |
| Enter text | |
| Contact name | |
| Enter text | |
| Address | |
| Enter text | |
| Post code | City |
| Enter text | Enter text |
| Phone | Fax |
| Enter text | Enter text |
| E-mail | Country |
| Enter text | Enter text |

|  |  |
| --- | --- |
| E Submitter's information (if different from C or D) | |
| Name | |
| Enter text | |
| Contact name | |
| Enter text | |
| Address | |
| Enter text | |
| Post code | City |
| Enter text | Enter text |
| Phone | Fax |
| Enter text | Enter text |
| E-mail | Country |
| Enter text | Enter text |

|  |  |
| --- | --- |
| F Medical device information | |
| Medical device:  Class III  Class IIb  Class IIa | Active implant  System or procedure pack |
| Nomenclature system (preferable GMDN) | |
| Enter text | |
| Nomenclature code | |
| Enter text | |
| Nomenclature text | |
| Enter text | |
| Generic name (Group name) | |
| Enter text | |
| Commercial name/ brand name / make | |
| Enter text | |
| Alternative name (Catalogue number) | |
| Enter text | |
| Description and intended use | |
| Enter text | |

|  |  |
| --- | --- |
| G Notified body information | |
| Name | |
| Enter text | |
| Notified Body ID-number | |
| Enter text | |
| Certificate number | |
| Enter text | |
| Certificate type | |
| Enter text | |
| Date of issue | Expiration date |
| Enter text | Enter text |
| Scope of certificate | |
| Enter text | |

|  |
| --- |
| H Comments |
| Enter text |

I affirm that the information given above is correct to the best of my knowledge

Signature field

Signature