|  |  |  |
| --- | --- | --- |
|  |  | 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